SINHGAD TECHNICAL EDUCATION SOCIETY'S

## SMT. KASHIBAI KAVALE MEDICAL COLLEGE AND GENERAL HOSPITAL



HOSPITAL DRUG FORMULARY

Greated by Department Of Pharmacology



SINHGAD TECHNICAL EDUCATION SOCIETY

## DEPARTMENT OF PHARWACOLOGY

# HOSPITAL FORMULARY

## FOREWORD



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MBBS MD (Microbiology) **Director**Smt. Kashibai Navale Medical
College and General Hospital

It gives me immense pleasure to release the much awaited handbook on "Hospital Formulary". Our college has created this formulary as we are dedicated to promote the college mission of academic excellence and patient care.

To ensure success of an individual and an institution, values such as respect, righteousness, morality and inclusiveness are of utmost importance. All the clinicians are expected to uphold these and contribute to create a positive and disease free environment. We would also encourage them to know where and how to access available drug information.

This Handbook contains all principles and information to ensure an environment suitable for best possible drug treatment and to imbibe high ethical standards and civic virtues among members of the organization.

## FOREWORD



MBBS MD (Community Medicine) **DEAN**Smt. Kashibai Navale Medical

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It is with great pride that we are releasing the carefully tailored Hand book of Hospital Formulary". It is formulated keeping in mind our aim to guide young passionate doctors who are not only going to be physicians but are also responsible citizens. Doctors must understand the depth of treatment provided by them, and shall work with integrity to strive for excellence.

I believe the purpose of the teaching hospital is to cater excellent medical treatment and education. The Hospital Formulary has been formulated to set forth the standards of treatment expected from clinicians with respect to prescribing behavior.

I hope this Handbook will give an overview of authentic information of prescribed drugs which will guide clinicians to acquaint rational prescribing.



It is my great pleasure to present & offer this Hospital Formulary for the benefit of clinicians. It comprises the surgicals, drug formulations, medical devices & implants available & stocked in our Central Pharmacy. Almost all drug formulations are listed in the current Essential Drugs List of India or form part of the WHO Essential Medicines List.

The content has been categorized into various sections of Injectable, Tablets & Capsules. Topical, Inhalational, Liquid Formulations for easy reference and this categorization also reflects the stocking arrangement in the Pharmacy. In each section the formulations are listed alphabetically.

Concise & relevant information of each formulation which could guide correct prescribing practices in line with standard treatment guidelines has been compiled with care & dedication by the faculty of my department. Your valuable feedback on the form & content of the formulary will serve to improve the utility of this formulary.

Dr. Uma Bhosale Professor & Head Department of Pharmacology SKNMC & GH, Narhe Pune



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### **HOSPITAL FORMULARY**

SMT KASHIBAI NAVALE MEDICAL COLLEGE

&

**GENERAL HOSPITAL NARHE, PUNE** 

**COMPILED BY** 

DEPARTMENT OF PHARMACOLOGY

SMT KASHIBAI NAVALE MEDICAL COLLEGE

NARHE, PUNE

## INJECTABLES

## INJECTIONS

#### INJECTIBLES

#### 1. ACYCLOVIR Inj 250 mg, vial

#### SALIENT ACTIONS:

It is selectively converted into acyclo-guanosine monophosphate (acyclo-GMP) by viral thymidine kinase, which is further phosphorylated into the active *triphosphate* form, acyclo-guanosine triphosphate (acyclo-GTP), by cellular kinases. Acyclo-GTP is a very potent **viral DNA polymerase inhibitor**. Acyclovir is active against most known species in the herpes virus family. Activity is predominantly against HSV, and to a lesser extent VZV. It is only of limited efficacy against EBV and CMV. It is inactive against latent viruses in nerve ganglia.

#### INDICATIONS:

HSV and VZV infections, including: Genital herpes simplex (treatment and prophylaxis), Herpes zoster (shingles), Acute chickenpox in immunocompromised patients, Herpes simplex encephalitis, Acute mucocutaneous HSV infections in immunocompromised patients, Prophylaxis against herpes viruses in immunocompromised patients (such as patients undergoing cancer chemotherapy.

#### DOSAGE REGIMENS:

The intravenous injection is used when high concentrations of acyclovir are required.

1. Mucocutaneous herpes simplex in immunocompromised patients: Adult: 5 mg/kg every 8 hr for 7 days. Dose to be given as IV infusion over 1 hr. Child: 10 mg/kg every 8 hr for 7 days.

2.Herpes simplex encephalitis: Adult: 10 mg/kg every 8 hr for 10 days. Child: ≥3 mth: 20 mg/kg every 8 hr for 10 days.

3.Genital herpes: Adult: 5 mg/kg every 8 hr for 5-7 days.

4. Neonatal herpes simplex virus infections: Birth - 3 mth: 10 mg/kg every 8 hr for 10 days.

5. Herpes zoster in immunocompromised patients: Adult: ≥12 yr: 10 mg/kg every 8 hr for 7 days.

Child: 20mg/kgevery8hrfor7days.

Renal impairment: Peritoneal dialysis: Half the usual dose once daily. Haemodialysis: Half the usual dose every 24 hr and an additional half-dose after haemodialysis.

#### CONTRAINDICATIONS:

None except hypersensitivity to acyclovir

#### PRECAUTIONS:

Acyclovir has been associated with renal failure, in some cases fatal. Patients receiving acyclovir should be adequately hydrated to prevent renal toxicity secondary to crystalluria. Intravenous acyclovir should not exceed a concentration of 7 mg per mL and should be infused over one hour to minimize crystallization of drug in renal tubules. Always ensure ample fluid supply! (Example: for a daily dose of 4 g, at least 3 liters/day). Do not inject intravenously as bolus (duration of infusion is at least 1 hour).

#### INTERACTIONS:

Probenecid delays the renal excretion of acyclovir. Coadministration with other nephrotoxic agents may increase the risk and severity of renal impairment due to additive effects on the kidney

#### ADVERSE EFFECTS:

Nausea, vomiting. diarrhea and/or headache. In high doses, hallucinations have been reported. Infrequent adverse effects (0.1–1% of patients) include: agitation, vertigo, confusion, dizziness, oedema, arthralgia, sore throat, constipation, abdominal pain, hair loss, rash and/or weakness. Rare adverse effects (<0.1% of patients) include: coma, seizures, neutropenia, leukopenia, crystalluria, anorexia, fatigue, hepatitis, Stevens–Johnson syndrome, toxic epidermal necrolysis and/or anaphylaxis.

IV administration: encephalopathy (1% of patients) and injection site reactions: local tissue pain and irritation. Renal impairment has been reported when acyclovir is given in large, fast doses intravenously, due to the crystallization of acyclovir in the kidneys.

#### 2. ACETYLCYSTEINE (200mg Inj)

#### SALIENT ACTIONS:

Acetyleysteine exerts mucolytic action through its free sulfhydryl group which opens the disulfide bonds in the mucoproteins thus lowering mucous viscosity. In paracetamol toxicity, acetyleysteine acts as a hepatoprotective agent by restoring hepatic glutathione, serving as a glutathione substitute, and enhancing the nontoxic sulfate conjugation of paracetamol.

#### INDICATIONS:

Paracetamol poisoning

#### DOSAGE REGIMEN:

Adult: Initially, 150 mg/kg (max: 16.5 g) in 200 mL diluent over 60 min, followed by 50 mg/kg (max: 5.5 g) in 500 mL diluent over the next 4 hour, then 100 mg/kg (max: 11 g) in 1 L diluent over the next 16 hr.

Child: <20 kg: Initially, 150 mg/kg in 3 mL/kg diluent over 60 min, followed by 50 mg/kg in 7 mL/kg diluent over 4 hour, then 100 mg/kg in 14 mL/kg diluent over 16 hour:

20-40 kg: Initially, 150 mg/kg in 100 mL diluent over 60 min, followed by 50 mg/kg in 250 mL diluent over 4 hour, then 100 mg/kg in 500 mL diluent over 16 hour;

>40 kg: Same as adult dose.

#### CONTRAINDICATIONS:

Hypersensitivity to acetylcysteine, asthma

#### PRECAUTIONS:

Patient with asthma or history of bronchospasm, history of peptic ulcer disease. Pregnancy and lactation. Monitoring Parameters in Paracetamol poisoning: Monitor serum paracetamol levels, AST, ALT, bilirubin, prothrombin time, INR, serum creatinine, BUN, serum glucose, Hb, haematocrit and electrolytes.

#### INTERACTIONS:

Administration of activated charcoal and oral acetylcysteine at the same time may cause a reduction in acetylcysteine (NAC) absorption.

#### ADVERSE ACTIONS:

Bronchospasm, angioedema, rash, pruritus, hypotension, HTN, flushing, nausea, vomiting, fever, syncope, sweating, arthralgia, blurred vision, liver function disturbances, acidosis, convulsion, cardiac or respiratory arrest.

#### 3. ADENOSINE INJ. 3MG IP

#### SALIENT ACTIONS:

A denosine is an endogenous purine nucleoside that is involved in numerous biological processes. It stimulates A1-receptors to slow conduction time through the AV node; and A2-receptors to produce peripheral and coronary vasodilation, thus, increasing blood flow in normal arteries w/ little to no increase in stenotic arteries. In dication: Paroxysmal supraventricular tachycardia, Differential diagnosis of supraventricular tachycardia

#### DOSAGE REGIMEN:

In travenous: Paroxysmal supraventricular tachycardia

Adult: Initially, 3 mg via rapid inj into a central or large peripheral vein over 2 seconds; 6 mg may be given after 1-2 min if necessary, then 12 mg after a further 1-2 min. Alternatively, an initial dose of 6 mg, followed by 2 further doses of 12 mg, if necessary, at 1-2 min intervals. Follow each dose w/ normal saline flush.

Child: <50 kg: Initially, 50-100 mcg/kg as rapid bolus, may be increased by 50-100 mcg/kg increments at 1-2 min intervals until sinus rhythm is established. Max: 300 mcg/kg. Alternatively, an initial dose of 100mcg/kg (Max: 6 mg), followed by 200 mcg/kg (Max: 12 mg) if necessary; ≥50 kg: Same as adult dose.

Differential diagnosis of supraventricular tachycardia

Adult: Initially, 3 mg via rapid inj into a central or large peripheral vein over 2 seconds; 6 mg may be given after 1-2 min if necessary, then 12 mg after a further 1-2 min.

#### CONTRAINDICATION:

2nd or 3rd degree AV block, sick sinus syndrome (except in patient w/ functional pacemaker), long QT syndrome, severe hypotension, unstable angina, decompensated heart failure, asthma, COPD

#### PRECAUTIONS:

Patient w/ QT prolongation, emphysema, bronchitis, autonomic dysfunction, pericarditis, pericardial effusion, left main coronary stenosis, stenotic vaivular heart disease, stenotic carotid artery disease (with cerebrovascular insufficiency), uncorrected hypovolemia, left to right shunt, recent MI or heart transplant, severe heart failure, minor conduction defects (e.g. 1st degree AV block, bundle branch block), atrial fibrillation/flutter, history of convulsion/seizure. Pregnancy and lactation. Monitoring Parameters Monitor: ECG, BP, and heart rate. Continuously monitor cardiac and haemodynamic states during infusion

#### INTERACTIONS:

Increased effect with dipyridamole, Reduced effect with xanthines (e.g. aminophylline, theophylline). May produce higher degree of heart block w/ carbamazepine. May cause ventricular fibrillation w/ digoxin or digoxin and verapamil combination

#### ADVERSE ACTIONS:

Nausea, light-headedness, tlushing, headache, angina-like chest pain, apprehension, dyspnoea, bronchospasm; bradycardia, heart block; tachy- and bradyarrhythmia, AF, MI; abdominal, throat, neck, and jaw discomfort, Rarely.

hypotension, reflex tachycardia, severe bradycardia. Potentially Fatal: Cardiac and respiratory arrest, asystole. Rarely, ventricular fibrillation.

#### 4. ADRENALINE Inj 1:1000, 1ml ampoule

#### **SALIENT ACTIONS:**

Epinephrine, an active principle of the adrenal medulla, is a direct-acting sympathomimetic. It stimulates  $\alpha$ - and  $\beta$ -adrenergic receptors resulting in relaxation of smooth muscle of the bronchial tree, cardiac stimulation and dilation of skeletal muscle vasculature. It is frequently added to local anaesthetics to retard diffusion and limit absorption, to prolong the duration of effect and to lessen the danger of toxicity.

#### INDICATIONS:

Acute asthma, advanced cardiac life support, anaphylactic shock

#### DOSAGE REGIMENS:

- 1.Acute asthma: Adult: As 1:1,000 aqueous solution: 0.3-0.5 ml (300-500 mcg). Dose may be given via IM or SC inj. Child: As 1:1,000 aqueous solution: 0.01 ml/kg (10 mcg/kg). Max: 0.5 ml (500 mcg). Dose may be given via IM or SC inj.
- 2.Advanced cardiac life support: *Adult:* Initially, 1 mg (10 mL of a 1:10,000 solution), may repeat as often as every 2-3 minutes throughout the resuscitation process. May also be given via intraosseous route at the same dosage. For endotracheal doses: 2-3 times of the IV dose. *Child:* Initially, 10 mcg/kg, may repeat as often as every 2-3 minutes throughout the resuscitation process. Endotracheal doses: 100 mcg/kg. Intraosseous doses are the same as IV doses. *Max Dosage:* Intraosseous doses for adults and children are the same as IV doses.
- 3.Anaphylactic shock: *Adult:* 0.5 mg (5 mL of a 1:10,000 solution) given at a slow rate of 100 mcg/minute, stopping when a response is achieved. *Child:* 10 mcg/kg. If autoinjectors are used, doses are based on body wt: 15-30 kg: 150 mcg and >30 kg: 300 mcg.
- Intramuscular use; Adult: As 1:1,000 solution: 500 mcg (0.5 ml), repeat every 5 minutes as needed until improvement occurs. For emergency self-admin (e.g. via autoinjector): A dose of 300 mcg (0.3 ml) may be used. Child: Dose depends on age and weight. Usual dose: 10 mcg/kg.

#### CONTRAINDICATIONS:

Preexisting hypertension; occlusive vascular disease; angle-closure glaucoma (eye drops); hypersensitivity; cardiac arrhythmias or tachycardia. When used in addition to local anaesthetics: Procedures involving digits, ears, nose, penis or scrotum.

#### PRECAUTIONS:

CV diseases; hyperthyroidism; DM; Parkinson's disease; elderly; pregnancy, lactation.

#### INTERACTIONS:

Halogenated inhalation anaesthetics;  $\beta$ - or  $\alpha$ -blocking agents; methyldopa, guanethidine; drugs with vasoconstrictor and pressor effects; antihypertensives; adrenergic neuron blockers; potassium-depleting drugs; cardiac glycosides; ephedra, yohimbe. TCAs may induce hypertension and arrhythmia.

#### ADVERSE REACTIONS:

- CNS effects; GI disturbances; epigastric pain; CV disorders; difficulty in micturition with urinary retention; dyspnoea; hyperglycaemia; sweating; hypersalivation; weakness, tremors; coldness of extremities; hypokalaemia.
- Gangrene, tissue necrosis and sloughing (extravasation) when used in addition to local anaesthetics. Eye drops: Severe smarting, blurred vision, photophobia; naso-lachrymal ducts obstruction. Oedema, hyperaemia and inflammation of the eyes with repeated administration.

#### 5. AMIKACIN Inj 500 mg, 2ml vial

#### SALIENT ACTIONS:

Amikacin binds to 30S ribosomal subunits of susceptible bacteria, thus inhibiting its protein synthesis.

#### INDICATIONS:

Uncomplicated urinary tract infections.

Severe Gram-negative infections resistant to gentamicin and tobramycin.

#### **DOSAGE REGIMENS:**

- 1. Uncomplicated urinary tract infections: Adult: 250 mg bid, given via IM, IV inj over 2-3 minutes or as IV infusion.
- 2. Severe Gram-negative infections resistant to gentamicin and tobramycin: *Adult:* 15 mg/kg daily in equally divided doses injected every 8 or 12 hr for 7-10 days. Max: Up to 500 mg every 8 hr in life-threatening infections. Max cumulative dose: 15 g. Doses may be given via IM, slow IV inj over 2-3 minutes or IV infusion. *Child:* 15

mg/kg daily in equally divided doses injected every 8 or 12 hr for 7-10 days. Neonates:10mg/kg daily in 2 divided doses.

Renal impairment: Dosing interval (in hr) can be calculated by multiplying the patient's serum creatinine (mg/100ml) by 9. Maintenance doses can be calculated by dividing the normal dose by the patient's serum creatinine.

#### CONTRAINDICATIONS:

Pregnancy, perforated ear drum, myasthenia gravis, hypersensitivity. Enhanced neuromuscular blockade with neuromuscular blocking drugs. Increased risk of ototoxicity with potent diuretics.

#### PRECAUTIONS:

Renal impairment; vertigo, tinnitus. Discontinue if signs of ototoxicity, neurotoxicity or hypersensitivity occurs; lactation. Safety has not been established for treatment period >14 days. Monitor renal function before and during treatment.

#### INTERACTIONS:

Amphotericin B may lead to increased nephrotoxicity and reduced clearance of amikacin when used together. *Potentially Fatal:* Increased ototoxic or nephrotoxic effects with other nephrotoxic or ototoxic drugs. Enhanced neuromuscular blockade with neuromuscular blocking drugs. Increased risk of ototoxicity with potent diuretics.

#### ADVERSE DRUG REACTIONS:

Tinnitus, vertigo; ataxia and overt deafness.

Potentially Fatal: Ototoxicity, nephrotoxicity, neuromuscular blockade.

#### 6. AMINOPHYLLINE Inj 250 mg, 10 ml ampoule

#### SALIENT ACTIONS:

Aminophylline is a combination of theophylline and ethylenediamine. Ethylenediamine is inactive; it increases the solubility of theophylline in water. Theophylline relaxes bronchial smooth muscle. Suggested mechanisms are an increase in intracellular cAMP through inhibition of phosphodiesterase; adenosine receptor antagonism, prostaglandin antagonism and effects on intracellular calcium

#### INDICATIONS:

Acute severe bronchospasm

#### DOSAGE REGIMENS:

1. Acute severe bronchospasm: *Adult:* Loading dose: 5 mg/kg (ideal body weight) or 250-500 mg (25 mg/ml) by slow inj or infusion over 20-30 min. Maintenance infusion dose: 0.5 mg/kg/hr. Max rate: 25 mg/min. *Child:* Loading dose: same as adult dose. Maintenance dose: 6 mth-9 yr: 1 mg/kg/hr and 10-16 yr: 0.8 mg/kg/hr. *Elderly:* Dose reduction may be neessary. *Special Populations:* Reduce maintenance dose in patients with cor pulmonale, heart failure or liver disease and in elderly. Increase maintenance dose for smokers. Should be taken on an empty stomach. (Take on an empty stomach at least 1 hr before or 2 hr after meals.)

#### **CONTRAINDICATIONS:**

Hypersensitivity.

#### PRECAUTIONS:

Neonates, elderly, lactation, pregnancy, cardiac/hepatic diseases, peptic ulceration, hyperthyroidism, hypertension, epilepsy, heart failure, chronic alcoholism, acute febrile illness.

#### DRUG INTERACTIONS:

Other xanthines. Clearance reduced by allopurinol, some antiarrhythmics, cimetidine, disulfiram, fluvoxamine, interferon- $\alpha$ , macrolide antibiotics, quinolones, oral contraceptives, thiabendazole and viloxazine. Clearance increased by phenytoin, anticonvulsants, ritonavir, rifampicin, sulfinpyrazone, cigarette smoking. Corticosteroids, diuretics,  $\beta_2$ -agonists.

Potentially Fatal: Increased risk of cardiac arrhythmias with sympathomimetics and halothane. Tachycardia with pancuronium. β-blockers inhibit metabolism. Increased risk of convulsion with quinolones, ketamine..

#### ADVERSE DRUG REACTIONS:

Nausea, vomiting, abdominal pain, diarrhoea, headache, insomnia, dizziness, anxiety, restlessness; tremor, palpitations. *Potentially Fatal:* Convulsions, cardiac arrhythmias, hypotension and sudden death after too rapid IV injection

#### 7. AMOXYCILLIN + CLAVULENIC ACID Inj - 1.2 gm/vial, Tablets- 375 /625 mg SALIENT ACTION:

Clavulanic acid has a high affinity for and binds to certain \( \beta \)-lactamases that generally inactivate amoxicillin by

hydrolyzing its  $\beta$ -lactam ring. Combining clavulanate potassium with amoxicillin extends the antibacterial spectrum of amoxicillin to include many bacteria normally resistant to amoxicillin and other penicillins and cephalosporins.

#### INDICATIONS AND DOSAGE REGIMEN:

- 1.Otitis media, sinusitis, skin and soft tissue infections, upper and lower respiratory tract infections, susceptible infections, dental abscesses, acute uncomplicated urinary tract infections- *Adult:* Based on amoxicillin dose, 250–500 mg every 8 hr or 500-750 mg every 12 hr.*Child:* Based on amoxicillin dose: 125-250 mg every 8 hr. Children weighing <40 kg: 20-40 mg/kg/day in divided doses every 8 hr. Infants <3 mth: up to 30 mg/kg/day in divided doses every 12 hr.
- 2. Severe or recurrent respiratory tract infections: Adult: Based on amoxicillin dose: 3 g bid.
- 3.Uncomplicated gonorrhea: Adult: Based on amoxicillin dose: 3 g as a single dose with 1 g of oral probenecid.
- 4.Prophylaxis of endocarditis: *Adult:* Based on amoxicillin dose: 2 or 3 g as a single dose. To be taken 1hr before the hr before the dental procedure.
- 5. *H.pylori* infection: *Adult*: Based on amoxicillin dose: 0.75-1 g bid or 500 mg tid. To be taken with metronidazole or claithromycin and a PPI or ranitidine bismuth citrate.
- Parenteral dosage: In susceptible infections, Adult: Based on amoxicillin dose: 500 mg every 8 hr. In severe infections, may increase to 1 g every 6 hr. Can be given via IM inj or slow IV inj over 3-4 minutes or IV infusion over 30-60 minutes, Child: <10 yr: 50-100 mg/kg/day in divided doses.

#### **CONTRAINDICATIONS:**

Penicillin allergy

#### PRECAUTIONS:

History of allergy especially to cephalosporins, infectious mononucleosis, severe renal impairment.

#### INTERACTIONS:

Allopurinol may reduce renal tubular secretion of amoxicillin thus increasing the serum levels of amoxicillin. Concurrent use may reduce the efficacy of oral contraceptives.

#### ADVERSE EFFECTS:

Nausea, vomiting, diarrhoea, indigestion, rash and urticaria, candida superinfection, Anaphylactic reaction with CVcollapse esp with parenteral use.

#### 8. AMIODARONE HCL INJ

#### SALIENT ACTION:

Amiodarone is a class III antiarrhythmic agent but exhibits characteristics of all Vaughn-Williams classes. Its main effect is to delay repolarisation by prolonging the action potential duration (APD) and effective refractory period (ERP) in myocardial tissues. Additionally, it inhibits transmembrane influx of Na via fast channels, decreasing the maximal rate of depolarisation similar to class I. It is a non-competitive inhibitor of  $\alpha$ - and  $\beta$ - adrenergic actions as that of class II. Lastly, it produces negative chronotropic effect in nodal tissues.

#### INDICATIONS:

Supraventricular and ventricular arrhythmias

#### Dosage:

Adult: Initially, 5 mg/kg over 20-120 min, may be repeated if required, up to a total dose of 1,200 mg (approx 15 mg/kg) w/ a rate adjusted based on clinical response for 24 hr. For emergency cases, 150-300mg by slow inj over ≥3 min. The next inj should be given at least 15 min after.

Elderly: Initiate at lower end of dosing range.

Hepatic impairment: Reduce dose if necessary.

#### CONTRAINDICATIONS:

Evidence or history of thyroid dysfunction, iodine sensitivity, severe resp failure, circulatory collapse, severe hypotension, cardiogenic shock, sinus bradycardia, SA heart block; 2nd or 3rd degree AV block, severe conduction disturbances (e.g. high grade AV block, bifascicular/trifascicular block), sinus node disease (except in patient w/pacemaker). Lactation. Concomitant use w/ drugs that prolong QT interval.

#### PRECAUTIONS:

Patient w/ hypotension, decompensated cardiomyopathy, severe heart failure, acute porphyria, conduction disturbances, hypokalaemia. Patient who underwent surgery. Elderly. Hepatic impairment. Pregnancy. Patient Counselling Avoid exposure to sunlight. This drug may cause eye disorders, if affected, do not drive or operate machinery.

Monitoring Parameters: Monitor BP, heart rate and rhythm, serum electrolyes

(esp K and Mg) throughout therapy; and LFT prior to treatment then semi-annually. Assess thyroid function before initiation and then every 3-6 mth. Perform chest X-ray before treatment and regular ophthalmic exams. Monitor pacing/defibrillation thresholds in patient w/ implantable cardiac device.

#### INTERACTIONS:

Increased concentration w/ inhibitors of CYP3A4 (e.g. HIV-protease inhibitors, cimetidine). Reduced concentration w/ inducers of CYP3A4 (e.g. rifampicin, phenytoin). May induce bradycardia w/ β-blockers, Ca channel blockers, and other antiarrhythmic drugs. May increase risk of arrhythmia w/ drugs that cause hypomagnesaemia and hypokalaemia (e.g. diuretics, systemic corticosteroids). May increase concentration of ciclosporin, clonazepam, digoxin, flecainide, phenytoin, procainamide, quinidine, simvastatin, and warfarin. May affect drugs that are P-glycoprotein substrates. Potentially Fatal: May cause prolongation of QT interval w/ fluoroquinolones (e.g. moxifloxacin), antipsychotics (e.g. chlorpromazine, thioridazine, fluphenazine), lithium, TCAs (e.g. doxepin, maprotiline, amitriptyline), halofantrine, and terfenadine.

#### ADVERSE REACTIONS:

Significant: Bradycardia, hypotension, peripheral neuropathy. Nervous: Benign intracranial pressure, paraesthesia, tremor, nightmares, sleeplessness, headache, ataxia. CV: Thrombophlebitis. GI: Nausea, vomiting, metallic taste. Genitourinary: Epididymitis. Endocrine: Phospholipidosis. Haematologic: Haemolytic/aplastic anaemia. Musculoskeletal: Myopathy. Ophthalmologic: Benign yellowish-brown corneal micro-deposits, optic neuropathy/neuritis, blindness. Dermatologic: Hot flushes, sweating, bluegrey skin discolouration. Others: Fatigue. Potentially Fatal: Cirrhosis, hepatitis, hepatic failure, cholestasis; ventricular tachyarrhythmia, worsening of arrhythmia, cardiac arrest; pulmonary fibrosis, interstitial pneumonitis, thyrotoxicosis, Stevens-Johnson syndrome, toxic epidermal necrolysis. Rarely, torsade de pointes.

#### 9. AMPICILLIN Inj 500 mg, vial SALIENT ACTIONS:

Ampicillin exerts bactericidal action on both gm+ve and gm-ve organisms. Its spectrum includes gm+ve organisms eg, S pneumoniae and other Streptococci, L monocytogenes and gm-ve bacteria eg, M catarrhalis, N gonorrhoea, N meningitidis, E coli, P mirabilis, Salmonella, Shigella, and H influenzae. Ampicillin exerts its action by inhibiting the synthesis of bacterial cell wall.

#### INDICATIONS:

Intrapartum prophylaxis against group B Streptoccocal infection in neonates, septicaemia: As supplement in systemic therapy for treatment of susceptible infections, meningitis, susceptible infections

#### DOSAGE REGIMENS:

- 1. Intrapartum prophylaxis against group B Streptoccocal infection in neonates: *Adult:* Initially, 2 g via IV inj followed by 1 g every 4 hr until delivery.
- 2. Septicaemia: Adult: 150-200 mg/kg daily. Initiate with IV admin for at least 3 days, then continue with IM inj every 3-4 hr. Continue treatment for at least 48-72 hr after the patient has become asymptomatic or when there is evidence of bacterial eradication. Recommended treatment duration for infections caused by group-A β-haemolytic streptococci: At least 10-days to prevent occurrence of acute rheumatic fever or acute glomerulonephritis.
- 3.As supplement in systemic therapy for treatment of susceptible infections: *Adult:* For intrapleural or intraperitoneal injections: 500 mg daily, dissolved in 5-10 ml of water. For intra-articular inj: 500 mg daily, dissolved in up to 5 ml of water or a solution of 0.5% procaine HCl. *Child:* ½ the adult dose.
- 4. Meningitis: Adult: 150-200 mg/kg daily in equally divided doses every 3-4 hr. May initiate with IV admin followed by IM injections. Child: and infants: 150 mg/kg daily in divided doses. Neonates: <1 wk: 50 mg/kg every 12 hr; older neonates: 50 mg/kg every 8 hr. Max: 3 g/day. May initiate with IV admin followed by IM injections.
- 5. Susceptible infections: *Adult*: 250-500 mg every 6 hr, can be given via IM or slow IV inj over 3-5 minutes or infusion. *Child*: 100-400 mg/kg daily in divided doses every 6 hr. Max: 12 g daily. Dose can be given via IM or slow IV inj over 3-5 minutes or infusion.

#### CONTRAINDICATIONS:

Hypersensitivity; infectious mononucleosis.

#### PRECAUTIONS:

Renal failure; patients with lymphatic leukaemia or HIV infections; pregnancy and lactation.

#### INTERACTIONS:

Simultaneous use with oral contraceptives may lead to increased risk of breakthrough bleeding and reduced efficacy of the contraceptive. Skin rash increased with allopurinol. Probenecid increases blood levels. Synergism with  $\beta$ -lactamase inhibitors, clavulanic acid or sulbactam, penicillinase-stable drugs eg, cloxacillin or flucloxacillin

and aminoglycosides. Potentially Fatal: Increases disulfiram and anticoagulant effects.

#### ADVERSE DRUG REACTIONS:

GI upset, nausea, vomiting, diarrhoea; blood dyscrasias; urticaria, exfoliative dermatitis, rash; fever, seizures; interstitial nephritis. *Potentially Fatal:* Anaphylactic shock; pseudomembranous colitis; neuromuscular hypersensitivity; electrolyte imbalance.

#### 10. AMPHOTERICIN-B Inj 50 mg/vial

#### SALIENT ACTIONS:

Amphotericin B is a polyene antifungal antibiotic which alters cell membrane permeability by binding to ergosterol, thus causing leakage of cell components and subsequent cell death. It is active against *Absidia spp*, *Aspergillus spp*, *Basidiobolus spp*, *B. dermatitidis*, *Candida spp*, *C. immitis*, *Conidobolus spp*, *C. neoformans*, *H. capsulatum*, *Mucor spp*, *P. brasiliensis*, *Rhizopus spp*, *Rodotorula spp*, and *S. schenckii*.

#### INDICATIONS:

Severe systemic fungal infections, aspergillosis, disseminated, endocarditis, severe meningitis

#### DOSAGE REGIMENS:

1.Severe systemic fungal infections: *Adult:* Using conventional amphotericin B: If needed, test dose of 1 mg infused IV over 20-30 minutes. Initial dose: 250 mcg/kg daily, increased gradually to a max of 1 mg/kg/day. For seriously ill patients, up to 1.5 mg/kg may be given daily or on alternate days may be needed. Daily dose is infused over 2-4 hr at a concentration of 100 mcg/ml in glucose 5%. If treatment is interrupted for more than 7 days, then restart at 250 mcg/kg daily and increase slowly.

2. Aspergillosis, disseminated: Adult: Using conventional amphotericin B: If needed, test dose of 1 mg infused IV over 20-30 minutes. 0.6-0.7 mg/kg daily for 3-6 mth.

3.Endocarditis: *Adult:* Using conventional amphotericin B: If needed, test dose of 1 mg infused IV over 20-30 minutes. 0.6-1 mg/kg/day for 1 wk, then 0.8 mg/kg/day every other day for 6-8 wk post-operatively.

4. Severe meningitis: *Adult:* Using conventional amphotericin B: If needed, test dose of 1 mg infused intrathecally over 20-30 minutes. Initially, 25 mcg increased gradually to the max that can be tolerated without excessive discomfort. Usual dose: 0.25-1 mg 2-4 times a wk.

#### CONTRAINDICATIONS:

Hypersensitivity; lactation; do not give to patients receiving antineoplastics.

#### PRECAUTIONS:

Renal and hepatic impairment; pregnancy; monitor renal and liver function changes.

#### DRUG INTERACTIONS:

Increased toxicity with flucytosine. Drug induced renal toxicity enhanced in presence of other nephrotoxic medications. Antagonises effects of azole antifungals. *Potentially Fatal*: Potentiates K loss by corticosteroids. Avoid diuretics. Enhances digitalis toxicity and neuromuscular blocker effects.

#### ADVERSE DRUG REACTIONS:

Topical: Local irritation, pruritus and skin rash. IV infusion: Fever, chills, convulsions, malaise; nausea, vomiting, diarrhoea, anorexia; tinnitus, vertigo, hearing loss; hypotension, hypertension, cardiac arrhythmias; peripheral neuropathy; phloebitis, pain at Inj site, disturbances in renal function and renal toxicity.

Potentially Fatal: Anaphylactic reaction; leucoencephalopathy. Overdosage can result in cardio-respiratory arrest.

#### 11. ARTESUNATE Inj 60 mg, vial

#### SALIENT ACTIONS:

Artesunate is a potent and rapidly-acting blood schizontocide derived from the leaves of the chinese herb, *Armesia annua*. The exact mode of action is not clear but clinical studies have confirmed the effectiveness of artesunate of in *P. vivax* and falciparum malaria.

#### INDICATION:

Falciparum malaria

#### DOSAGE REGIMENS:

Falciparum malaria

Adult: 2.4 mg/kg via IM or IV admin. Repeat 12 hr and 24 hr later, then once daily thereafter. Child: 2.4 mg/kg via IM or IV admin. Repeat 12 hr and 24 hr later, then once daily thereafter.

#### DRUG INTERACTIONS:

Antimalarial potentiating action seen with mefloquine, primaquine and tetracycline. Additive effect with chloroquine. Antagonistic effect with pyrimethamine and sulphonamides.

#### CONTRAINDICATIONS:

Hypersensitivity.

#### PRECAUTIONS:

Hepatic or renal insufficiency. Pregnancy and lactation.

#### ADVERSE DRUG REACTIONS:

Transient and reversible reticulocytopaenia, drug fever, rash, bradycardia, transient 1st-degree heart block and reversible elevation of serum transaminases.

#### 12. ASCORBIC ACID (VITAMIN C) Inj 100 mg/5ml, Tablet 500 mg

#### SALIENT ACTION:

Ascorbic acid is a functional and principal *in vivo* form of vitamin C, an essential water-soluble vitamin which is fundamental in the synthesis of collagen and intercellular materials.

#### INDICATIONS:

Scurvy, thalassaemia, metabolic disorders

#### DOSAGE REGIMEN:

1.Scurvy:Adult: Prevention: 25-75 mg daily. Treatment: ≥250 mg daily, given in divided doses. May also be given via IM/IV/SC admin. Child: 1 mth-4 yr: 125-250 mg daily; 4-12 yr: 250-500 mg daily; 12-18 yr: 500 mg-1 g daily. Doses to be given in 1-2 divided doses.

2. Thalassaemia: Adult: 100-200 mg daily, to be given with desferrioxamine. Child: 100-200 mg daily, to be given with desferrioxamine.

3.Metabolic disorders: tyrosinaemia type III; transient tyrosinaemia of the newborn; glutathione synthase deficiency; Hawkinsinuria. Child: Neonate: 50-200 mg daily, adjust if needed; 1 mth-18 yr: 200-400 mg Daily in 1-2 divided doses, up to 1g daily may be needed.

#### **CONTRAINDICATIONS:**

No

#### PRECAUTIONS:

G6PD deficiency, haemochromatosis, hyperoxaluria, diabetics, patients prone to recurrent renal calculi. Neonates; pregnancy (Ingestion of large doses has resulted in scurvy in neonates); lactation.

#### INTERACTIONS:

Deferroxamine, hormonal contraceptives, flufenazine, warfarin, elemental iron, salicylates, warfarin, fluphenazine, disulfiram, mexiletine, vitamin B<sub>12</sub>. *Lab Interference*- Presence of ascorbic acid in urine results in false decreases in the glucose conc determined by the glucose oxidase method; while in glucose determinations measured by cupric sulfate reagent, false increases have resulted.

#### ADVERSE EFFECTS:

Diarrhea, GI disturbances. May cause acidification of the urine; precipitation of urate, cystine or oxalate stones, or drugs in the urinary tract.

#### 13. A.S.V.S.

#### SALIENT ACTIONS:

Anti-venom is immunoglobulin usually enzyme refined F(ab)2 fragments of IgG purified from the serum or plasma of a horse or sheep that has been immunized with the venom of snakes. Anti-venom acts to neutralize the poisonous venom of the snake and causes the venom to be released from the receptor site. Thus, the receptor sites that were previously blocked by venom are now free to interact with the acetylcholine molecule, and normal respiration resumes. The spent anti-venom and the neutralized venom are then excreted from the body.

#### Indication: management of snake bite

#### DOSAGE REGIMEN:

It is administered by intravenous infusion diluted in approximately

5-10 ml/kg of body weight or 250-500 ml of normal saline or

5% dextrose in case of adults over a period of 1 hour.

#### CONTRAINDICATIONS:

There is no absolute contra indication to ASV treatment but patient were atopic (like severe asthma) and/or who have reacted to horse serum in the past should be given ASV only if they have signs of systemic envenoming after giving prophylactic adrenaline subcutaneously.

#### PRECAUTIONS:

Intra dermal skin testing is indicated to predict anti venom reaction prior to administration of ASV.

#### INTERACTIONS:

ASVS may interact with heparin & warfarin.

#### ADR:

Early anaphylactic reactions, pyrogenic reactions, late serum sickness type reactions

#### 14. ATRACURIUM BESILATE INJ IP

#### SALIENT ACTIONS:

Atracurium produces neuromuscular blockade by competing w/ acetylcholine for receptors on the motor end-plate of the myoneural junction.

#### INDICATION & DOSAGE:

Muscle relaxant in general anaesthesia, Endotracheal intubation, Facilitate mechanical ventilation in intensive care Adult: Initially, 300-600 mcg/kg as bolus inj, w/ subsequent doses of 100-200 mcg/kg by inj every 15-25 min or 5-10 mcg/kg/min by infusion in prolonged procedures. Higher infusion rate may be used in patients undergoing controlled ventilation in intensive care.

Child: >1 mth Same as adult dose.

#### CONTRAINDICATIONS:

suspected hypersensitivity to atracurium besilate.

#### PRECAUTIONS:

Patient w/ CV disease, burn injury, asthma; conditions which may antagonise neuromuscular blockade (e.g. resp alkalosis, hypercalcaemia, demyelinating lesions, peripheral neuropathies, denervation, muscle trauma); conditions which may potentiate neuromuscular blockade (e.g. electrolyte abnormalities, neuromuscular diseases, metabolic acidosis, resp acidosis, Eaton-Lambert syndrome, myasthenia gravis). Pregnancy and lactation. Patient Counselling May impair ability to drive or operate machinery.

Monitoring Parameters Monitor heart rate, BP, resp rate; degree of muscle relaxation; renal and hepatic function when in the intensive care unit.

#### INTERACTIONS:

Enhanced neuromuscular blocking effect w/ general anaesth (e.g. enflurane, isoflurane, halothane), certain antibiotics (e.g. aminoglycosides, polymyxins), lithium, Mg salts, procainamide, quinidine.

#### ADVERSE REACTION:

Skin flush, erythema, pruritus, urticaria, wheezing, increased bronchial secretions, bronchospasm, cyanosis, angioedema, CV effects (e.g. bradycardia); wheals and erythema at inj site.

Potentially Fatal: Anaphylaxis.

#### 15. ATROPINE Inj 0.6 mg, 1ml ampoule

#### SALIENT ACTIONS:

Atropine is an anticholinergic agent which competitively blocks the muscarinic receptors in peripheral tissues such as the heart, intestines, bronchial muscles, iris and secretory glands. Some central stimulation may occur. Atropine abolishes bradycardia and reduces heart block due to vagal activity. Smooth muscles in the bronchi and gut are relaxed while glandular secretions are reduced. It also has mydriatic and cycloplegic effect.

#### INDICATIONS:

- 1. Premedication in balanced anaesthesia Organophosphorus poisoning.
- 2. Poisoning or overdosage with compounds having muscarinic actions
- 3. Bradycardia

#### DOSAGE REGIMENS:

#### Parenteral

#### 1. Premedication I n balanced anaesthesia

Adult: 300-600 mcg IM/SC 30-60 minutes before anaesthesia. Alternatively, 300-600 mcg IV immediately before induction of anaesthesia.

Child: >20 kg: 300-600 mcg; 12-16 kg: 300 mcg; 7-9 kg: 200 mcg; >3 kg: 100 mcg. Doses to be given via IM/SC admin 30-60 minutes before anaesthesia.

#### 3. Organophosphorus poisoning

**Adult:** 2 mg IV/IM, every 10-30 minutes until muscarinic effects disappear or atropine toxicity appears. In severe cases, dose can be given as often as every 5 minutes. In moderate to severe poisoning, a state of atropinisation is maintained for at least 2 days and continued for as long as symptoms are present. **Child:** 20 mcg/kg given every 5-10 minutes.

#### 4. Poisoning or overdosage with compounds having muscarinic actions

Adult: 0.6-1 mg IV/IM/SC, repeated every 2 hr.

Intravenous

#### 1. Bradycardia

Adult: 500 mcg every 3-5 minutes. Total: 3mg.

Max Dosage: 0.04 mg/kg body weight.

#### CONTRAINDICATIONS:

Glaucoma, chronic respiratory disease, sick sinus syndrome, thyrotoxicosis, cardiac failure, pyloric stenosis, prostatic hypertrophy.

#### SPECIAL PRECAUTIONS:

Reflux oesophagitis, elderly, infants and children. Pregnancy.

#### DRUG INTERACTIONS:

Additive anticholinergic effects with quinidine, antidepressants and some antihistamines.

#### ADVERSE DRUG REACTIONS:

Dry mouth, dysphagia, constipation, flushing and dryness of skin, tachycardia, palpitations, arrhythmias, mydriasis, photophobia, cycloplegia, raised intraocular pressure. Toxic doses cause tachycardia, hyperpyrexia, restlessness, confusion, excitement, hallucinations, delirium and may progress to circulatory failure and resp depression. Eye drops: Systemic toxicity esp in children, on prolonged use may lead to irritation, hyperaemia, oedema and conjunctivitis. Increased intraocular pressure. Inhalation: Dryness of mouth, throat. *Potentially Fatal:* Atrial arrhythmias, AV dissociation, multiple ventricular ectopics.

#### 16. AZITHROMYCIN INJECTION

#### SALIENT ACTIONS:

Azithromycin blocks transpeptidation by binding to 50s ribosomal subunit of susceptible organisms and disrupting RNA-dependent protein synthesis at the chain elongation step.

#### INDICATIONS & DOSAGE REGIMENS:

Community-acquired pneumonia

500 mg as a single IV daily dose for 2 days, then 500 mg single oral dose daily to complete 7-10 days of therapy. Pelvic inflammatory disease 500 mg as a single IV daily dose for 1-2 days, then 250 mg single oral dose daily to complete a 7-day therapy.

#### CONTRAINDICATIONS:

Hypersensitivity.

#### PRECAUTIONS:

Impaired liver and renal function; pregnancy and lactation; children.

#### INTERACTIONS:

Antacids containing aluminium and magnesium salts reduce rate of absorption. Increased risk of ergot toxicity, Potentially Fatal: Increased serum concentrations of digoxin and ciclosporin.

Adverse Drug Reactions:

Mild to moderate nausea, vomiting, abdominal pain, dyspepsia, flatulence, diarrhoea, cramping; angioedema, cholestatic jaundice; dizziness, headache, vertigo, somnolence; transient elevations of liver enzyme values.

#### 17. BENZATHINE PENICILLIN INJ

#### SALIENT ACTIONS:

Benzathine benzylpenicillin interferes w/ bacterial cell wall synthesis during active multiplication causing cell wall death and resultant bactericidal activity against susceptible bacteria.

#### INDICATIONS & DOSAGE:

Syphilis

Adult: Primary, secondary and latent: 1.8 g (2.4 MIU) as a single dose. Late (tertiary and neurosyphilis): 1.8 g (2.4 MIU) once wkly for 3 doses.

Treponemal infections

Adult: 900 mg (1.2 MIU) as a single dose.

Child: 450 mg (600,000 U) as a single dose.

Streptococcal pharyngitis

Adult: 900 mg (1.2 MIU) as a single dose.

Child: <27 kg: 225-450 mg (300,000-600,000 U) as a single dose; ≥27 kg: 675 mg (900,000 U) as a single dose.

Congenital syphilis

Child: Normal CSF: <2 yr 37.5 mg/kg (50,000 U/kg) as a single dose; 2-12 yr Adjust dosage based on adult dosage schedule.

Primary prophylaxis of rheumatic fever

Adult: 900 mg (1.2 MIU) as a single dose. Prevention of recurrence of acute attack: 900 mg (1.2 MIU) once every 3 or 4 wk or 450 mg (600,000 U) once every 2 wk.

Child:  $\langle 27 \text{ kg: } 225\text{-}450 \text{ mg} (300,000\text{-}600,000 \text{ U})$  as a single dose;  $\geq 27 \text{ kg: } 675 \text{ mg} (900,000 \text{ U})$  as a single dose. Prevention of recurrence of acute attack:  $\langle 27 \text{ kg: } 450 \text{ mg} (600,000 \text{ U}) \text{ once every 3 or 4 wk; } \geq 27 \text{ kg: } 900 \text{ mg} (1.2 \text{ MIU})$  once every 3 or 4 wk.

#### CONTRAINDICATIONS:

Hypersensitivity to penicillins.

#### PRECAUTIONS:

Patient w/ previous hypersensitivity reactions to cephalosporins, history of allergy, asthma, seizure disorder. Not intended for IV or intra-arterial admin or inj near major peripheral nerves of blood vessels. Prolonged use may result in bacterial or fungal superinfection. Renal impairment.

Monitoring Parameters: Periodic evaluation of renal and haematopoietic functions. Assess culture and sensitivity test prior to initiation of therapy. Monitor for hypersensitivity reactions and opportunistic infections.

#### INTERACTIONS:

Bactericidal effect may be antagonised by tetracycline. Decreased rate of excretion and increased serum concentration when used w/ probenecid.

#### ADVERSE REACTIONS:

Hypersensitivity reactions including skin eruptions, urticaria, laryngeal oedema, serum sickness-like reactions, allergic vasculitis, pruritus, fatigue, asthenia, pain, headache; fever; haemolytic anaemia, leucopenia, thrombocytopenia; neuropathy; nephropathy; hypotension, tachycardia, palpitations, pulmonary HTN, pulmonary embolism, vasodilation, vasovagal reaction, cerebrovascular accident, syncope; nausea, vomiting, intestinal necrosis, blood in stool, intestinal necrosis; lymphadenopathy; inj site reactions (e.g. pain, inflammation), joint disorder, periostitis, exacerbation of arthritis, myoglobinuria, rhabdomyolysis; nervousness, tremors, dizziness, somnolence, confusion, anxiety, euphoria, transverse myelitis, seizures, coma; hypoxia, apnoea, dyspnoea; diaphoresis; blurred vision, blindness; neurogenic bladder, haematuria, proteinuria, renal failure, impotence, priapism.

Potentially Fatal: Anaphylaxis, antibiotic-associated pseudomembranous colitis.

#### 18. BLEOMYCIN SULPHATE INJ

**SALIENT ACTIONS:** Bleomycin causes breakage of single- and double-stranded DNA by binding to DNA and inhibiting DNA synthesis. To a lesser extent, it also inhibits RNA and protein synthesis.

#### INDICATIONS & DOSAGE:

Parenteral

Squamous cell or testicular tumours

Adult: IM/IV: 15,000 IU 3 times wkly or 30,000 IU twice wkly, repeated at usual intervals of 3-4 wk up to a total cumulative dose of 500,000 IU.

Elderly: Max total cumulative dose: <60 yr 500,000 IU (30,000-60,000 IU wkly); 60-69 yr 300,000 IU (30,000-60,000 IU wkly); 70-79 yr 200,000 IU (30,000 IU wkly); ≥80 yr 100,000 IU (15,000 IU wkly).

Renal impairment: CrCl 20-40 mcg/mL: Admin 50% of normal dose.

Reconstitution: IM/SC: Add 1-5 mL or 2-10 mL of sterile water for inj, NaCl 0.9% inj, or bacteriostatic water for inj to the vial labelled as containing 15 IU or 30 IU of bleomycin, respectively, to provide a soln containing 3-15 IU/mL. IV: Add 5 mL or 10 mL of NaCl 0.9% into the vial labelled as containing 15 IU or 30 IU of bleomycin, respectively, to provide a soln containing ≤3 IU/mL. Admin slowly over a 10-min period. Intrapleural: Dissolve 60 IU of bleomycin in 50-100 mL NaCl 0.9% inj.

Incompatibility: Incompatible w/ soln of essential amino acids, riboflavin, dexamethasone or furosemide; carbenicillin, cefazolin or cefalotin Na, nafcillin Na, benzylpenicillin Na, methotrexate, mitomycin, hydrocortisone Na succinate, aminophylline, ascorbic acid or terbutaline.

Intramuscular

Lymphoma

Adult: 15,000 IU once or twice a wk, up to a total cumulative dose of 225,000 IU.

Elderly: Max total cumulative dose: <60 yr 500,000 IU (30,000-60,000 IU wkly); 60-69 yr 300,000 IU (30,000-

60,000 IU wkly); 70-79 vr 200,000 IU (30,000 IU wkly); ≥80 yr 100,000 IU (15,000 IU wkly).

Renal impairment: CrCl 20-40 mcg/mL: Admin 50% of normal dose.

Reconstitution: IM/SC: Add 1-5 mL or 2-10 mL of sterile water for inj, NaCl 0.9% inj, or bacteriostatic water for inj to the vial labelled as containing 15 IU or 30 IU of bleomycin, respectively, to provide a soln containing 3-15 IU/mL. IV: Add 5 mL or 10 mL of NaCl 0.9% into the vial labelled as containing 15 IU or 30 IU of bleomycin, respectively, to provide a soln containing ≤3 IU/mL. Admin slowly over a 10-min period. Intrapleural: Dissolve 60 IU of bleomycin in 50-100 mL NaCl 0.9% inj.

Incompatibility: Incompatible w/ soln of essential amino acids, riboflavin, dexamethasone or furosemide; carbenicillin, cefazolin or cefalotin Na, nafcillin Na, benzylpenicillin Na, methotrexate, mitomycin, hydrocortisone

Na succinate, aminophylline, ascorbic acid or terbutaline.

Intracavitary

Malignant effusions

Adult: 60,000 IU in 100 mL NaCl 0.9% instilled into the affected serous cavity, may be repeated up to a total cumulative dose of 500,000 IU.

Elderly: Max total cumulative dose: <60 yr 500,000 IU (30,000-60,000 IU wkly); 60-69 yr 300,000 IU (30,000-60,000 IU wkly); 70-79 yr 200,000 IU (30,000 IU wkly); ≥80 yr 100,000 IU (15,000 IU wkly).

Renal impairment: CrCl 20-40 mcg/mL: Admin 50% of normal dose.

Reconstitution: IM/SC: Add 1-5 mL or 2-10 mL of sterile water for inj, NaCl 0.9% inj, or bacteriostatic water for inj to the vial labelled as containing 15 IU or 30 IU of bleomycin, respectively, to provide a soln containing 3-15 IU/mL. IV: Add 5 mL or 10 mL of NaCl 0.9% into the vial labelled as containing 15 IU or 30 IU of bleomycin, respectively, to provide a soln containing ≤3 IU/mL. Admin slowly over a 10-min period. Intrapleural: Dissolve 60 IU of bleomycin in 50-100 mL NaCl 0.9% inj.

Incompatibility: Incompatible w/ soln of essential amino acids, riboflavin, dexamethasone or furosemide; carbenicillin, cefazolin or cefalotin Na, nafcillin Na, benzylpenicillin Na, methotrexate, mitomycin, hydrocortisone Na succinate, aminophylline, ascorbic acid or terbutaline.

#### CONTRAINDICATIONS:

Acute pulmonary infection or greatly reduced lung function. Concomitant brentuximab, cisplatin or oxygen. Lactation.

#### PRECAUTIONS:

Patient w/ severe heart disease. Renal impairment. Elderly. Pregnancy.

Monitoring Parameters: Closely monitor for signs of pulmonary toxicity; take chest radiographs every 1-2 wk. Perform sequential measurement of pulmonary diffusion capacity for carbon monoxide mthly during therapy. Carefully monitor fluid replacement, renal and liver function.

#### INTERACTIONS:

Increased incidence and severity of lung toxicity w/ previous or concurrent radiotherapy to the chest. Combination w/ vinca alkaloids may result to a syndrome corresponding to morbus Raynaud, ischaemia which can lead to necrosis of peripheral parts of the body (fingers, toes, nose tip). May reduce the absorption of phenytoin. Increased risk of agranulocytosis w/ clozapine.

Potentially Fatal: Increased pulmonary toxicity w/ oxygen, cisplatin or brentuximab.

#### ADVERSE REACTIONS:

Rash, erythema, pruritus, vesiculation, hyperkeratosis, nail changes, alopecia, hyperpigmentation, striae, stomatitis, fever, acute anaphylactoid reactions w/ hyperpyrexia and cardioresp collapse, depression of bone marrow, local reactions and thrombophlebitis (site of inj).

Potentially Fatal: Pulmonary toxicity, severe idiosyncratic reactions consisting of hypotension, mental confusion, fever, chills and wheezing; renal toxicity, hepatotoxicity.

#### 19. BUPIVACAINE Inj 2.5 and 5 mg, 20 ml vial

#### SALIENT ACTIONS:

Bupivacaine blocks both the initiation and conduction of nerve impulses reducing the permeability of neuronal membranes to Na ions resulting in inhibition of depolarization with resultant blockade of conduction

#### INDICATION & DOSAGE:

#### 1. Percutaneous infiltration anaesthesia

Adult: 0.25% solution is typically used. For prolonged action: 9 mg (1.8 ml) of a 0.5% solution with adrenaline (1:200,000) can be admin, repeated once after 2-10 min if necessary. Max total: 90 mg/dental sitting. Max single dose: 150 mg with or without adrenaline, followed by 50 mg every 2 hr if needed.

#### 2. Peripheral nerve block

Adult: 12.5 mg (5 ml) of a 0.25% solution or 25 mg (5 ml) of a 0.5% solution. Max single dose: 150 mg with or without adrenaline, followed by 50 mg every 2 hr if needed.

#### 3. Sympathetic nerve block

Adult: 50-125 mg (20-50 ml) of a 0.25% solution.

#### 5. Retrobulbar block

Adult: 15-30 mg (2-4ml) of a 0.75% solution

#### 6. Caudal block

*Adult:* In surgery: 37.5-75 mg (15-30 ml) of a 0.25% solution or 75-150 mg (15-30 ml) of a 0.5% solution. With analgesia during labour: 25-50 mg (10-20 ml) of a 0.25% solution or 50-100 mg (10-20 ml) of a 0.5% solution.

#### 6. Lumbar epidural block

Adult: In surgery: 25-50 mg (10-20 ml) of a 0.25% solution or 50-100 mg (10-20 ml) of a 0.5% solution. With analgesia during labour: 15-30 mg (6-12 ml) of a 0.25% solution or 30-60 mg (6-12 ml) of a 0.5% solution. In non-obstetric surgery: 75-150 mg (10-20 ml) of a 0.75% solution.

Special Populations: Reduce dose in children, elderly or debilitated patients and in cardiac or hepatic disease.

#### CONTRAINDICATIONS:

Hypersensitivity to local anaesthetics of amide type. IV regional anaesthesia; paracervical block in obstetrics; spinal anaesthesia <18 yr. Lactation. Solutions containing preservatives for caudal or epidural block.

#### PRECAUTIONS:

Hepatic disease; CV disease; children <12 yr; pregnancy. Elderly and debilitated patients.

#### DRUG INTERACTIONS:

Decreased duration with hyaluronidase. Decreased clearance with cimetidine and ranitidine. Potentiates lidocaine and mepivacaine. Allergic-type reactions with formulations containing sodium metabisulfite.

Potentially Fatal: May potentiate systemic toxicity of other local amide anaesthetics. Increased risk of myocardial depression with antiarrhythmics.

#### ADVERSE DRUG REACTIONS:

CNS excitation may be followed by depression. Hypotension, bradycardia, arrhythmias and cardiac arrest; methaemoglobinaemia; seizures, restlessness, dizziness. Hypersensitivity. Prolonged block.

Potentially Fatal: Cardiac and sudden respiratory arrest.

#### 20. BUTORPHANOL TARTRATE INJ. USP

#### SALIENT ACTIONS:

Butorphanol is a phenanthrene derivative w/ mixed opioid agonist and antagonist effect. It causes inhibition of ascending pain pathways, thus alters the perception of and response to pain. It also produces resp depression and sedation similar to opioids.

#### INDICATIONS & DOSAGE:

Parenteral

Moderate to severe pain

Adult: 1-4 mg via IM inj or 0.5-2 mg via IV inj, repeated after 3-4 hr if necessary.

Elderly: Initiate at half the usual dose. Adjust subsequent doses according to response at intervals of ≥6 hr.

Renal impairment: Initiate at half the usual dose. Adjust subsequent doses according to response at intervals of ≥6 hr.

Hepatic impairment: Initiate at half the usual dose. Adjust subsequent doses according to response at intervals of ≥6 hr.

Incompatibility: Y-site admin: Incompatible w/ amphotericin B cholesteryl sulfate complex, midazolam. Syringe: Incompatible w/ dimenhydrinate, pentobarbital.

Parenteral

Anaesthesia

Adult: As premedication: 2 mg via IM inj 60-90 min prior to surgery. As balanced anaesth: 2 mg via IV inj before induction and/or 0.5-1 mg in increments during anaesth.

Incompatibility: Y-site admin: Incompatible w/ amphotericin B cholesteryl sulfate complex, midazolam. Syringe: Incompatible w/ dimenhydrinate, pentobarbital.

Parenterai

Obstetric analgesia

Adult: 1-2 mg via IM or IV inj during early labour, may be repeated after 4 hr, if necessary.

Incompatibility: Y-site admin: Incompatible w/ amphotericin B cholesteryl sulfate complex, midazolam. Syringe: Incompatible w/ dimenhydrinate, pentobarbital.

#### CONTRAINDICATIONS:

Significant resp depression, unmonitored acute or severe brochial asthma.

#### PRECAUTIONS:

Patient w/ head injury, increased intracranial pressure, acute MI, ventricular dysfunction, coronary insufficiency, adrenal insufficiency, biliary tract dysfunction, CNS depression, prostatic hyperplasia, hypercapnia/hypoxia, COPD, thyroid dysfunction; obese patients and those at risk for drug abuse. Renal and hepatic impairment. Elderly. Pregnancy (may cause neonatal opioid withdrawal syndrome in prolonged use during pregnancy) and lactation. Patient Counselling This drug may cause drowsiness and dizziness, if affected, do not drive or operate machinery. Monitoring Parameters Monitor pain relief, resp and mental status, BP, signs and symptoms of hypogonadism or hypoadrenalism.

#### INTERACTIONS:

Additive effect w/ other CNS depressants (e.g. general anaesth, phenothiazines or other tranquilizers, sedatives, hypnotics, antihistamines). May increase risk of transient high BP when used w/ sumatriptan nasal spray. Increased conjunctival changes when used w/ pancuronium. Decreased rate of absorption when used w/ oxymetazoline (nasal).

#### ADVERSE REACTIONS:

Asthenia/lethargy, headache, heat sensation, vasodilation, palpitations, anorexia, constipation, dry mouth, nausea and vomiting, stomach pain, anxiety, confusion, dizziness, euphoria, floating feeling, insomnia, nervousness, paraesthesia, somnolence, tremor, bronchitis, cough, dyspnoea, epistaxis, nasal congestion, nasal irritation, pharyngitis, rhinitis, sweating, pruritus, blurred vision, ear pain, tinnitus, unpleasant taste, hypotension, syncope, abnormal dreams, agitation, dysphoria, hallucinations, hostility, rash, impaired urination, oedema, chest pain, HTN, tachycardia, depression, shallow breathing.

Potentially Fatal: Resp depression.

#### 21. BENZYL PENICILLIN Inj 500000 IU (300mg), vial

#### SALIENT ACTIONS:

Benzylpenicillin has a bactericidal action against gram-positive bacteria, gram-negative cocci, some other gram-negative bacteria, spirochetes and actinomycetes. It inhibits final cross-linking stage of peptidoglycan production through binding and inactivation of transpeptidases on the inner surface of the bacterial cell membrane thus inhibiting bacterial cell wall synthesis. It is inhibited by penicillinase and other  $\beta$ -lactamases.

#### INDICATIONS & DOSAGE REGIMENS:

#### Parenteral

#### I. Susceptible infections

Adult: 0.6-4.8 g/day in 2-4 divided doses via IM, slow IV inj or infusion, higher doses may be needed in more serious infections. IV doses >1.2 g should be given at a rate of not >300 mg/minute.

Child: 1 mth-12 yr: 100 mg/kg daily in 4 divided doses. Infant 1-4 wk: 75 mg/kg daily in 3 divided doses.

Premature infant and neonate up to 7 days old: 50 mg/kg daily in 2 divided doses.

Renal impairment: Dose adjustments may be necessary.

#### Intravenous

#### 1. Bacterial endocarditis

Adult: 1.2 g every 4 hr by slow inj or infusion, usually used with an aminoglycoside.

2. Intrapartum prophylaxis against group B Streptoccocal infection in neonates

Adult: Initially, 3 g via IV inj, followed by 1.5 g every 4 hr until delivery. Child: 150 mg/kg daily in 4 divided doses.

#### 3. Meningococcal meningitis or Pneumococcal meningitis

Adult: 2.4 g every 4 hr by slow inj or infusion. Up to 18 g/day in meningococcal meningitis. Administer high doses (>1.2 g) at a rate not >300 mg/minute to prevent CNS irritation and electrolyte imbalance.

Child: 1 mth-12 yr: 180-300 mg/kg daily in 4-6 divided doses. Infant 1-4 wk: 150 mg/kg daily in 3 divided doses. Premature infant and neonate: 100 mg/kg daily in 2 divided doses.

#### CONTRAINDICATIONS:

Hypersensitivity to penicillins.

#### PRECAUTIONS:

Very high doses in poor renal function (risk of neurotoxicity) or heart failure. Avoid contact, skin sensitization may occur. Monitor serum potassium concentration, renal and haematological status. Spirochete infections particularly syphilis; suprainfection with penicillin-resistant organisms with prolonged use; avoid intrathecal route. Lactation.

#### DRUG INTERACTIONS:

Probenecid prolongs  $T_{1/2}$  of benzylpenicillin. Bacteriostatic drugs e.g. chloramphenicol, tetracyclines; other antibacterials; anticoagulants.

#### ADVERSE DRUG REACTIONS:

Hypersensitivity reactions including uticaria; fever; joint pains; rashes; angioedema; serum sickness-like reactions; haemolytic anaemia; interstitial nephritis; neutropenia; thrombocytopenia; CNS toxicity including convulsions; diarrhoea; antibiotic-associated colitis.

Potentially Fatal: Anaphylaxis.

#### 22. CAFFEINE CITRATE USP INJ

#### **SALIENT ACTIONS:**

Caffeine, a methylxanthine, is a phosphodiesterase inhibitor. It has an antagonistic effect at central adenosine receptors. It is a CNS and resp stimulant. It has bronchodilating and diuretic properties and it facilitates the performance of muscular work.

#### INDICATION & DOSAGE:

Intravenous

Short-term treatment of neonatal apnoea of prematurity

Child: As citrate: 20 mg/kg (equivalent to 10 mg/kg caffeine) via IV infusion. Maintenance: 5 mg/kg daily. May also be given orally.

#### CONTRAINDICATIONS:

Hypersensitivity.

#### PRECAUTIONS:

Peptic ulceration; symptomatic cardiac arrhythmias and/or palpitations; 1st several days to wk after an acute MI; neonates; pregnancy; lactation.

#### INTERACTIONS:

Concurrent use may reduce the sedative/anxiolytic effect of benzodiazepines. Reduced levels when used with aminoglutethimide, carbamazepine, phenobarbital or rifampin. Increased levels when used with fluvoxamine, ketoconazole, rofecoxib, ciprofloxacin, norfloxacin or ofloxacin. β-adrenergic agonists, disulfiram, aspirin.

#### ADVERSE REACTIONS:

Insomnia, restlessness, nervousness, mild delirium; nausea, vomiting, gastric irritation.

#### 23. CALCIUM GLUCONATE Inj 0.1375 gm, 10 ml ampoule

#### SALIENT ACTIONS:

Calcium gluconate is used to prevent or treat negative calcium balance. It also helps facilitate nerve and muscle performance as well as normal cardiac function.

#### INDICATIONS&DOSAGE REGIMENS:

#### Intravenous

1. Severe acute hypocalcaemia 2. Hypocalcaemic tetany

Adult: 2.25 mmol by slow IV inj over 10 minutes, followed by 58-77 ml of 10% calcium gluconate solution in 0.5-11\_of 5% dextrose solution as continuous IV infusion.

Child: Neonate and 1 mth-18 yr: 0.5 ml/kg of 10% calcium gluconate solution as a single dose. Max: 20 ml of 10% calcium gluconate solution.

#### 3. Severe hyperkalaemia 4. Antidote in severe hypermagnesaemia

Adult: 10 ml of 10% calcium gluconate solution over 2 minutes, repeated every 10 minutes if needed.

Child: Neonate and 1 mth-18 yr: 0.5 ml/kg of 10% calcium gluconate solution as a single dose. Max: 20 ml of 10% calcium gluconate solution.

#### CONTRAINDICATIONS:

Patients with calcium renal calculi or history of renal calculi. Conditions associated with hypercalcaemia and hypercalciuria.

#### PRECAUTIONS:

Impaired renal function; cardiac disease; hypercalcaemia-associated diseases, e.g. sarcoidosis; other malignancies. Pregnancy.

#### DRUG INTERACTIONS:

Co-admin of high calcium doses with thiazide diuretics may result in milk-alkali syndrome and hypercalcaemia. May potentiate digoxin toxicity. Decreases effects of calcium-channel blockers. Enhanced absorption with calcitriol (a vitamin D metabolite).

#### ADVERSE DRUG REACTIONS:

GI irritation; soft-tissue calcification, skin sloughing or necrosis after IM/SC inj. Hypercalcaemia characterised by anorexia, nausea, vomiting, constipation, abdominal pain, muscle weakness, mental disturbances, polydipsia, polyuria, nephrocalcinosis, renal calculi; chalky taste, hot flushes and peripheral vasodilation. *Potentially Fatal:* Cardiac arrhythmias and coma.

#### 24. CARBOPROST TROMETHAMINE INJ. I P

#### SALIENT ACTIONS:

Carboprost, a synthetic analogue of naturally occurring prostaglandin  $F_{2\alpha}$ , stimulates uterine contractility, resulting in expulsion of the products of conception. It is also used to induce abortion between 13-20 wk of pregnancy. It produces myometrial contractions responsible for placental haemostasis.

#### INDICATIONS & DOSAGE:

Intramuscular

Pregnancy termination in the 2nd trimester

Adult: Initially, 250 mcg. Alternatively, initiate w/ test dose of 100 mcg. May be repeated at 1.5- to 3.5-hr intervals depending on uterine response. May be increased to 500 mcg if uterine contractility is inadequate. Max: 12 mg. Max duration: 2 days.

Intramuscular

Postpartum haemorrhage

Adult: Initially, 250 mcg by deep inj. May be repeated every 15-90-min. Max: 2 mg.

#### CONTRAINDICATIONS:

Acute pelvic inflammatory disease; active cardiac, pulmonary, renal or hepatic disease.

#### PRECAUTIONS:

Patient w/ compromised (scarred) uteri; history of asthma, seizure disorders, DM, anaemia, glaucoma or raised intra-ocular pressure, HTN, hypotension, CV disease, hepatic disease, including jaundice or renal disease. Pregnancy and lactation. Patient Counselling This drug may cause syncope, dizziness and somnolence, if affected, do not drive or use machines. Monitoring Parameters Monitor for reductions in arterial-oxygen content in patients w/ cardiopulmonary disorders.

#### INTERACTIONS:

May potentiate effect of other oxytocics.

#### ADVERSE REACTIONS:

Vomiting, diarrhoea, nausea, transient fever, flushing, increased BP, bronchospasm, dyspnoea, pulmonary oedema.

#### 25. CEFOTAXIME Inj 1gm, vial

#### SALIENT ACTIONS:

Cefotaxime binds to one or more of the penicillin-binding proteins (PBPs) which inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell wall, thus inhibiting biosynthesis and arresting cell wall assembly resulting in bacterial cell death.

#### INDICATIONS & DOSAGE REGIMENS:

- 1. Septicaemia
- 2. Skin and skin structure infections
- 3. Central nervous system infections
- 4. Bacteraemia
- 5. Bone and joint infections

- 6. Genitourinary infections
- 7. Gynaecological infections
- 8. Intra-abdominal infections
- 9. Lower respiratory tract infections

Adult: 1-2 g every 4-12 hr depending on the severity of the infection. May be given via deep IM inj or slow IV inj over 3-5 minutes or by IV infusion over 20-60 minutes. Max: 12 g daily.

Child: ≤1 mth: 50 mg/kg/dose, given every 8-12 hr; 1 mth-12 yr and <50 kg: 50-180 mg/kg/day, given in 4-6 equally divided doses. Higher doses may be used in more severe infections. ≥50 kg: 1-2 g every 4-12 hr

depending on the severity of the infection. May be given via deep IM inj or slow IV inj over 3-5 minutes or by IV infusion over 20-60 minutes.

**10.Prophylaxis of surgical infections**: *Adult:* 1 g, given 30-90 minutes before surgery. May be given via IM or IV inj or infusion.

#### 11.Gonorrhoea

Adult: A single dose of 0.5-1 g, given via Im inj or slow IV inj or infusion

Renal impairment: Dose reduction is necessary.

Special Populations: In renal impairment with CrCl of ≤5 mg/min, cefotaxime dose is reduced by 50%. Treatment is continued for up to 72 hr after relief of symptoms and for at least 10 days in Group A beta-haemolytic streptococcal infections.

#### CONTRAINDICATIONS:

Hypersensitivity to cephalosporins.

#### PRECAUTIONS:

History of penicillin allergy; colitis; impaired renal function; pregnancy, lactation.

#### DRUG INTERACTIONS:

Probenecid decreases cefotaxime elimination.

Potentially Fatal: Nephrotoxicity with furosemide and aminoglycosides...

#### ADVERSE DRUG REACTIONS:

Pain at inj site; hypersensitivity reactions, rash, pruritus; diarrhoea, nausea, vomiting; candidiasis; eosinophilia, neutropenia, leucopenia, thrombocytopenia.

Potentially Fatal: Anaphylactic reaction; nephrotoxicity

#### 26. CEFTAZIDIME Inj 1 gm, vial

#### SALIENT ACTIONS:

Ceftazidime binds to one or more of the penicillin-binding proteins (PBPs) which inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell wall, thus inhibiting biosynthesis and arresting cell wall assembly resulting in bacterial cell death.

#### INDICATION & DOSAGE REGIMENS:

#### Parenteral

#### 1. Pseudomonal lung infections in cystic fibrosis

Adult: 90-150 mg/kg/day in 3 divided doses via IM or IV inj or IV infusion, up to 9 g/day. Doses >1 g should be given via IV route.

Max Dosage: 9 g daily. Doses > 1 g should be administered IV.

#### Prophylaxis of surgical infection in patients undergoing prostate surgery

Adult: 1 g at induction of anesth repeated if necessary upon removal of catheter.

- 2. Biliary tract infections
- 3. Bone and joint infections
- 4. Infections in immunocompromised patients
- 5. Meningitis
- 6. Peritonitis
- Peritonitis
   Pneumonia

- Skin infections
- Melioidosis
- 10. Upper respiratory tract infections
- 11. Endophthalmitis
- 12. Urinary tract infections

Adult: 1-6 g daily in divided doses every 8 or 12 hr as deep IM, slow IV Inj over 3-5 min or infusion for up to 30 min.

Child: 30-100 mg/kg/day in 2 or 3 divided doses increased up to 150 mg/kg daily in severe cases. Neonates and infants ≤2 mth: 25-60 mg/kg/day in 2 divided doses. Max dose: 6 g daily in divided doses. Elderly: Max dose: 3 g daily.

Renal impairment: Loading dose: 1 g; maintenance doses based on CrCl. May need to increase doses by 50% in severe infections. Peritoneal dialysis: Loading dose is followed by 500 mg every 24 hr; may add ceftazidime to the dialysis fluid (usually 125-250 mg for 2 litres of dialysis fluid). Haemodialysis:

Special Populations: Renal impairment: 1 g loading dose followed by a maintenance dose based on patients creatinine clearance. CrCl: 31-50 mL/min: 1 g every 12 hrs; 16-30 mL/min: 1 g every 12 hrs;

6-15 mL/min: 0.5 g every 24 hrs; <5 mL/min: 0.5 g every 48 hrs. Increase dose by 50% in severe infections. Patients undergoing peritoneal dialysis: 1 g loading dose followed by 500 mg every 24 hrs. Patients undergoing haemodialysis: 1 g loading dose repeated after each dialysis period.

#### CONTRAINDICATIONS:

Hypersensitivity to cephalosporins.

#### PRECAUTIONS:

History of penicillin allergy; severe renal impairment; pregnancy, lactation.

#### DRUG INTERACTIONS:

Probenecid may decrease ceftazidime elimination time.

Potentially Fatal: Furosemide and aminoglycosides may increase nephrotoxicity.

#### ADVERSE DRUG REACTIONS:

Hypersensitivity, dizziness, diarrhoea, nausea, vomiting, renal impairment, rash, erythema multiforme, thrombocytopaenia, superinfection, phloebitis and thrombophloebitis at the site of injection. *Potentially Fatal:* Anaphylactic reactions, nephrotoxicity, pseudomembranous colitis

#### 27. CEFTRIAXONE Inj 1gm, vial

#### SALIENT ACTIONS:

Ceftriaxone inhibits the synthesis in the bacterial cell wall. Ceftriaxone is highly efficient against streptococci, Haemophilus influenzae, neisseriae, penicillin resistant strains of Staphylococcus aureus, multiresistant enterobacters, as well as other bacteria. Its effect against Pseudonomas aeruginosa is limited and it is ineffective against methicillin resistant strains of Staphylococcus aureus, Enterococcus faecalis, Clostridium difficile, and Bacteroides fragilis.

#### INDICATIONS:

Meningitis in neonates, children, and adults (except pseudomonas infections), Multiresistant Gram-negative infections, in particular caused by enterobacters., Gonorrhoea caused by β-lactamase producing gonococci (single dose of 250 mg i.m.), Osteomyelitis caused by Staphylococcus aureus, Disseminated and persisting forms of Lyme disease, urinary tract infections, lower respiratory tract infections, infections of the skin and soft tissue, adnexitis, typhus, as well as in the prevention of infections in neutropenia and perioperative infections (single dose), endocarditis or septicemia, not always effective against syphilis and chancroid (Haemophilus ducreyi)

#### DOSAGE REGIMENS:

#### Intramuscular

1. Uncomplicated gonorrhoea, prophylaxis of secondary meningococcal meningitis

Adult: 250 mg as a single dose, Child: 125 mg as a single dose, Max Dosage: 2 g daily.

#### Parenteral

- **1.Susceptible infections:** Adult: 1-2 g daily as a single or in 2 divided doses given as deep IM inj or slow IV inj over 2-4 minutes or as infusion over at least 30 minutes, increased to 4 g daily in severe infections. Child: <50 kg: 25-50 mg/kg once daily increased to 80 mg/kg in severe infections. Doses >50 mg/kg should be given as IV infusion. IV infusion in neonates should be given over 60 min. Max dose (neonates): 50 mg/kg/day.
- 2. Prophylaxis of surgical infections: Adult: 1 g as a single dose given 0.5-2 hr prior to surgery via deep IM inj or slow IV inj over at least 2-4 minutes or IV infusion over at least 30 minutes. A 2 g dose is recommended for colorectal surgery.

#### Intravenous

1. Typhoid fever: Adult: 2 g once daily for 14 days.

#### CONTRAINDICATIONS:

Cephalosporin hypersensitivity.

#### PRECAUTIONS:

Is available as a powder. Dissolve in sterile water (i.v. injection), in a 1% lidocaine solution (only i.m. injection), or in a calcium-free infusion solution (e.g. 0.9% sodium chloride solution, glucose 5% or 10%).

#### INTERACTIONS:

Ceftriaxone can increase the cyclosporin levels. In combination with alcohol an antabus reaction occasionally occurs. Other relevant interactions are not known.

#### ADVERSE REACTIONS:

Hematological changes (eosinophilia, thrombocytosis, less frequently leucopenia); an increase of the transaminases is not uncommon (5-7%). Diarrhea occurs in about 3% (children 5-6%), reversible biliary pseudolithiasis mainly in young women and children, allergic skin reactions, headaches, dizziness, nausea, vomiting, abdominal pains, reduction of the renal functions, vaginitis, pain at the site of injection. Isolated cases of pseudomembranous colitis have been observed, may cause bilirubin encephalopathy in neonates.

#### 28. CEFUROXIME SOD 750MG INJ

#### SALIENT ACTIONS:

Cefuroxime inhibits bacterial cell wall synthesis by binding to 1 or more of the penicillin-binding proteins (PBPs) which in turn inhibit the final transpeptidation step of peptidoglycan synthesis in bacterial cell walls, thus inhibiting cell wall biosynthesis and arresting cell wall assembly resulting in bacterial cell death.

#### INDICATIONS & DOSAGE:

Intravenous

Meningitis

Adult: As cefuroxime Na: 3 g 8 hrly.

Child: ≤3 wk 30-100 mg/kg daily by IV inj given as 2 or 3 divided doses; >3 wk <40 kg: 30-100 mg/kg daily by IV inj given as 3 or 4 divided doses; 60 mg/kg daily to most infections.

Renal impairment: Patients on haemodialysis should receive an additional 750-mg dose after each dialysis.

Patients on continuous peritoneal dialysis may be given 750 mg bid.

CrCl (ml/min)	Dosage Recommendation
<10	750 mg once daily.
10-20	750 mg bid.

Reconstitution: Powd for inj: Add 8 mL or 16 mL of sterile water for inj to a vial labelled as 0.75 g or 1.5 g, respectively, to provide a soln containing approx 90 mg/mL. For IV infusion: Reconstitute 50 mL or 100 mL of dextrose 5% inj, NaCl 0.9% inj or NaCl 0.45% inj to a vial labelled as 0.75 g or 1.5 g to a suitable container. Incompatibility: Aminoglycosides. Y-site: Azithromycin, filgrastim, fluconazole, midazolam, pantoprazole, vinorelbine.

Intramuscular

Gonorrhoea

Adult: As cefuroxime Na: 1.5 g as a single dose divided between 2 inj sites. May be given w/ oral probenecid 1 g.

Renal impairment: Patients on haemodialysis should receive an additional 750-mg dose after each dialysis. Patients on continuous peritoneal dialysis may be given 750 mg bid.

CrCl (ml/min)	Dosage Recommendation
<10	750 mg once daily.
10-20	750 mg bid.

Reconstitution: Powd for inj: Add 8 mL or 16 mL of sterile water for inj to a vial labelled as 0.75 g or 1.5 g, respectively, to provide a soln containing approx 90 mg/mL.

Incompatibility: Aminoglycosides. Y-site: Azithromycin, filgrastim, fluconazole, midazolam, pantoprazole, vinorelbine.

Parenteral

Prophylaxis of surgical infections

Adult: 1.5 g IV before the procedure followed by 750 mg IM 8 hrly for up to 24-48 hr depending on the procedure. For total joint replacement: 1.5 g, may be mixed w/ methylmethacrylate cement.

Renal impairment: Patients on haemodialysis should receive an additional 750-mg dose after each dialysis. Patients on continuous peritoneal dialysis may be given 750 mg bid.

CrCl (ml/min) Dosage Recommendation <10 750 mg once daily.

Reconstitution: Powd for inj: Add 8 mL or 16 mL of sterile water for inj to a vial labelled as 750 mg 0.75 g or 1.5 g, respectively, to provide a soln containing approx 90 mg/mL. For IV infusion: Reconstitute 50 mL or 100 mL of dextrose 5% inj, NaCl 0.9% inj or NaCl 0.45% inj to a vial labelled as 0.75 g or 1.5 g to a suitable container.

Incompatibility: Aminoglycosides. Y-site: Azithromycin, filgrastim, fluconazole, midazolam, pantoprazole, vinorelbine.

Parenteral

Susceptible infections

Adult: As cefuroxime Na: 0.75 g 8 hriy, by deep IM or slow IV inj over 3-5 min or IV infusion, may increase up to 1.5 g 6-8 hrly in more severe infections.

Child: ≤3 wk 30-100 mg/kg daily by IV inj given as 2 or 3 divided doses; >3 wk <40 kg: 30-100 mg/kg daily by IV inj given as 3 or 4 divided doses; 60 mg/kg daily to most infections.

Renal impairment: Patients on haemodialysis should receive an additional 750-mg dose after each dialysis. Patients on continuous peritoneal dialysis may be given 750 mg bid.

CrCl (ml/min)	Dosage Recommendation
<10	750 mg once daily.
10-20	750 mg bid.

Reconstitution: Powd for inj: Add 8 mL or 16 mL of sterile water for inj to a vial labelled as 0.75 g or 1.5 g, respectively, to provide a soln containing approx 90 mg/mL. For IV infusion: Reconstitute 50 mL or 100 mL of dextrose 5% inj, NaCl 0.9% inj or NaCl 0.45% inj to a vial labelled as 0.75 g or 1.5 g to a suitable container. Incompatibility: Aminoglycosides. Y-site: Azithromycin, filgrastim, fluconazole, midazolam, pantoprazole, vinorelbine.

#### Parenteral

#### Pneumonia

Adult: 1.5 g bid by deep IM or slow IV inj over 3-5 min or IV infusion, followed by an oral dose 0.5 g bid. Child:  $\leq 3$  wk 30-100 mg/kg daily by IV inj given as 2 or 3 divided doses;  $\geq 3$  wk  $\leq 40$  kg: 30-100 mg/kg daily by IV inj given as 3 or 4 divided doses; 60 mg/kg daily to most infections.

Renal impairment: Patients on haemodialysis should receive an additional 750-mg dose after each dialysis. Patients on continuous peritoneal dialysis may be given 750 mg bid.

CrCl (ml/min)	Dosage Recommendation
<10	750 mg once daily.
10-20	750 mg bid.

Reconstitution: Powd for inj: Add 8 mL or 16 mL of sterile water for inj to a vial labelled as 0.75 g or 1.5 g, respectively, to provide a soln containing approx 90 mg/mL. For IV infusion: Reconstitute 50 mL or 100 mL of dextrose 5% inj, NaCl 0.9% inj or NaCl 0.45% inj to a vial labelled as 0.75 g or 1.5 g to a suitable container. Incompatibility: Aminoglycosides. Y-site: Azithromycin, filgrastim, fluconazole, midazolam, pantoprazole, vinorelbine.

#### Parenteral

Acute exacerbations of chronic bronchitis

Adult: 750 mg bid by deep IM or slow IV inj over 3-5 min or IV infusion, followed by an oral dose 500 mg bid. Child: ≤3 wk 30-100 mg/kg daily by IV inj given as 2 or 3 divided doses; >3 wk <40 kg: 30-100 mg/kg daily by IV inj given as 3 or 4 divided doses; 60 mg/kg daily to most infections.

Renal impairment: Patients on haemodialysis should receive an additional 750-mg dose after each dialysis. Patients on continuous peritoneal dialysis may be given 750 mg bid.

CrCl (ml/min)	Dosage Recommendation
10-20	750 mg bid.
<10	750 mg once daily

Reconstitution: Powd for inj: Add 8 mL or 16 mL of sterile water for inj to a vial labelled as 0.75 g or 1.5 g, respectively, to provide a soln containing approx 90 mg/mL. For IV infusion: Reconstitute 50 mL or 100 mL of dextrose 5% inj, NaCl 0.9% inj or NaCl 0.45% inj to a vial labelled as 0.75 g or 1.5 g to a suitable container. Incompatibility: Aminoglycosides. Y-site: Azithromycin, filgrastim, fluconazole, midazolam, pantoprazole, vinorelbine.

#### CONTRAINDICATIONS:

Hypersensitivity to cefuroxime or to other cephalosporins.

#### PRECAUTION:

History of hypersensitivity to penicillin, and GI disease (particularly colitis). Renal impairment. Pregnancy and lactation. Monitoring Parameters Monitor renal, hepatic and haematologic function periodically. Monitor prothrombin time in patients at risk of prolongation. Observe for signs and symptoms of anaphylaxis during 1st dose.

#### INTERACTIONS:

May enhance the nephrotoxic effect of strong-acting diuretics (e.g. furosemide) and aminoglycosides. May enhance the effect of oral anticoagulants. May reduce the efficacy of OCs. Probenecid prolongs the excretion of cefuroxime and elevated peak serum levei.

#### ADVERSE REACTIONS:

Rash, fever, pruritus, erythema, urticaria, Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis, serum sickness-like reactions, angioedema; mild to moderate hearing loss (childn); nausea, vomiting, gagging, epigastric burning, GI bleeding and infection, abdominal pain, flatulence, ptyalism, indigestion, mouth

ulcers, swollen tongue, anorexia, thirst, dyspepsia, stomach cramps, diarrhoea; decreased Hb and haematocrit, thrombocytosis, lymphocytosis, haemolytic anaemia, increased prothrombin time; transient increase in serum AST (SGOT), ALT (SGPT), alkaline phosphatase, LDH and bilirubin levels; transient increase in BUN and/or serum creatinine concentration, decreased CrCl, bilateral renal cortical necrosis; UTI, kidney pain, urethral pain or bleeding, dysuria, vaginitis, vag candidiasis, vulvovaginal pruritus, vag discharge or irritation; Jarisch-Herxheimer reaction; neck muscle spasm, muscle cramps or stiffness, chest pain or tightness, shortness of breath, tachycardia, chills, lockjaw-type reaction, viral illness, upper resp infection, sinusitis, cough, joint swelling, arthralgia; pain at inj site, thrombophlebitis (IV). Rarely, transient eosinophilia and neutropenia, pancytopenia, leucopenia, thrombocytopenia; headache, somnolence or sleepiness, dizziness, hyperactivity, irritable behaviour, myoclonic jerks, seizures, generalised hyperexcitability; jaundice; acute renal failure, interstitial nephritis.

Potentially Fatal: Anaphylaxis, pseudomembranous colitis.

#### 29. CISATRACURIUM BESYLATE

#### 2mg/ml Injection

#### SALIENT ACTIONS:

Cisatracurium is a nondepolarizing skeletal muscle relaxant for intravenous administration.

CisatracuriumBesylate binds to the nicotinic acetycholine (cholinergic) receptors in the motor endplate and blocks access to the receptors.

#### INDICATIONS & DOSAGES REGIMENS:

As an adjunct to general anaesthesia, to facilitatetracheal intubation and to provide skeletal muscle relaxation during surgery.

Initial intubating doses: 0.15-0.2 mg/kg IV

Maintenance Dose

- 1. 0.03 mg/kg IV
- 2. Dose necessary 40-50 minutes following initial dose of 0.15 mg/kg
- 3. Dose necessary 50-60 minutes following initial dose of 0.2 mg/kg

#### CONTRAINDICATIONS:

- 1. Hypersensitivity
- 2. premature infants because the formulation contains benzyl alcohol

#### PRECAUTIONS:

Severe anaphylactic reactions, profound effect in myasthenia gravis patients, Bradycardia, Cross sensitivity with other neuromuscular-blocking agents, Hepatic impairment

#### INTERACTIONS:

- 1. antibiotics (e.g., aminoglycosides, tetracyclines, bacitracin, polymyxins, lincomycin, <u>clindamycin</u>, colistin, and sodium colistemethate), magnesium salts, <u>lithium</u>, local anesthetics, procainamide, and quinidine may enhance neuromuscular blockade of cisatracurium
- 2. May be antagonized by chronically administered phenytoin or carbamazepine.

#### ADVERSE EFFECTS

Bradycardia, hypotension, flushing, bronchospasm, rash, anaphylactic reactions, prolonged neuromuscular block, inadequate neuromuscular block, muscle weakness, myopathy.

#### 30. CISPLASTIN 1.0MG INJ

#### SALIENT ACTIONS:

Cisplatin modifies cell cycle by interfering with DNA structure and function. Effects are most prominent during the S phase but cells are killed at all stages. Cisplatin synergises with other anticancer drugs e.g. fluorouracil. It has a narrow therapeutic margin and is highly toxic.

#### INDICATIONS & DOSAGE:

Intravenous

Metastatic ovarian cancer

Adult: As monotherapy: 100 mg/m<sup>2</sup> per cycle, given as a single dose infused in 0.9% sodium chloride or glucose once every 4 wk. For combination therapy with cyclophosphamide: 75-100 mg/m<sup>2</sup> on day 1 of every 4-wk cycle.

Child:

Rena! impairment: Dose adjustment may be needed.

Incompatibility: Incompatible w/ sodium bicarbonate. Y-site incompatibility: Amphotericin B cholesteryl

sulfate complex, gallium nitrate, amifostine, cefepime, thiotepa, piperacillin/tazobactam.

Intravenous

Metastatic testicular tumours

Adult: 20 mg/m<sup>2</sup> BSA daily for 5 days per cycle.

Renal impairment: Dose adjustment may be needed.

Incompatibility: Incompatible w/ sodium bicarbonate. Y-site incompatibility: Amphotericin B cholesteryl sulfate complex, gallium nitrate, amifostine, cefepime, thiotepa, piperacillin/tazobactam.

Intravenous

Advanced bladder cancer

Adult: 50-70 mg/m<sup>2</sup> per cycle once every 3-4 wk, depending on the extent of prior exposure to radiation and/or chemotherapy treatment. An initial dose of 50 mg/m<sup>2</sup> every 4 wk may be used in heavily pre-treated patients. Renal impairment: Dose adjustment may be needed.

Incompatibility: Incompatible w/ sodium bicarbonate. Y-site incompatibility: Amphotericin B cholesteryl sulfate complex, gallium nitrate, amifostine, cefepime, thiotepa, piperacillin/tazobactam.

#### CONTRAINDICATIONS:

Patients with severe renal or auditory disorder, known hypersensitivity, severe bone marrow suppression, peripheral neuropathy, pregnancy, lactation.

#### PRECAUTIONS:

Patients with severe renal or auditory disorder, known hypersensitivity, severe bone marrow suppression, peripheral neuropathy, pregnancy, lactation.

#### INTERACTIONS:

Synergistic with 5-fluorouracil and etoposide. Efficacy increased and toxicity reduced when combined with radioprotecting agent WR 2721. At doses ≤100 mg, cisplatin is an ideal drug to combine with other cytotoxic drugs; unlike other antineoplastic drugs, it causes little myelosuppression.

Potentially Fatal: Potentiates nephrotoxicity with aminoglycosides. Increased toxicity when combined with other cytotoxic drugs.

#### ADVERSE REACTIONS:

Severe nausea and vomiting. Serious toxic effects on the kidneys, bone marrows and ears. Hypomagnesaemia, hypocalcaemia, hyperuricaemia. Peripheral neuropathies, papilloedema, optic neuritis, seizures. Ototoxicity (children) manifested as tinnitus, loss of hearing, deafness or vestibular toxicity.

Potentially Fatal: Rarely, renal damage due to inadequate hydration during therapy. Very rarely life-threatening myelosuppression. Anaphylactoid reactions (rare) and cardiac abnormalities.

#### 31. CITICOLINE INJ. I.P.

#### SALIENT ACTIONS:

Citicoline increases blood flow and O<sub>2</sub> consumption in the brain. It is also involved in the biosynthesis of lecithin.

#### INDICATIONS & DOSAGE:

Parenteral

Cerebrovascular disorders, Head injury, Parkinsonism

Adult: Up to 1 g IM/IV daily.

#### CONTRAINDICATIONS:

Hypersensitivity

#### PRECAUTIONS:

Caution should be exercised in patients with history of mental illness, during pregnancy and breastfeeding.

#### INTERACTIONS:

NA

#### A DVERSE REACTIONS:

Sleeplessness, headache, diarrhea, low or high blood pressure, nausea, blurred vision, chest pain

#### 32. CLARITHROMYCIN FOR INJ

#### SALIENT ACTIONS:

C Iarithromycin inhibits protein synthesis in susceptible organisms by penetrating the cell wall and binding to 5OS ribosomal subunits. It has activity against a variety of aerobic and anaerobic gm+ve and gm-ve bacteria.

#### INDICATIONS & DOSAGE:

Intravenous

Respiratory tract infections

Adult: 500 mg bid for 2-5 days. Infuse over 60 min using a 0.2% soln. Revert to oral therapy whenever possible. Child:

Renal impairment:

CrCl (ml/min)	Dosage Recommendation
<30	Half the dose or double the dosing interval.

Reconstitution: Inject 10 mL of water for inj into the 500 mg vial. Shake until contents have dissolved. Add the 10 mL vial soln to 250 mL using one of the following: NaCl 0.9%, dextrose 5%, dextrose 5% in NaCl 0.3%, dextrose 5% in NaCl 0.45%, dextrose 5% in Ringer's lactate soln or Ringer's lactate soln.

Intravenous

Skin and soft tissue infections

Adult: 500 mg bid for 2-5 days. Infuse over 60 min using a 0.2% soln. Revert to oral therapy whenever possible.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation
30	Half the dose or double the dosing interval.

Reconstitution: Inject 10 mL of water for inj into the 500 mg vial. Shake until contents have dissolved. Add the 10 mL vial soln to 250 mL using one of the following: NaCl 0.9%, dextrose 5%, dextrose 5% in NaCl 0.3%, dextrose 5% in NaCl 0.45%, dextrose 5% in Ringer's lactate soln or Ringer's lactate soln.

Intravenous

Susceptible infections

Adult: 500 mg bid for 2-5 days. Infuse over 60 min using a 0.2% soln. Revert to oral therapy whenever possible.

Renal impairment:

CrCl (ml	/min) Dosage Recommendation
<30	Half the dose or double the dosing interval.

Reconstitution: Inject 10 mL of water for inj into the 500 mg vial. Shake until contents have dissolved. Add the 10 mL vial soln to 250 mL using one of the following: NaCl 0.9%, dextrose 5%, dextrose 5% in NaCl 0.3%, dextrose 5% in NaCl 0.45%, dextrose 5% in Ringer's lactate soln or Ringer's lactate soln.

#### CONTRAINDICATIONS:

Patient w/ known hypersensitivity to clarithromycin or any other macrolide antibiotic, history of QT prolongation or ventricular cardiac arrhythmia, including torsades de pointes, hypokalaemia, history of cholestatic jaundice or hepatic dysfunction associated w/ prior use of clarithromycin. Patient receiving terfenadine, astemizole, pimozide, cisapride, ergotamine or dihydroergotamine, and colchicine.

#### PRECAUTIONS:

Patient w/ coronary artery disease, severe cardiac insufficiency, hypomagnesaemia, bradycardia (<50 bpm). May exacerbate symptoms of myasthenia gravis. Renal and hepatic impairment. Pregnancy and lactation. Monitoring Parameters Monitor CBC w/ differential, BUN and creatinine.

#### INTERACTIONS:

Reduced efficacy w/ CYP3A inducers (e.g. phenytoin, carbamazepine). Strong inducers of CYP450 system (e.g. efavirenz, rifampicin) may accelerate metabolism, thus lower plasma levels of clarithromycin. Inhibition of metabolism w/ ritonavir. Torsades de pointes may result from concomitant quinidine or disopyramide. Increased phosphodiesterase inhibitor exposure w/ sildenafil, tadalafil or vardenafil. Increased risk of digoxin toxicity. Decreased concentration of zidovudine. Concomitant use w/ atazanavir, itraconazole or saquinavir may result to bi-directional drug interactions. Hypotension, bradyarrhythmias, and lactic acidosis may result when taken w/ verapamil. Increased risk of myopathy, including rhabdomyolysis w/ HMG-CoA reductase inhibitors. Increased risk of hypoglycaemia w/ oral hypoglycaemic drugs (e.g. pioglitazone) and insulin. Risk of serious haemorrhage and elevation of INR and prothrombin time w/ oral anticoagulants. Increased ototoxicity w/ aminoglycosides. Increased and prolonged sedation w/ triabenzodiazepines (e.g. midazolam).

Potentially Fatal: Concurrent use w/ ergot alkaloids (e.g. ergotamine or dihydroergotamine) is associated w/ acute ergot toxicity characterised by vasospasm and ischaemia of the extremities. Concomitant use w/ astemizole, cisapride, pimozide and terfenadine may result in QT prolongation or ventricular cardiac arrhythmia. Increases serum levels and toxicity of colchicine.

#### ADVERSE REACTIONS:

Smell and taste disturbances, stomatitis, glossitis, tongue and tooth discolouration, headache, arthralgia, myalgia, hypoglycaemia, leucopenia, thrombocytopenia, interstitial nephritis, muscle weakness, agranulocytosis, elevated serum amylase levels, QT prolongation, torsades de pointes, corneal opacities, fever, pulmonary infiltration w/ eosinophilia, delirium, visual hallucinations, pancreatitis.

Potentially Fatal: Hepatic failure, pseudomembranous colitis, anaphylaxis, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug rash w/ eosinophilia and systemic symptoms (DRESS) syndrome and Henoch-Schonlein purpura.

#### 33. CLINDAMYCIN INJ

#### SALIENT ACTIONS:

Clindamycin inhibits protein synthesis by reversibly binding to the 50S ribosomal subunit, thus blocking the transpeptidation or translocation reactions of susceptible organisms resulting to stunted cell growth.

#### INDICATIONS & DOSAGE:

Parenteral

Severe anaerobic infections

Adult: 0.6-2.7 g daily in 2-4 divided doses, increased to 4.8 g daily in life-threatening infections. Infuse IV admin over 10-60 min and at a rate of  $\leq 30$  mg/min. Single dose of IM inj should not exceed 600 mg nor is admin of above 1.2 g in a single 1 hr infusion.

Child: >1 mth 15-25 mg/kg daily in 3 or 4 divided doses; in severe infections, increase to 40 mg/kg daily and a min dose of 300 mg daily should be given regardless of body wt.

Reconstitution: IV: Clindamycin phosphate inj (including that contained in ADD-Vantage vials) must be diluted w/ a compatible IV soln to a concentration not exceeding 18 mg/mL.

Incompatibility: Incompatible w/ alkaline preparations or drugs unstable at low pH. Ampicillin, aminophylline, barbiturates, Ca gluconate, ceftriaxone, ciprofloxacin, idarubicin, Mg sulfate, phenytoin and ranitidine. Incompatible w/ natural rubber closures.

#### CONTRAINDICATIONS:

Hypersensitivity to clindamycin or lincomycin.

#### PRECAUTIONS:

Patient w/ history of GI disease particularly colitis, atopic individuals. Not intended for the treatment of CNS infections. Severe renal and/or hepatic impairment. Pregnancy and lactation. Monitoring ParametersMonitor CBC, liver and renal function during prolonged therapy.

#### INTERACTIONS:

May enhance the action of neuromuscular blocking agents (e.g. atracurium). May antagonise the effects of parasympathomimetics. May competitively inhibit the effects of macrolides, ketolides, streptogramins, linezolid and chloramphenicol. Increased coagulation tests (prothrombin time/INR) and/or bleeding w/ vit K antagonists (e.g. warfarin, acenocoumarol, fluindione).

#### ADVERSE REACTIONS:

Nausea, vomiting, abdominal pain or cramps, taste disturbances, oesophagitis, oesophageal ulceration, rashes, urticaria, erythema multiforme, Stevens-Johnson syndrome, drug rash w/ eosinophilia and systemic symptoms (DRESS), exfoliative and vesiculobullous dermatitis, leucopenia, agranulocytosis, eosinophilia, thrombocytopenia, polyarthritis, renal dysfunction (e.g. azotemia, oliguria, proteinuria), local irritation, skin dryness, contact dermatitis, cervicitis, vaginitis, vag candidiasis, vulvovaginal irritation, sterile abscess and thrombophlebitis.

Potentially Fatal: Clostridium difficile-associated diarrhoea (CDAD) or pseudomembranous colitis, toxic epidermal necrolysis (TEN).

#### 34. COLISTIMETHATE SODIUM 1 MILLION IU INJ

#### SALIENT ACTIONS:

Colistin is a polymyxin antibiotic which is active against aerobic gram-ve bacteria including most enterobacteria except Proteus, Providentia and Serratia. Susceptible organisms include P. aeruginosa, Legionella spp, H. influenzae, Acinetobacter, V. cholera, Salmonella, Shigella and Pasteurella. It acts as a cationic detergent that causes leaking of intracellular substances and cell death by damaging the bacterial cytoplasmic membrane.

#### INDICATIONS & DOSAGE:

Parenteral

Severe Gram-negative infections

Adult: As colistimethate Na (strength expressed in terms of colistin base): 2.5-5 mg/kg/day in 2-4 divided doses. Max: 5 mg/kg/day.

Child: As colistimethate Na (strength expressed in terms of colistin base): 2.5 mg/kg/day divided 6-12 hrly.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation
	1.5 mg/kg 36 hrly.
30-49	2.5 mg/kg/day once daily or in 2 divided doses.
Chicago Sections	2.5-3.8 mg/kg/day in 2 divided doses.
(ASSESSED 1997)	Same as adult dose.

Reconstitution: Reconstitute 150 mg vial w/ 2 mL sterile water for inj. Reconstituted soln provides colistimethate Na at a concentration equivalent to 75 mg/mL colistin base.

#### CONTRAINDICATIONS:

Hypersensitivity. Myasthenia gravis.

#### PRECAUTIONS:

Patients w/ renal impairment, porphyria. Pregnancy and lactation. Patient Counselling Due to neurologic disturbances that may occur, if affected, do not drive or operate machinery. Monitoring Parameters Monitor serum creatinine and BUN regularly while on treatment.

#### INTERACTIONS:

Potentiates action of curariform muscle relaxants. Increased nephrotoxicity w/ aminoglycosides, amphotericin B, capreomycin, vancomycin.

#### ADVERSE REACTIONS:

Superinfection; renal damage; visual disturbances; GI disturbances, dizziness, nausea, vomiting; confusion, peripheral neuropathy; respiratory insufficiency and muscle weakness. Potentially Fatal: Severe colitis.

#### 35. DACARBAZINE INJ

#### SALIENT ACTIONS:

Dacarbazine is a non-cell cycle specific antineoplastic agent. The exact mechanism of action by which it exerts cytotoxic effects is still unclear. However, three possible mechanisms have been postulated, including inhibition of DNA synthesis by acting as a purine analog, action as an alkylating agent, and interaction w/ sulfydryl group in the inhibition of bacterial cell growth.

#### INDICATIONS & DOSAGE:

Intravenous

Metastatic melanoma

Adult: 2-4.5 mg/kg daily for 10 days, repeat at 4-wk intervals or 200-250 mg/m² daily via inj over 1 min for 5 days, repeat at 3-wk intervals or 850 mg/m² via infusion over 15-30 min once every 3 wk.

Renal impairment: Severe: Contraindicated. Hepatic impairment: Severe: Contraindicated.

Reconstitution: Reconstitute 100 mg and 200 mg w/ 9.9 mL and 19.7 mL sterile water for inj, respectively, to a concentration of 10 mg/mL. Further dilute for infusion by adding up to 250 mL of dextrose 5% or NaCl 0.9%. Incompatibility: Incompatible w/ allopurinol, cefepime, piperacillin/tazobactam, heparin, hydrocortisone Na succinate, L-cysteine, Na hydrogen carbonate.

Intravenous

Hodgkin's disease

Adult: In combination w/ doxorubicin, bleomycin and vinblastine (ABVD regimen): 150 mg/m² daily for 5 days, repeat at 4-wk intervals or 375 mg/m² via infusion over 15-30 min once every 15 days.

Renal impairment: Severe: Contraindicated.

Hepatic impairment: Severe: Contraindicated.

Reconstitution: Reconstitute 100 mg and 200 mg w/ 9.9 mL and 19.7 mL sterile water for inj, respectively, to a concentration of 10 mg/mL. Further dilute for infusion by adding up to 250 mL of dextrose 5% or NaCl 0.9%. Incompatibility: Incompatible w/ allopurinol, cefepime, piperacillin/tazobactam, heparin, hydrocortisone Na succinate, L-cysteine, Na hydrogen carbonate.

Intravenous

Soft tissue sarcoma

Adult: In combination w/ doxorubicin: 250 mg/m<sup>2</sup> once daily by infusion over 15-30 min for 5 days, repeat at 3-

wk intervals.

Renal impairment: Severe: Contraindicated.

Hepatic impairment: Severe: Contraindicated.

Reconstitution: Reconstitute 100 mg and 200 mg w/ 9.9 mL and 19.7 mL sterile water for inj, respectively, to a concentration of 10 mg/mL. Further dilute for infusion by adding up to 250 mL of dextrose 5% or NaCl 0.9%. Incompatibility: Incompatible w/ allopurinol, cefepime, piperacillin/tazobactam, heparin, hydrocortisone Na succinate, L-cysteine, Na hydrogen carbonate.

CONTRAINDICATIONS:

Hypersensitivity. Severe myelosuppression (e.g. leucopenia and/or thrombocytopenia). Severe hepatic or renal impairment. Pregnancy and lactation.

PRECAUTIONS:

Hepatic and renal impairment. Patient Counselling May impair ability to drive or operate machinery. Monitoring Parameters Monitor CBC w/ differential, leukocyte, erythrocyte and platelet count, LFT; infusion site for extravasation. Assess signs of infection and hepatotoxicity.

INTERACTIONS:

Increased metabolism when used w/ enzyme inducers (e.g. barbiturates, rifampicin, phenytoin). May potentiate the effect of mercaptopurine, azathioprine, allopurinol. May impair immune response to vaccines. May enhance the effects of methoxsalen due to photosensitisation.

ADVERSE REACTIONS:

Anorexia, vomiting, nausea, rash, alopecia, facial flushing and paraesthesia, orthostatic hypotension, ECG abnormalities, flu-like syndrome, myalgia, malaise, blurred vision, seizure, headache, confusion, lethargy, pain at inj site, tissue damage, cellulitis. Rarely, diarrhoea, photosensitivity, stomatitis.

Potentially Fatal: Anaphylaxis, bone marrow suppression (particularly leucopenia and thrombocytopenia), hepatotoxicity accompanied by hepatic vein thrombosis and hepatocellular necrosis.

#### 36. DACTINOMYCIN 0.5 MG INJECTION

SALIENT ACTIONS:

Dactinomycin binds to the guanine portion of DNA forming a complex which interferes w/ DNA and RNA synthesis as well as protein synthesis. It is also immunosuppressive and possesses some hypocalcaemic activity.

#### INDICATIONS & DOSAGE:

Intravenous

Ewing's sarcoma

Adult: 15 mcg/kg daily for 5 days, in combination regimens. Max: 15 mcg/kg or 400-600 mcg/m<sup>2</sup> daily for 5 days per 2-wk cycle.

Child: ≥6 mth Same as adult dose.

Reconstitution: Add 1.1 mL of sterile water for inj (w/o preservative), using aseptic precautions to make a soln containing approx 500 mcg/mL. The reconstituted soln can be added to infusion soln of dextrose 5% inj or NaCl inj either directly or to the tubing of a running IV infusion.

Incompatibility: Filgrastim.

Intravenous

Wilm's tumour

Adult: 15 mcg/kg daily for 5 days, in combination regimens. Max: 15 mcg/kg or 400-600 mcg/m<sup>2</sup> daily for 5 days per 2-wk cycle.

Child: ≥6 mth Same as adult dose.

Reconstitution: Add 1.1 mL of sterile water for inj (w/o preservative), using aseptic precautions to make a soln containing approx 500 mcg/mL. The reconstituted soln can be added to infusion soln of dextrose 5% inj or NaCl inj either directly or to the tubing of a running IV infusion.

Incompatibility: Filgrastim.

Intravenous

Childhood rhabdomyosarcoma

Adult: 15 mcg/kg daily for 5 days, in combination regimens. Max: 15 mcg/kg or 400-600 mcg/m<sup>2</sup> daily for 5 days per 2-wk cycle.

Child: ≥6 mth Same as adult dose.

Reconstitution: Add 1.1 mL of sterile water for inj (w/o preservative), using aseptic precautions to make a soln containing approx 500 mcg/mL. The reconstituted soln can be added to infusion soln of dextrose 5% inj or NaCl inj either directly or to the tubing of a running IV infusion.

Incompatibility: Filgrastim.

Intravenous

Gestational trophoblastic tumours

Adult: 12 mcg/kg daily for 5 days as a single agent or 500 mcg daily on days 1 and 2 of combination regimens. Max: 15 mcg/kg or 400-600 mcg/m<sup>2</sup> daily for 5 days per 2-wk cycle.

Reconstitution: Add 1.1 mL of sterile water for inj (w/o preservative), using aseptic precautions to make a soln containing approx 500 mcg/mL. The reconstituted soln can be added to infusion soln of dextrose 5% inj or NaCl inj either directly or to the tubing of a running IV infusion.

Incompatibility: Filgrastim.

Intravenous

Metastatic nonseminomatous testicular cancer

Adult: 1 mg/m<sup>2</sup> on day 1 of combination regimens. Max: 15 mcg/kg or 400-600 mcg/m<sup>2</sup> daily for 5 days per 2-

Reconstitution: Add 1.1 mL of sterile water for inj (w/o preservative), using aseptic precautions to make a soln containing approx 500 mcg/mL. The reconstituted soln can be added to infusion soln of dextrose 5% inj or NaCl inj either directly or to the tubing of a running IV infusion. Incompatibility: Filgrastim.

#### CONTRAINDICATIONS:

Hypersensitivity. Patient w/ varicella or herpes zoster infection.

#### PRECAUTIONS:

Patient w/ impaired bone marrow. Renal and hepatic impairment. Pregnancy and lactation. Patient Counselling Avoid inhalation of vapours or contact w/ skin, mucous membrane or eyes. Monitoring Parameters Monitor blood counts, renal, hepatic and bone marrow functions frequently.

#### INTERACTIONS:

Combination w/ radiation therapy may result in increased toxicity esp when w/in 2 mth of radiation treatment for right-sided Wilm's tumour. May diminish the therapeutic effect of live vaccines.

#### ADVERSE REACTIONS:

Nausea, vomiting, cheilitis, oesophagitis, GI ulceration, proctitis, fever, malaise, hypocalcaemia, myalgia, alopecia, pneumonitis, kidney and liver abnormalities, eruptions, acne, toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme, severe tissue damage, oedema, neutropenia and febrile neutropenia. Potentially Fatal: Hepatic failure, hepatic veno-occlusive disease, particularly in childn <4 yr, myelosuppression, sepsis, including neutropenic sepsis.

#### 37. DAUNORUBICIN 20MG INJ

#### SALIENT ACTIONS:

Daunorubicin forms a stable complex with DNA and interferes with the nucleic acid synthesis. It is a cell-cycle nonspecific agent, but its cytotoxic effects are mostly marked in the S-phase. It also has immunosuppressant and antibacterial effects.

#### INDICATIONS & DOSAGE:

Intravenous

Acute leukaemias

Adult: 30-45 mg/m<sup>2</sup> BSA daily on days 1-3 of the induction course and days 1 and 2 for the subsequent courses. Admin as a solution in 0.9% sodium chloride into a fast-running infusion of sodium chloride or glucose. May repeat course 3-6 wk later. Max (total cumulative dose): 550 mg/m<sup>2</sup> in patients without risk factors for cardiotoxicity and 400 mg/m<sup>2</sup> in patients who have received chest radiotherapy.

Child: For acute lymphoblastic leukaemia: 25 mg/m<sup>2</sup> BSA once wkly in combination with other regimens. <2 yr old or BSA <0.5 m<sup>2</sup>: 1 mg/kg once wkly. Max (total cumulative dose): 300 mg/m<sup>2</sup> and in children <2 yr: 10

Renal impairment: Based on serum-creatinine concentrations: 105-265 micromoles/l: 75% of the usual dose; >265 micromoles/l: 50% of the usual dose.

Hepatic impairment: Based on serum bilirubin concentrations of 12-30 mcg/ml: 75% of the usual dose; >30 mcg/ml: 50% of the usual dose.

Incompatibility: Incompatible with heparin sodium and dexamethasone sodium phosphate solution.

AIDS-related Kaposi's sarcoma

Adult: As the liposomal formulation: Initially, 40 mg/m² once every 2 wk, diluted in glucose 5% to a

concentration of 0.2-1 mg/ml and given over 30-60 minutes. May continue for as long as disease control can be maintained.

Renal impairment: Based on serum-creatinine concentrations: 105-265 micromoles/l: 75% of the usual dose;

>265 micromoles/l: 50% of the usual dose.

Hepatic impairment: Based on serum bilirubin concentrations of 12-30 mcg/ml: 75% of the usual dose; >30 mcg/ml: 50% of the usual dose.

Incompatibility: Incompatible with heparin sodium and dexamethasone sodium phosphate solution.

# CONTRAINDICATIONS:

Heart failure. Pregnancy, lactation.

# PRECAUTIONS:

Regular blood count and ECG monitoring; elderly, children. Hepatic or renal impairment may increase risk of toxicity. Pre-existing cardiac disease and previous treatment with doxorubicin. Myocardial toxicity leading to potentially fatal congestive heart failure may occur during therapy or mth to yr after therapy cessation. Incidence of myocardial toxicity increases after total cumulative dose exceeds 400-550 mg/m² in adults, 300 mg/m² in children >2 yr, or 10 mg/kg in children <2 yr. Risk of severe myelosuppression leading to infection or haemorrhage.

# INTERACTIONS:

Increased risk of cardiotoxicity when used with cyclophosphamide. Increased risk of hepatic toxicity when used with hepatotoxic drugs e.g. high-dose methotrexate.

Potentially Fatal: Immunisation with live vaccines is not recommended. Concurrent radiation may lead to increased radiation reaction.

# ADVERSE REACTIONS:

GI disturbances; stomatitis; alopoecia and dermatological reactions. Extravasation of daunorubicin may cause severe local tissue necrosis damaging surrounding muscles, tendons and nerves. IV infusion, back pain, flushing and chest tightness.

Potentially Fatal: Bone marrow suppression, cardiac toxicity, cardiomyopathy and congestive heart failure.

# 38. DEXAMETHASONE Inj 8mg/2ml, vial

SALIENT ACTIONS:

Like other glucocorticoids, dexamethasone acts on the metabolism (in particular on the carbohydrates) and it inhibits the adrenal cortex through feedback on the hypothalamus and pituitary; it also has strong antiinflammatory and immunosuppressive action. The effect on sodium and potassium is negligible, but it does cause calcium loss and osteoporosis like other corticoids. The effects of glucocorticoids are based largely on the interaction with intracellular receptors that cause the synthesis of specific proteins.

# INDICATIONS AND DOSAGE REGIMENS:

1. Acute Asthma 2. Croup

Adult: IV and IM (injections as sodium phosphate):0.75 to 9 mg per day in divided doses every 6 to 12 hours Pediatric: IM, IV: 0.6 mg/kg once (maximum: 20 mg). A single dose of 0.15 mg/kg has also been shown effective.

3. Anti-inflammatory

Adult: IV and IM (injections as sodium phosphate):0.75 to 9 mg per day in divided doses every 6 to 12 hours Intraarticular, intralesional, or soft tissue (as sodium phosphate):0.4 to 6 mg per day. Pediatric: 0.08 to 0.3 mg/kg/day or 2.5 to 5 mg/meter squared/day in divided doses every 6 to 12 hours.

4. Cerebral Edema

Adult: Initial 10 mg IV once, followed by 4 mg IM every 6 hours until symptoms of cerebral edema subside. Dosage may be reduced after 2 to 4 days, and discontinued slowly over a period of 5 to 7 days. Pediatric: Initial loading dose: 1 to 2 mg/kg once IV or IM.Maintenance: 1 to 1.5 mg/kg/day, give in divided doses every 4 to 6 hours for 5 days then taper for 5 days, then discontinue. Maximum dose: 16 mg/day.

5. Nausea/Vomiting - Chemotherapy Induced

Adult Prophylaxis: 10 mg to 20 mg orally or IV, 15 to 30 minutes before treatment on each treatment day For continuous infusion of chemotherapy: 10 mg IV every 12 hours on each treatment day.

For mildly emetogenic therapy: 4 mg IV or IM every 4 to 6 hours. Pediatric Prophylaxis: 10 mg/meter squared IV for first dose (maximum 20 mg) then 5 mg/meter squared/dose every 6 hours as needed.

Addisonian crisis/shock:4 to 10 mg IV as single dose, repeat if necessary.

Unresponsive shock:1 to 6 mg/kg IV as a single dose or up to 40 mg initially followed by repeat doses every 2 to 6 hours while shock persists.

7.Multiple Myeloma: IV: 40 mg/day, days 1 to 4, 9 to 12, and 17 to 20, repeated every 4 weeks (alone or as part of a regimen).

#### 8.Adrenal Insufficiency

**Adult:** Physiological replacement: IM, IV (should be given as sodium phosphate): 0.03 to 0.15 mg/kg/day or 0.6 to 0.75 mg/m2/day in divided doses every 6 to 12 hours.

**Pediatric:** Physiological replacement: Oral, IM, IV (should be given as sodium phosphate): 0.03 to 0.15 mg/kg/day or 0.6 to 0.75 mg/m2/day in divided doses every 6 to 12 hours.

# 2. Meningitis - Meningococcal / Haemophilus influenzae/ Pneumococcal/ Listeriosis

Pediatric: Meningitis (H. influenzae type b): Infants and Children 6 weeks or older: IV: 0.15 mg/kg/dose every 6 hours for the first 2 to 4 days of antibiotic treatment; start dexamethasone 10 to 20 minutes before or with the first dose of antibiotic.

#### CONTRAINDICATIONS:

Depending on the indication and the general condition, peptic ulcers, osteoporosis, psychoses, infectious diseases (e.g. herpes simplex, keratitis), diabetes and hypertension can be considered contraindications.

#### PRECAUTIONS:

The anti-inflammatory effect of  $0.75~\mathrm{mg}$  of dexamethasone approximately corresponds to  $5~\mathrm{mg}$  of prednisolone or  $20~\mathrm{mg}$  of hydrocortisone.

#### INTERACTIONS:

Enzyme inducers such as phenobarbitone, phenytoin and rifampicincan reduce the effect of dexamethasone.

# ADVERSE REACTIONS:

While short-term administration rarely causes side-effects, the consequences of a longer lasting, moderate to high dose treatment are multifarious and potentially fatal. Long-term therapy involves the *suppression of adrenal function, Cushing's syndrome and impaired immune defense*, glaucoma, subcapsular cataract, gastrointestinal bleeding, pancreatitis, aseptic bone necrosis, osteoporosis, myopathies, obesity, edemas, hypertension, proteinuria, diabetes, sleep disturbances, psychiatric syndromes, delayed wound healing, atrophy and fragility of the skin, ecchymosis, pseudotumor cerebri.

# 39. DEXMEDETOMIDINE HCL 100MCG INJ

#### SALIENT ACTIONS:

Dexmedetomidine is a selective  $\alpha_2$ -adrenoceptor agonist w/ anaesth and sedative properties. Its action is thought to be due to activation of G-proteins by  $\alpha_{2a}$ -adrenoceptors in the brainstem resulting in inhibition of norepinephrine release.

# INDICATIONS & DOSAGE:

Intravenous

Sedation in critical care

Adult: 0.7 mcg/kg/hr adjusted according to response, w/in the dose range 0.2-1.4 mcg/kg/hr.

#### CONTRAINDICATIONS:

2nd or 3rd degree AV block (unless paced), uncontrolled hypotension, acute cerebrovascular disorders.

# PRECAUTIONS:

Patient w/ severe neurological disorders, pre-existing bradycardia, ischaemic heart disease, spinal cord injury, malignant hyperthermia. Avoid abrupt withdrawal after prolonged use. Hepatic and renal impairment. Pregnancy and lactation.

#### INTERACTIONS:

Enhanced pharmacologic effects of anaesth, sedatives, hypnotics, opiate agonists, other vasodilators or drugs that have negative chronotropic effects (e.g. cardiac glycosides).

#### ADVERSE REACTIONS:

Nausea, vomiting, dry mouth, BP changes, bradycardia, tachycardia, AF, MI, myocardial ischaemia, fever, hypoxia, hyperthermia, anaemia, agitation, pain, pleural effusion, changes in blood sugar.

# 40. DIATRIZOATE MEGLUMINE INJ

#### SALIENT ACTIONS:

diatrizoic acid; Belongs to the class of watersoluble, nephrotropic, high osmolar preparations used as X-ray contrast media.

# INDICATIONS & DOSAGE:

Intravenous & retrograde urography, cerebral, thoracic, abdominal & extremity angiography & other special examinations.

# CONTRAINDICATIONS:

Hypersensitivity

#### INTERACTIONS:

NA

#### ADVERSE REACTIONS:

Hypersensitivity reactions, hypothyroidism.

# 41. DIAZEPAM Inj10 mg, 2ml ampoule

#### SALIENT ACTIONS

Diazepam is a long-acting benzodiazepine with anticonvulsant, anxiolytic, sedative, muscle relaxant and amnestic properties. It increases neuronal membrane permeability to chloride ions by binding to stereospecific benzodiazepine receptors on the postsynaptic GABA neuron within the CNS and enhancing the GABA inhibitory effects resulting in hyperpolarisation and stabilisation.

#### INDICATION & DOSAGE REGIMENS

#### Parenteral

1. Muscle spasms

Adult: 10 mg IM/IV repeated if necessary after 4 hr. Higher doses may be used in tetanus: 100-300 mcg/kg every 1-4 hr via IV inj; alternatively 3-10 mg/kg may be given over 24 hr by continuous IV infusion or by nasoduodenal tube using a suitable liquid oral dosage form. Child: ≥1 mth: Higher doses may be used in tetanus: 100-300 mcg/kg every 1-4 hr via IV inj; alternatively 3-10 mg/kg may be given over 24 hr by continuous IV infusion or by nasoduodenal tube using a suitable liquid oral dosage form. Elderly: Dose reduction may be required.

2. Alcohol withdrawal syndrome: Adult: 10-20 mg IM/IV if symptoms are severe and if delirium tremens

has developed. Elderly: Dose reduction may be required.

3. Severe anxiety: Adult: Up to 10 mg may be used, repeat if needed after 4 hr. Dose can be given via IM or IV inj.

Intravenous

# 4. Premedication before anaesthesia

Adult: Usual dose: 100-200 mcg/kg.

Child: >1 mth: 100-200 mcg/kg. Max: 1 mth-12 yr: 5 mg/day; 12-18 yr: 20 mg/day.

Elderly: Dose reduction may be required.

# 5. Sedation in minor surgical and medical procedures/ Adjunct in seizures

Adult: 10-20 mg given via IV inj over 2-4 min.

Child: ≥1 mth: 100-200 mcg/kg via IV inj over 2-4 min, to be given immediately before the procedure.

Max: 5 mg (up to 12 yr); 20 mg (up to 18 yr).

Renal impairment: Dosage adjustments may be needed.

**Special Populations:** Max dose for elderly and debilitated patients is ½ the adult dose. Reduce dose in patients with liver or kidney dysfunction.

# CONTRAINDICATIONS:

Hypersensitivity; myasthenia gravis, preexisting CNS depression or coma, respiratory depression; acute pulmonary insufficiency or sleep apnoea syndrome; severe hepatic impairment; acute narrow angle glaucoma; children <6 mth (oral); pregnancy and lactation.

# PRECAUTIONS:

Impaired renal and hepatic function, respiratory disease, organic cerebral changes, elderly, psychotic patients, epileptics, history of alcohol or drug addiction, impaired gag reflux, obese patients. May cause CNS depression. Discontinue treatment if patient develops psychiatric and paradoxical reactions. Caution when used in patients with depression or anxiety associated with depression, especially if patient has suicidal risk. May increase risk of fails. Abrupt withdrawal or large dose reduction may cause rebound or withdrawal symptoms.

#### INTERACTIONS:

Increased clearance of diazepam when used with phenytoin, carbamazepine and phenobarbital. Reversible deterioration of parkinsonism may occur when given together with levodopa. Combination with lithium may produce hypothermia. May need to reduce dose of narcotics when used concurrently.

Potentially Fatal: Phenothiazines, barbiturates, MAOIs potentiate action of diazepam. Additive CNS depressant effects with alcohol and CNS depressants or psychoactive medications. Mutual potentiation of action with

analgesics, anaesthetics and some anticonvulsants.

### ADVERSE DRUG REACTIONS:

Psychological and physical dependence with withdrawal syndrome, fatigue, drowsiness, sedation, ataxia, vertigo, confusion, depression, GI disturbances, changes in salivation, amnesia, jaundice, paradoxical excitation, elevated liver enzyme values; muscle weakness, visual disturbances, headache, slurring of speech and dysarthria, mental changes, incontinence, constipation, hypotension, tachycardia, changes in libido, pain and thrombophlebitis at inj site (IV).

Potentially Fatal: Respiratory and CNS depression, coma.

# $42.\ DICLOFENAC\ Inj\ 25mg/ml/30ml\ vial,\ Tab\ 50\ mg,\ SR\ tab\ 100mg,\ 30mg\ topical\ gel,\ 100mg\ suppositories$

#### SALIENT ACTIONS:

Diclofenac has potent anti-inflammatory and antipyretic action, inhibit cyclo-oxygenase enzyme and reduces PG synthesis.

#### INDICATIONS:

Tablets- Sprains, strains, tendinitis, musculoskeletal and joint pain, bursitis, acute gout, dysmenorrhoea Injection: IV infusion for postoperative pain, IM injection in gluteal muscle for renal colic Topical gel: applied locally in arthritis, rheumatoid arthritis, polymyositis, dermatomyositis, osteoarthritis, spodylo-arthritis, ankylosing spondylitis

Rectal suppository: for postoperative pain

# DOSAGE REGIMENS:

Tablet Diclofenac 75 mg two times a day, IV 25-75 mg in 5 % Dextrose or 0.9 sodium chloride given over 30-120 minutes. IM injection 75 mg once may be repeated once after 30 minutes, Rectal preparation :75-150 mg/day; child-1-2 mg/kg/day

# CONTRAINDICATIONS:

Active peptic ulcer disease, hypersensitivity reaction, treatment of peri-operative pain in CABG patient, 3<sup>rd</sup> trimester of pregnancy, topical:not to apply over damaged or nonintact cream.

#### PRECAUTIONS:

Patient with GI ulceration, impaired cardiac, renal or hepatic function, hypertension, lactation, pregnancy, asthma, porphyria, may prolong bleeding time with anticoagulants or coagulation disorder, elderly, debilated patients

# INTERACTIONS:

IV not given in patients receiving NSAID or oral anticoagulant or heparin, increase in renal impairment with ciclosporinor triamterene, altered absorption with sucralfate, clestyramineor colestipol, increase in GI bleeding with corticosteroids, aspirin or anticoagulants, increase blood levels of digoxin, lithium, methotrexate and potassium sparing diuretic

#### ADVERSE EFFECTS:

GI disturbances, headache, dizziness, rash, GI bleeding, peptic ulceration, pain and tissue at site of injection, local rectal irritation, Stevens- Johnson sundromme, exfoliative dermatitis, toxic epidermai necrolysis

#### 43. DIGOXIN INJECTION IP 2ML

#### SALIENT ACTIONS:

Digoxin is a cardiac glycoside which has positive inotropic activity characterized by an increase in the force of myocardial contraction. It also reduces the conductivity of the heart through the atrioventricular (AV) node. Digoxin also exerts direct action on vascular smooth muscle and indirect effects mediated primarily by the autonomic nervous system and an increase in vagal activity.

# INDICATION & DOSAGE:

Intravenous

Emergency heart failure

Adult: For patients who have not received cardiac glycosides in the previous 2 wk. 0.5-1 mg by IV infusion as a single dose over at least 2 hr or in divided doses with each dose given over 10-20 minutes. Maintenance dose is usually given orally.

Renal impairment: Dosage reductions may be needed.

Reconstitution: Admin undiluted or diluted with a 4-fold or greater volume of sterile water for inj, NaCl 0.9% inj, or dextrose 5% inj.

Incompatibility: Using less than a 4-fold volume of diluent could lead to precipitation of the digoxin.

# CONTRAINDICATIONS:

Digitalis toxicity, ventricular tachycardia/fibrillation, obstructive cardiomyopathy. Arrhythmias due to accessory pathways (e.g. Wolff-Parkinson-White syndrome).

#### PRECAUTIONS:

Cardiac dysrhythmias, hypokalaemia, hypertension, IHD, hypercalcaemia, hypomagnesaemia, electroconversion, chronic cor pulmonale, aortic valve disease, acute myocarditis, congestive cardiomyopathies, constrictive pericarditis, heart block, elderly, renal impairment, abnormalities in thyroid function; pregnancy. IV digoxin can only be given to patients who have not received cardiac glycosides in the preceding 2 wk.

#### INTERACTIONS:

Effectiveness reduced by phenytoin, neomycin, sulphasalazine, kaolin, pectin, antacids and in patients receiving radiotherapy. Metoclopramide may alter the absorption of solid dosage forms of digoxin. Blood levels increased by calcium channel blockers, spironolactone, quinidine and calcium salts.

Potentially Fatal: Electrolyte imbalances such as hypokalaemia and hypomagnesemia (e.g. admin of potassium-losing diuretics, corticosteroids) can increase the risk of cardiac toxicity.

#### ADVERSE REACTIONS:

Extra beats, anorexia, nausea and vomiting. Diarrhoea in elderly, confusion, dizziness, drowsiness, restlessness, nervousness, agitation and amnesia, visual disturbances, gynaecomastia, local irritation (IM/SC inj), rapid IV admin may lead to vasocostriction and transient hypertension.

Potentially Fatal: Cardiac arrhythmias in combination with heart block.

# 44. DOBUTAMINE HYDROCHLORIDE IP 50MG INJ

#### SALIENT ACTIONS:

**Dobutamine** is a <u>sympathonimetic drug</u> used in the treatment of <u>heart failure</u> and <u>cardiogenic shock</u>. Its primary mechanism is direct stimulation of  $\underline{\beta_1}$  receptors of the sympathetic nervous system.

#### INDICATIONS:

Dobutamine is used to treat acute but potentially reversible heart failure, such as which occurs during cardiac surgery or in cases of septic or cardiogenic shock, on the basis of its positive inotropic action. Dobutamine can be used in cases of congestive heart failure to increase cardiac output. It is indicated when parenteral therapy is necessary for inotropic support in the short-term treatment of patients with cardiac decompensation due to depressed contractility, which could be the result of either organic heart disease or cardiac surgical procedures.

#### DOSAGE REGIMENS:

1)Cardiac Decompensation

0.5-1 mcg/kg/min IV continuous infusion initially, then 2-20 mcg/kg/min; not to exceed 40 mcg/kg/min 2)Low Cardiac Output

2-20 mcg/kg/min IV or IO; titrate to desired effect; not to exceed 40 mcg/kg/min

#### CONTRAINDICATIONS:

Dobutamine hydrochloride is contraindicated in patients with idiopathichypertrophic subaortic stenosis and in patients who have shown previous manifestations of hypersensitivity to dobutamine injection.

#### PRECAUTIONS:

During the administration of dobutamine injection, as with any adrenergic agent, ECG and blood pressure should be continuously monitored. In addition, pulmonary wedge pressure and cardiac outputshould be monitored whenever possible to aid in the safe and effective infusion of dobutamine hydrochloride. Hypovolemia should be corrected with suitable volume expanders before treatment with dobutamine is instituted.

No improvement may be observed in the presence of marked mechanical obstruction, such as severe valvular aortic stenosis.

#### INTERACTIONS:

Concomitant use of dobutamine and nitroprusside results in a higher cardiac output and, usually, a lower pulmonary wedge pressure than when either drug is used alone.

There was no evidence of drug interactions in clinical studies in which dobutamine was administered concurrently with other drugs, including digitalis preparations, furosemide, spironolactone, lidocaine, nitroglycerin, isosorbide dinitrate, morphine, atropine, heparin, protamine, potassium chloride, folic acid, and acetaminophen.

#### ADVERSE EFFECTS:

Primary side effects include those commonly seen for  $\beta_1$  active sympathomimetics, such as hypertension,

angina, arrhythmia, and tachycardia. Used with caution in atrial fibrillation as it has the effect of increasing the atrioventricular (AV) conduction.[3]

The most dangerous side effect of dobutamine is increased risk of arrhythmia, including fatal arrhythmias.

# 45. DOCETAXEL INJ

# SALIENT ACTIONS:

Docetaxel belongs to a class of chemotherapy drugs called plant alkaloids. It works by stopping the cancer cells from separating into 2 new cells, so it blocks the growth of cancer.

# INDICATIONS:

- breast cancer
- head and neck cancer
- prostate cancer
- · stomach cancer
- · For the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy. Also used as a single agent in the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior platinum-based chemotherapy. It is also used in combination with prednisone, in the treatment of patients with androgen independent (hormone refractory) metastatic prostate cancer. Furthermore, docetaxel has uses in the treatment of gastric adenocarinoma and head and neck cancer.

# DOSAGE REGIMENS:

Intravenous: 3 weeks: 1,54-79 75-100 mg/m2 IV for one dose on day 1 (total dose per cycle 75-100 mg/m2) 8 weeks: 83-86 36 mg/m<sup>2</sup> IV for one dose on days 1, 8, 15, 22, 29, 36 (total dose per cycle 216 mg/m<sup>2</sup>)

#### CONTRAINDICATIONS:

should not be used in patients with neutrophil counts of < 1500 cells/mm<sup>3</sup>.

#### PRECAUTIONS:.

- Do not receive any kind of immunization or vaccination while taking docetaxel.
- · For both men and women: Do not conceive a child (get pregnant) while taking docetaxel. Barrier methods of contraception, such as condoms, are recommended.
- · Do not breast feed while taking this medication.

#### INTERACTIONS:

Erythromycin, ketoconazole and cyclosporine are CYP3A4 inhibitors and therefore inhibit the metabolic pathway of docetaxel. [12] When used with anticonvulsants, which induce CYP3A4, an increased dose of docetaxel may be required.[12]

Pre-treatment with corticosteroids has been used to decrease hypersensitivity reactions and oedema in response to docetaxel and has shown no effect on the pharmacokinetics of docetaxel. [12]

# ADVERSE EFFECTS:

- Low white blood cell count. (This can increase your risk for infection)
- · Low red blood cell count (anemia) Fluid retention with weight gain, swelling of the ankles or abdominal area.
- · Peripheral neuropathy (numbness in your fingers and toes) may occur with repeated doses. This should be reported to your healthcare provider.
- Nausea
- Diarrhea
- Mouth sores
- · Hair loss
- Fatigue and weakness
- Infection
- Nail changes (Color changes to your fingernails or toenails may occur while taking docetaxel. In extreme, but rare, cases nails may fall off. After you have finished docetaxel treatments, your nails will generally grow back) (see skin problems).

# 46. DOPAMINE Inj 40 mg, 5ml ampoule

# SALIENT ACTIONS:

Dopamine stimulates dopaminergic receptors at lower doses producing renal and mesenteric vasodilation while at higher doses stimulate both dopaminergic and β-adrenergic receptors producing cardiac stimulation and renal vasodilation. It increases heart rate and force of contraction. At low infusion rates vasodilatation occurs in the

renal, mesenteric, coronary and cerebral beds. At higher rates vasoconstriction in skeletal muscles and a rise in BP.

#### INDICATION & DOSAGE REGIMEN

#### Intravenous

#### 1. Acute heart failure

Adult: As hydrochloride: Initially, 1-5 mcg/kg/min increased gradually by up to 5-10 mcg/kg/min according to the patient's BP, cardiac output and urine output. Up to 20-50 mcg/kg/min may be required in seriously ill patients.

#### CONTRAINDICATIONS:

Pheochromocytoma, uncorrected tachyarrhythmias, ventricular fibrillation. Hypersensitivity.

#### PRECAUTIONS:

Shock secondary to MI, history of peripheral vascular disease. Correct hypovolaemia before infusion. History of occlusive vascular disease e.g, atherosclerosis, Raynaud's disease, Buerger's disease, diabetic endarteritis; disproportionate increase in diastolic pressure. Pregnancy.

#### INTERACTIONS:

Cyclopropane and halogenated hydrocarbon anaesthetics may sensitise myocardium to dopamine and precipitate ventricular arrhythmias. MAO inhibitors prolong and increase dopamine effects. Ergots potentiate vasoconstriction action of dopamine. Alpha-blockers unmask dopamine's beta action.

#### ADVERSE DRUG REACTIONS:

Nausea, vomiting, tachycardia, ectopic beats, palpitation, anginal pain, hypotension, vasoconstriction, bradycardia, hypertension, dyspnoea, headache, widened QRS complexes, azotaemia.

#### 47. DOXORUBICIN HCL 10MG INJ

#### SALIENT ACTIONS:

Doxorubicin belongs to the class of cytotoxic antibiotics, anthracyclines and related substances. Used in the treatment of cancer.

#### INDICATIONS & DOSAGE REGIMENS:

Adult: IV AIDS-related Kaposi's sarcoma As pegylated liposome: 20 mg/m<sup>2</sup> once 2-3 wkly. Ovarian carcinoma As pegylated liposome: 50 mg/m<sup>2</sup> once 4 wkly. Metastatic breast carcinoma w/ cyclophosphamide: 60-75 mg/m<sup>2</sup> once 3 wkly. Irrigation Local malignant neoplasms in the bladder As 1 mg/mL soln: Instill 50 mL into the bladder for 1 hr once mthly.

#### CONTRAINDICATIONS:

Cardiac disease, neonates, pregnancy and lactation, prior irradiation to mediastinum.IM/SC admin.Severe myelosuppression due to previous treatment with antitumour agents or radiotherapy.

#### PRECAUTIONS:

lderly, children, hepatic impairment. Monitor blood counts and ECG.

#### INTERACTIONS:

Doxorubicin interacts with a number of other drugs e.g. antibiotics (aminoglycosides), steroids, aminophylline and propranolol.

Potentially Fatal: Cholestasis induced by mercaptopurine may be potentiated by concurrent administration of the drug. Toxicity may be increased if streptozocin is given concurrently.

# ADVERSE EFFECTS:

Leucopenia, thrombocytopenia, nausea, vomiting, diarrhoea.Rarely facial flushing, rash, alopecia.Blurred vision, headache, seizures, paraesthesia, confusion, malaise, lethargy, skin pigmentation.

Potentially Fatal: Bone marrow suppression, cardiotoxicity.

#### 48. DOXYCYCLINE HCL IP 100MG INJ

#### SALIENT ACTIONS:

Doxycycline binds to 30S and 50S ribosomal subunits thus causing alterations on the cytoplasmic membrane of susceptible organisms.

# INDICATIONS & DOSAGE REGIMENS:

- 1. Susceptible infections: Adult: 200 mg on day 1 followed by 100 mg once daily. Maintain initial dose in severe infections.
- 2. Uncomplicated gonorrhea: Adult: 100 mg bid for 7 days or a single dose of 300 mg followed by another dose repeated 1 hr later.
- 3. Syphilis: Adult: 200 or 400 mg daily in divided doses for 10-15 days.

4. Relapsing fever and louse-borne typhus: Adult: 100 or 200 mg as a single dose.

5. Acne: Adult: 50 mg daily for 6-12 wk.

#### CONTRAINDICATIONS:

Children <8 yr; pregnancy, lactation; porphyria; hypersensitivity to tetracyclines; severe hepatic dysfunction; prolonged exposure to sunlight or tanning equipment.

#### PRECAUTIONS:

Impaired hepatic function; history or predisposition to oral candidiasis. Should be taken with at least a glass of water in an upright position to reduce the risk of oesophageal injury.

#### INTERACTIONS:

Reduction in absorption and bioavailability when used with antacids, calcium, magnesium and iron. Chronic ethanol ingestion reduces serum concentrations. Metabolism increased by hepatic enzyme inducers such as rifampicin, phenytoin and carbamazepine. May reduce the efficacy of oral contraceptives.

# ADVERSE DRUG REACTIONS:

Permanent staining of teeth; rash, superinfection; nausea, GI upsets, glossitis; dysphagia; photosensitivity, hypersensitivity; haemolytic anaemia, thrombocytopenia, neutropenia and eosinophilia. Potentially Fatal: Anaphylaxis.

# 49. DROTAVERINE HYDROCHLORIDE IP 40MG INJ

#### SALIENT ACTIONS:

Drotaverine is an effective medicine to treat spasm or twitches of the smooth muscles in the stomach and heart. It is used to relieve pain caused due to irritable bowel syndrome, headache, menstrual periods, and is also used to relieve cervical spasm during labor.

# INDICATIONS & DOSAGE REGIMENS:

The preparation is indicated for intramuscular, subcutaneous, intravenous injections.

The average 24 hour dose is 40 - 240 mg divided into 1 - 3 intramuscular or subcutaneous injections 2 - 4 ml of 2% solution each for adults and children older 12.

In case of acute hepatic and/or renal colic the preparation in injected intravenous slowly the dose being 40 - 80 mg (2 – 4 ml of 2% solution).

When the peripheral blood circulation is changed (obliterating endarteritis, Raynaud's disease) intra-arterial injections (slow) are possible.

For shortening the phase of the neck of the uterine opening during the physiologic labor at the beginning of the extension drotaverine hydrochloride is injected intramuscular as a single dose of 40 mg, when the effect is not satisfactory it is reinjected once within 2 hours.

# CONTRAINDICATIONS:

- Allergy
- · Sever liver/kidney damage
- Heart Failure

# PRECAUTIONS:

# Pregnancy

This medicine is not recommended for use by pregnant women unless necessary and the benefits outweigh the risks.

#### · Breast-feeding

This medicine is not recommended for use if you are breastfeeding as the risks of adverse effects on the infant are significantly high.

# INTERACTIONS:

- Atropine
- Dielotenae
- Levodopa
- Diazepam

#### ADVERSE EFFECTS:

- · Nausea and Vemiting
- Dry mouth
- Change in pulse rate
- Dizziness
- Headache
- Difficulty in breathing

- · Allergic skin reaction
- · Swelling of face, lips, eyelids, tongue, hands and feet
- Fall in blood pressure

# 50. EPHEDRINE INJ B.P

#### SALIENT ACTIONS:

Ephedrine sulfate is a potent sympathomimetic that stimulates both  $\alpha$  and  $\beta$  receptors and has clinical uses related to both actions. Its peripheral actions, which it owes in part to the release of norepinephrine, simulate responses that are obtained when adrenergic nerves are stimulated. These include an increase in blood pressure, stimulation of heart muscle, constriction of arterioles, relaxation of the smooth muscle of the bronchi and gastrointestinal tract, and dilation of the pupils. In the bladder, relaxation of the detrusor muscle is not prominent, but the tone of the trigone and vesicle sphincter is increased. Ephedrine sulfate also has a potent effect on the CNS. It stimulates the cerebral cortex and subcortical centers, which accounts for its use in narcolepsy.

#### INDICATIONS:

Ephedrine Sulfate Injection, USP is indicated in the treatment of allergic disorders, such as bronchial asthma. The drug has long been used as a pressor agent, particularly during

spinal anesthesia when hypotension frequently occurs. In Stokes-Adams syndrome with complete heart block, ephedrine has a value similar to that of epinephrine. It is indicated as a central nervous system stimulant in narcolepsyand depressive states. It is also used in myasthenia gravis.

# DOSAGE REGIMENS:

Adults

The usual parenteral dose is 25 to 50 mg given subcutaneously or intramuscularly. Intravenously, 5 to 25 mg may be administered slowly, repeated in 5 to 10 minutes, if necessary.

Children

The usual subcutaneous or intramuscular dose is 0.5 mg/kg of body weight or 16.7 mg/square meter of body surface every 4 to 6 hours.

#### CONTRAINDICATIONS:

Allergic reactions to ephedrine sulfate are rare. The hypersensitivity, if known, is a specific contraindication. Patients hypersensitive to other sympathomimetics may also be hypersensitive to ephedrine sulfate.

#### PRECAUTIONS:

Special care should be used when administering Ephedrine Sulfate Injection, USP to patients with heart disease, angina pectoris, diabetes, hyperthyroidism, prostatic hypertrophy or hypertension and to patients receiving digitalis. Prolonged use may produce a syndrome resembling an anxiety state. Tolerance to ephedrine sulfate may develop, but temporary discontinuance to the drug restores its original effectiveness.

Nursing Mothers

Ephedrine sulfate is excreted in breast milk. Use by nursing mothers is not recommended because of the higher than usual risk for infants.

# INTERACTIONS:

concurrent use of ephedrine sulfate with general anesthetics, especially cyclopropane or halogenated hydrocarbons or digitalis glycosides may cause cardiac arrhythmias, since these medications may sensitize the myocardium to the effects of ephedrine sulfate.

Therapeutic doses of ephedrine sulfate can inhibit the hypotensive effect of guanethidine, bethanidine, and debrisoquin by displacing the adrenergic blockers from their site of action in the sympathetic neurons. The effect in man is seen as a relative or a complete blockade of the antihypertensive drug by a sudden rise in blood pressure. Concomitant use of Ephedrine Sulfate Injection, USP and oxytocics may cause severe hypotension. Monoamine oxidase inhibitors may potentiate the pressor effect of ephedrine sulfate, possibly resulting in a hypertensive crisis. Ephedrine Sulfate Injection, USP should not be administered during or within 14 days following the administration of MAO inhibitors.

#### ADVERSE EFFECTS:

With large doses of ephedrine sulfate most patients will experience nervousness, insomnia, vertigo, headache, tachycardia, palpitation and sweating. Some patients have nausea, vomiting and anorexia. Vesical sphincter spasm may occur and result in difficult and painful urination. Urinary retention may develop in males with prostatism. Precordial pain and cardiac arrhythmias may occur following administration of Ephedrine Sulfate Injection, USP.

# 51. EPIRUBICIN HYDROCHLORIDE INJ

# SALIENT ACTIONS:

Epirubicin is an anthracycline cytotoxic agent. It is known that anthracyclines can interfere with a number of biochemical and biological functions within eukaryotic cells,

#### INDICATIONS:

Injection is indicated as a component of adjuvant therapy in patients with evidence of axillary node tumor involvement following resection of primary breast cancer

# DOSAGE REGIMENS:

Administered by intravenous infusion. Given in repeated 3-to 4-week cycles. The total dose may be given on Day 1 of each cycle or divided equally and given on Days 1 and 8 of each cycle. The recommended dose is 100 to 120 mg/m<sup>2</sup>.

# CONTRAINDICATIONS:

Cardiomyopathy and/or heart failure, recent myocardial infarction or severe arrhythmias

# PRECAUTIONS:

Before beginning treatment, patients should recover from acute toxicities (such as stomatitis, neutropenia, thrombocytopenia, and generalized infections) of prior cytotoxic treatment. Also, precede initial treatment with this by a careful baseline assessment of blood counts; serum levels of total bilirubin, AST, and creatinine; and cardiac function as measured by left ventricular ejection function (LVEF). Carefully monitor patients during treatment for possible clinical complications due to myelosuppression. Supportive care may be necessary for the treatment of severe neutropenia and severe infectious complications. Monitoring for potential cardiotoxicity is also important, especially with greater cumulative exposure to it.

#### INTERACTIONS:

- amiodarone
- amphotericin B
- azathioprine
- bevacizumab
- cimetidine
- cyclophosphamide
- daunorubicin
- digoxin

#### ADVERSE EFFECTS:

- Inhibition of blood cell production in the bone marrow (myelosuppression)
- decreased number of white blood cells (leucocytopenia)
- decreased number of a special form of white blood cells (granulocytopenia and neutropenia)
- neutropenia accompanied by fever (febrile neutropenia)
- decrease in red blood cells (anaemia)
- hair loss (alopecia) normally reversible
- urine may have a red colour for up to two days after treatment.

# 52. ENOXAPARIN Inj 40 mg/ 0.4 ml and 60 mg/ 0.6 ml, ampoules SALIENT ACTIONS:

Enoxaparin is a low molecular weight heparin with anticoagulant properties. It acts by enhancing the inhibition rate of activated clotting factors including thrombin and factor Xa through its action on antithrombin III.

# INDICATION & DOSAGE REGIMEN

# Subcutaneous

1. Prophylaxis of venous thromboembolism during surgical procedures

Adult: Low to moderate risk: 20 mg (2000 units) once daily with the 1st dose 2 hr pre-operatively. High risk: 40 mg (4000 units) once daily with the 1st dose 12 hr pre-operatively. Alternatively, 30 mg (3000 units) bid starting within 12-24 hr after the operation. After hip replacement surgery, continue treatment at 40 mg once daily for a further 3 wk. For immobilised patients, treatment should continue at 40 mg daily for at least 6 days or until patient becomes fully ambulant, up to a max of 14 days.

2. Deep vein thrombosis

Adult: 1 mg (100 units)/kg every 12 hr for 5 days and until oral anticoagulation is established.

3. Prophylaxis of clotting in the extracorporeal circulation during haemodialysis Adult: 1 mg/kg (100 units/kg) into the arterial line of the circuit at the beginning of the dialysis session. Give a further dose of 0.5-1 mg/kg (50-100 units/kg) if required. Reduce dose in patients at high risk of haemorrhage.

#### 4. Unstable angina

Adult: 1 mg/kg (100 units/kg) every 12 hr for 2-8 days with low-dose aspirin.

Special Populations: Reduce dose in patients at high risk of haemorrhage.

#### CONTRAINDICATIONS:

Hypersensitivity, acute bacterial endocarditis; major bleeding disorder, haemorrhagic stroke, drug-induced thrombocytopenia.

#### PRECAUTIONS:

Renal or hepatic impairment, history of GI ulceration, uncontrolled hypertension, spinal or epidural anaesthesia; lactation and pregnancy; elderly. Periodic blood counts, platelet count and stool occult blood test recommended INTERACTIONS:

Potentially Fatal: Risk of haemorrhage increased with oral anticoagulants, platelet aggregation inhibitors, NSAIDs including aspirin.

# ADVERSE DRUG REACTIONS:

Thrombocytopenia, mild bleeding, inj site irritation, pain and ecchymoses, hypersensitivity and erythema. *Potentially Fatal:* Haemorrhagic complications.

#### 53. ESMOLOL HCL 10MG/ML INJ

#### SALIENT ACTIONS:

Esmolol (trade name Brevibloc) is a cardioselective beta<sub>1</sub> receptor blocker with rapid onset,<sup>[1]</sup> a very short duration of action, and no significant intrinsic sympathomimetic or membrane stabilising activity at therapeutic dosages.

It is a class II antiarrhythmic. [2] Esmolol decreases the force and rate of heart contractions by blocking betaadrenergic receptors of the sympathetic nervous system, which are found in the heart and other organs of the body. Esmolol prevents the action of two naturally occurring substances: epinephrine and norepinephrine.

#### INDICATIONS:

- Atrial Fibrillation
- Atrial Flutter
- Supraventricular Tachycardia
- Intra- or Post-op SVT or Hypertension

# DOSAGE REGIMENS:

loading dose (500 mcg per kg over 1 minute), then 50 mcg per kg per min for 4 min

The effective maintenance dose for continuous and step-wise dosing is 50 to 200 mcg per kg per minute, although doses as low as 25 mcg per kg per minute have been adequate.

# CONTRAINDICATIONS:

- evere sinus bradycardia: May precipitate or worsen bradycardia resulting in cardiogenic shock and cardiac arrest
- Heart block greater than first degree: Second- or third-degree atrioventricular block may precipitate or worsen bradycardia resulting in cardiogenic shock and cardiac arrest
- Sick sinus syndrome: May precipitate or worsen bradycardia resulting in cardiogenic shock and cardiac arrest
- Decompensated heart failure: May worsen heart failure.
- Cardiogenic shock: May precipitate further cardiovascular collapse and cause cardiac arrest.

# PRECAUTIONS:

Safety and efficacy have not been established in patients younger than 18 years.

If a local infusion site reaction develops, an alternative infusion site should be used and caution should be taken to prevent extravasation.

-It is advised to terminate the infusion gradually because of the risk of rebound tachycardia and rebound hypertension.

#### INTERACTIONS:

- Digitalis glycosides: Concomitant administration of digoxin and esmolol leads to an approximate 10% to 20% increase of digoxin blood levels at some time points.. Both digoxin and beta blockers slow atrioventricular conduction and decrease heart rate. Concomitant use increases the risk of bradycardia.
- Anticholinesterases: esmolol prolonged the duration of succinylcholine-induced neuromuscular blockade and moderately prolonged clinical duration and recovery index of mivacurium.

- Antihypertensive agents clonidine, guanfacine, or moxonidine: Beta blockers also increase the risk of
  clonidine-, guanfacine-, or moxonidine-withdrawal rebound hypertension. If, during concomitant use of
  a beta blocker, antihypertensive therapy needs to be interrupted or discontinued, discontinue the beta
  blocker first, and the discontinuation should be gradual.
- Calcium channel antagonists: In patients with depressed myocardial function, use of esmolol with cardiodepressant calcium channel antagonists (e.g., verapamil) can lead to fatal cardiac arrests.

#### ADVERSE EFFECTS:

- Cardiac effects include bradycardia, atrioventricular block (1st -, 2nd -, 3rd degree), junctional rhythms, intraventricular conduction delays, decreased cardiac contractility, hypotension, cardiac failure (including cardiogenic shock), cardiac arrest/asystole, and pulseless electrical activity.
- Central nervous system effects include respiratory depression, seizures, sleep and mood disturbances,

fatigue, lethargy, and coma.

 In addition, bronchospasm, mesenteric ischemia, peripheral cyanosis, hyperkalemia, and hypoglycemia (especially in children) may occu

#### 54. ETHAMSYLATE BP 250MG INJ

#### SALIENT ACTIONS:

Ethamsylate Injection is a medicine that is used for the treatment of Blood In Urine, Abnormal Bleeding From The Womb, Excessive Blood Loss During Periods In Women, Post-Abortion Bleeding, Postpartum Bleeding, Vomiting Of Blood and other conditions.

#### INDICATIONS:

Ethamsylate Injection is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms:

- Blood In Urine
- Abnormal Bleeding From The Womb
- Excessive Blood Loss During Periods In Women
- Post-Abortion Bleeding
- Postpartum Bleeding
- Vomiting Of Blood
- · Upper Gastrointestinal Bleeding
- · Blood-Stained Mucus

# DOSAGE REGIMENS:

Adult: PO- Menorrhagia- The recommended dose is 500 mg 4 times/day during menstruation. Control of hemorrhage after surgery- The recommended dose is 250-500 mg 4-6 hourly as needed.

#### CONTRAINDICATIONS:

Contraindicated in patients with known hypersensitivity and porphyria (a blood disorder).

#### PRECAUTIONS:

Caution should be exercised in patients with history of coeliac disease, during pregnancy and breastfeeding. INTERACTIONS:

#### N/A

# ADVERSE EFFECTS:

- Headache
- Allergic Rejection
- Nausea
- Skin Rash
- Vomiting
- Fever

# 55. ETOMIDATE 10 ml INJ

# SALIENT ACTIONS:

Etomidate is a hypnotic drug without analgesic activity. Intravenous injection of etomidate produces hypnosis characterized by a rapid onset of action, usually within one minute.

#### INDICATIONS:

Etomidate is indicated by intravenous injection for the induction of general anesthesia.

# DOSAGE REGIMENS:

The dose for induction of anesthesia in adult patients and in pediatric patients above the age of 10 years will vary between 0.2 and 0.6 mg/kg of body weight, and it must be individualized in each case. The usual dose for induction in these patients is 0.3 mg/kg, injected over a period of 30 to 60 seconds.

#### CONTRAINDICATIONS:

Hypersensitivity

Sepsis

# PRECAUTIONS:

Etomidate may induce cardiac depression in elderly patients, particularly those with hypertension

#### INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

apnea

laryngospasm

bradycardia

arrhythmia exacerbation

anaphylactoid reactions

# 56. ETOPOSIDE INJECTION

#### SALIENT ACTIONS:

A semisynthetic derivative of podophyllotoxin that exhibits antitumor activity. Etoposide inhibits DNA synthesis by forming a complex with topoisomerase II and DNA. This complex induces breaks in double stranded DNA and prevents repair by topoisomerase II binding. Accumulated breaks in DNA prevent entry into the mitotic phase of cell division, and lead to cell death.

#### INDICATIONS:

Small Cell Lung Cancer

Testicular cancer

#### DOSAGE REGIMENS:

#### **Usual Adult Dose for Testicular Cancer**

IV:

In combination with other approved chemotherapeutic agents:

50 to 100 mg/m2 IV once a day on days 1 through 5 to 100 mg/m2 IV once a day on days 1,3, and 5

#### Usual Adult Dose for Small Cell Lung Cancer

-IV

# In combination with other approved chemotherapeutic agents:

35 mg/m2 IV once a day for 4 days to 50 mg/m2 IV once a day for 5 days

Chemotherapy courses are repeated at 3- to 4-week intervals after adequate recovery from any toxicity.

# CONTRAINDICATIONS:

Etoposide Injection USP is contraindicated in patients who have demonstrated a previous hypersensitivity to Etoposide or any component of the formulation.

#### PRECAUTIONS:

Daily use of alcohol while using this medicine may increase your risk for stomachbleeding.

Limit alcoholic beverages.

Since this drug can be absorbed through the skin and lungs and may harm an unborn baby, women who are pregnant or who may become pregnant should not handle this medication or breathe the dust from the capsules. his medication passes into breast milk. Because of the possible risk to the infant, breast-feeding while using etoposide is not recommended

# INTERACTIONS:

The serum concentration of Etoposide can be increased when it is combined with Abiraterone.

Etoposide may increase the anticoagulant activities of Acenocoumarol.

The serum concentration of Etoposide can be decreased when it is combined with Aldosterone.

# ADVERSE EFFECTS:

Nausea, vomiting, loss of appetite, or diarrhea may occur. Nausea and vomiting can be severe.

Temporary hair loss may occur. Normal hair growth should return after treatment has ended.

Pain or sores in the mouth and throat may occur.

numbness/tingling of arms/legs, sudden vision changes, eye pain, stomach/abdominal pain, yellowing eyes/skin, dark urine, painful/difficult swallowing.

# 57. FERRIC CARBOXYMALTOSE 50MG INJ 10ML

#### SALIENT ACTIONS:

It is a colloidal iron hydroxide in complex with carboxymaltose, a carbohydrate polymer that releases iron; replaces iron stores found in hemoglobin, myoglobin, and enzymes; works to transport oxygen via hemoglobin **INDICATIONS:** 50mg/ml Injection is used in the treatment of iron deficiency anemiaand anemia due to chronic kidney disease.

# DOSAGE REGIMENS:

 $\geq$ 50 kg: 750 mg IV once, follow 7 days later with second 750 mg dose; not to exceed cumulative dose of 1500 mg per course

<50 kg: 15 mg/kg IV once, follow 7 days later with second dose; not to exceed 1500 cumulative dose per course CONTRAINDICATIONS:

Hypersensitivity

#### PRECAUTIONS:

Only administer when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions

#### INTERACTIONS:

The absorption of oral iron is reduced when administered concomitantly with parenteral iron preparations. Therefore, if required, oral iron therapy should not be started for at least 5 days after the last injection of ferric carboxymaltose.

# ADVERSE EFFECTS:

Nausea, Flushing, Increased blood pressure, Dizziness, Decreased phosphate level in blood, Injection site reaction.

# 58. FERRIC HYDROXIDE Inj 20 mg, 2.5 ml ampoule

#### SALIENT ACTIONS:

Ferric hydroxide sucrose complex is a source of iron that is used in iron-deficiency anaemia whereby oral iron is ineffective or impractical. Iron sucrose is broken down into iron and sucrose by the reticuloendothelial system. The released iron increases serum iron concentrations and is incorporated into haemoglobin.

ON THE PERSON

# INDICATIONS & DOSAGE REGIMENS:

Iron-deficiency anaemia. *IV* Doses are expressed in terms of elemental iron. Haemodialysis-dependent patient: 100 mg 1-3 times/wk during dialysis, up to a cumulative total dose of 1000 mg; may continue at lowest effective dose if needed. Peritoneal dialysis-dependent patient: Two infusions of 300 mg each over 90 minutes 14 days apart followed by a single 400 mg infusion over 2.5 hours 14 days later (total cumulative dose: 1000 mg). Nondialysis-dependent patient: 200 mg on 5 different occasions within a 14-day period. Total cumulative dose: 1000 mg in 14-day period

#### CONTRAINDICATIONS:

Hypersensitivity. Evidence of iron overload. Anaemia not caused by iron deficiency. History of asthma, eczema, anaphylaxis, or other allergic disorders.

#### PRECAUTIONS:

Regular monitoring of haematologic parameters is needed to prevent iron overload. Periodic monitoring of haemoglobin, haematocrit, serum ferritin and transferrin saturation is recommended. Serum iron values can be reliably obtained 48 hr after IV admin. May take about 4 wk of treatment to see increased serum iron and ferritin. Caution during admin to reduce risk of hypotension and vascular flushing. Safety and efficacy have not been established in paediatrics. Caution when used in pregnant or lactating women.

# INTERACTIONS:

May reduce the serum levels of cefdinir; stools may appear red due to the formation of an insoluble iron-cefdinir complex. May reduce the serum levels of eltrombopag. May decrease absorption of phosphate supplements. Concurrent use with trientine may result in reduction of serum levels of iron sucrose and/or trientine. *Potentially Fatal:* Dimercaprol may increase the nephrotoxic effect of iron salts when used concurrently ADVERSE DRUG REACTIONS:

CV effects such as chest pain or tightness, shock, MI, hypertension, tachycardia, bradycardia, and arrhythmias. Rashes, urticaria, purpura, and pruritus. GI disturbances, haematuria, dyspnoea, and taste disturbance. *Potentially Fatal:* Anaphylaxis

# 59. FENTANYL CITRATE INJ 50MCG/ML SALIENT ACTIONS:

Fentanyl Citrate Injection, USP is a sterile, nonpyrogenic solution of fentanyl citrate in water for injection. Fentanyl Citrate is a potent narcotic analgesic which is administered only by the intravenous or intramuscular routes of injection. The principal actions of therapeutic value are analgesia and sedation. Alterations in respiratory rate and alveolar ventilation, associated with narcotic analgesics, may last longer than the analgesic effect.

#### INDICATIONS:

Fentanyl Citrate Injection is indicated:

- for analgesic action of short duration during the anesthetic periods, premedication, induction
  and maintenance, and in the immediate postoperative period (recovery room) as the need arises.
- · for use as a narcotic analgesic supplement in general or regional anesthesia.
- for administration with a neuroleptic such as droperidol injection as an anesthetic premedication, for the induction of anesthesia and as an adjunct in the maintenance of general and regional anesthesia.
- for use as an anesthetic agent with oxygen in selected high risk patients, such as those undergoing open heartsurgery or certain complicated neurological or orthopedic procedures.

#### DOSAGE REGIMENS:

- 1) Premedication Premedication (to be appropriately modified in the elderly, debilitated and those who have received other depressant drugs) 50 to 100 mcg (0.05 to 0.1 mg) (1 to 2 mL) may be administered intramuscularly 30 to 60 minutes prior to surgery.
- 2) As a General Anesthetic: When attenuation of the responses to surgical stress is especially important, doses of 50 to 100 mcg/kg (0.05 to 0.1 mg/kg) (1 to 2 mL/kg) may be administered with oxygen and a muscle relaxant. This technique has been reported to provide anesthesia without the use of additional anesthetic agents. In certain cases, doses up to 150 mcg/kg (0.15 mg/kg) (3 mL/kg) may be necessary to produce this anesthetic effect. 3)Adjunct to Regional Anesthesia 50 to 100 mcg (0.05 to 0.1 mg) (1 to 2 mL) may be administered intramuscularly or slowly intravenously, over one to two minutes, when additional analgesia is required.
- 4) Postoperatively (recovery room) 50 to 100 mcg (0.05 to 0.1 mg) (1 to 2 mL) may be administered intramuscularly for the control of pain, tachypnea and emergence delirium. The dose may be repeated in one to two hours as needed.

#### CONTRAINDICATIONS:

Fentanyl Citrate Injection is contraindicated in patients with known intolerance to the drug.

#### PRECAUTIONS:

The initial dose of fentanyl citrate should be appropriately reduced in elderly and debilitated patients. The effect of the initial dose should be considered in determining incremental doses.

Nitrous oxide has been reported to produce cardiovascular depression when given with higher doses of fentanyl.

# INTERACTIONS:

ther CNS depressant drugs (e.g., barbiturates, tranquilizers, narcotics, and general anesthetics) will have additive or potentiating effects with fentanyl. When patients have received such drugs, the dose of fentanyl required will be less than usual. Following the administration of fentanyl citrate, the dose of other CNS depressant drugs should be reduced.

#### ADVERSE EFFECTS:

Most common serious adverse reactions reported to occur with fentanyl are respiratory depression, apnea, rigidity, and bradycardia; if these remain untreated, respiratory arrest, circulatory depression or cardiac arrest could occur. Other adverse reactions that have been reported are hypertension, hypotension, dizziness, blurred vision, nausea, emesis, laryngospasm, and diaphoresis.

#### 60. FILGRASTIM 300MCG INJ

#### SALIENT ACTIONS:

Filgrastim injection is used to treat neutropenia (low white blood cells) that is caused by cancer medicines. It is a synthetic (man-made) form of a substance that is naturally produced in your body called a colony stimulating factor. Filgrastim helps the bone marrow to make new white blood cells.

# INDICATIONS & DOSAGE REGIMENS:

# Patients With Cancer Receiving Myelosuppressive Chemotherapy

It is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever

The recommended starting dosage of NEUPOGEN is 5 mcg/kg/day, administered as a single daily injection by subcutaneous injection, by short intravenous infusion (15 to 30 minutes), or by continuous infusion.

Patients With Acute Myeloid Leukemia Receiving Induction Or Consolidation Chemotherapy

It is indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidationchemotherapy treatment of patients with acute myeloid leukemia(AML)

The recommended starting dosage is 5 mcg/kg/day, administered as a single daily injection by subcutaneous injection, by short intravenous infusion (15 to 30 minutes), or by continuous intravenous infusion.

# Patients With Cancer Undergoing Bone Marrow Transplantation

It is indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation

The recommended dosage following bone marrow transplantation (BMT) is 10 mcg/kg/day given as an intravenous infusion no longer than 24 hours. Administer the first dose at least 24 hours after cytotoxic chemotherapy and at least 24 hours after bone marrow infusion.

Patients Undergoing Autologous Peripheral Blood Progenitor Cell Collection And Therapy

It is indicated for the mobilization of autologoushematopoietic progenitor cells into the peripheral blood for collection by leukapheresis .

The recommended dosage for the mobilization of autologous peripheral blood progenitor cells (PBPC) is 10 mcg/kg/day given by subcutaneous injection.

Patients With Severe Chronic Neutropenia

It is indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathicneutropenia

The recommended starting dosage in patients with Congenital Neutropenia is 6 mcg/kg as a twice daily subcutaneous injection and the recommended starting dosage in patients with Idiopathic or Cyclic Neutropenia is 5 mcg/kg as a single daily subcutaneous injection.

Patients Acutely Exposed To Myelosuppressive Doses Of Radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)

It is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation. The recommended dose is 10 mcg/kg as a single daily subcutaneous injection for patients exposed to myelosuppressive doses of radiation. Administer NEUPOGEN as soon as possible after suspected or confirmed exposure to radiation doses greater than 2 gray (Gy).

#### CONTRAINDICATIONS:

contraindicated in patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim

#### PRECAUTIONS:

N/A

#### INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

- Splenic Rupture
- Acute Respiratory Distress Syndrome
- Serious Allergic Reactions
- Sickle Cell Disorders
- Glomerulonephritis
- Alveolar Hemorrhage and Hemoptysis
- Capillary Leak Syndrome
- Thrombocytopenia
- Leukocytosis
- Cutaneous Vasculitis

#### 61. FLUOROURACIL (250MG/5ML INJ)

#### SALIENT ACTIONS:

Fluorouracil Injection, USP an antineoplastic antimetabolite, is a sterile, nonpyrogenic injectable solution for intravenous administration.

#### INDICATIONS:

Fluorouracil Injection, USP is effective in the palliative management of carcinoma of the colon, rectum, breast, stomach and pancreas.

#### DOSAGE REGIMENS:

12 mg/kg are given intravenously once daily for four successive days.

#### CONTRAINDICATIONS:

contraindicated for patients in a poor nutritional state, those with depressed bone marrow function, those with potentially serious infections or those with a known hypersensitivity to Fluorouracil Injection, USP.

#### PRECAUTIONS:

N/A

# INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

Cardiovascular: myocardial ischemia, angina.

Gastrointestinal: gastrointestinal ulceration and bleeding.

Allergic Reactions: anaphylaxis and generalized allergic reactions.

Neurologic: acute cerebellar syndrome (which may persist following discontinuance of treatment),nystagmus, headache.

Dermatologic: dry skin; fissuring; photosensitivity, as manifested by erythema or increased pigmentation of the skin; vein pigmentation; palmar-plantar erythrodysesthesia syndrome, as manifested by tingling of the hands and feet followed by pain, erythema and swelling.

Ophthalmic: lacrimal duct stenosis, visual changes, lacrimation, photophobia.

Psychiatric: disorientation, confusion, euphoria.

Miscellaneous: thrombophlebitis, epistaxis, nail changes (including loss of nails)

# 62. FLUPHENAZINE DECANOATE 25MG/ML 1ML INJ.

#### SALIENT ACTIONS:

Fluphenazine belongs to a class of medications called phenothiazines and is also referred to as a neuroleptic. It works by affecting the balance of natural chemicals (neurotransmitters) in the brain.

#### INDICATIONS:

Fluphenazine decanoate injection is a long-acting parenteral antipsychotic drug intended for use in the management of patients requiring prolonged parenteral neuroleptic therapy (e.g., chronic schizophrenics).

# DOSAGE REGIMENS:

A dose of 12.5 to 25 mg (0.5 to 1 mL) may be given to initiate therapy.

When administered as maintenance therapy, a single injection may be effective in controlling schizophrenic symptoms up to four weeks or longer.

# CONTRAINDICATIONS:

Coma.CNS or bone marrow depression.Liver disease.Subcortical brain damage.Blood dyscrasias.

#### PRECAUTIONS:

Cardiovascular or renal disease. Pheochromocytoma. Seizures. Glaucoma. History of brest cancer. Exposure to extreme heat or organophosphates. Gradually reduce to lowesteffective maintenance dose. Monitor blood, liver, renal, and ocular function. Mental retardation. Surgery. Pregnancy. Nursing mothers.

#### INTERACTIONS:

Potentiates anticholinergics, CNS depression with alcohol and other CNS depressants; both drugs with propranolol. Antagonized by anticholinergics. Decreased guanethidine effects. May cause false (+) pregnancy test.

#### ADVERSE EFFECTS:

Drowsiness, anticholinergic and other autonomic effects, insomnia, restlessness, rash, photosensitivity, tardive dyskinesia, blood dyscrasias, jaundice, pneumonia, hypertension, retinopathy, lowered seizure threshold, extrapyramidal reactions, neuroleptic malignant syndrome, weight changes, endocrine effects.

# 63. FLURESCEIN NA IP 20% INJ

#### SALIENT ACTIONS:

It is a sterile solution for use intravenously as a diagnostic aid.

#### INDICATIONS:

It is indicated in diagnostic fluorescein angiography or angioscopy of the retina and iris vasculature.

#### DOSAGE REGIMENS:

Adult Dose- The normal adult dose is 500 mg via intravenous administration.

For children, the dose should be calculated on the basis of 7.7 mg for each kg of actual body weight (or 35 mg for each 10 pounds of body weight) up to a maximum of 500 mg via intravenous administration.

# CONTRAINDICATIONS:

known hypersensitivity to fluorescein sodium or any other ingredients in this product.

# PRECAUTIONS:

N/A

#### INTERACTIONS:

N/A

# ADVERSE EFFECTS:

Thrombophlebitis

Skin And Urine Discoloration

# 64. FUROSEMIDE Inj 10 mg/ml, 2ml ampoule, Tab 40 mg SALIENT ACTIONS:

Furosemide is a sulfonamide diuretic. Furosemide inhibits reabsorption of Na and chloride mainly in the medullary portion of the ascending Loop of Henle. Excretion of potassium magnesium, calcium and to a lesser extent bicarbonates is also increased while uric acid excretion is reduced. It increases plasma-renin levels and secondary hyperaldosteronism may result. Furosemide reduces BP in hypertensives as well as in normotensives. It also reduces pulmonary oedema before diuresis has set in. Unlike the thiazide diuretics, the loop diuretics are still effective when the renal functions are severely limited.

# INDICATIONS & DOSAGE REGIMENS:

- 1. Congestive Heart Failure
- 2. Edema
- 3. Hypertension
- 4. Non-obstructive Oliguria
- 5. Pulmonary Edema, Renal Failure, Renal Transplant Oliguria: Adult Dose:
- 6. Hypercalcemia

Adult Dose: Intravenous/Intramuscular: 10 to 20 mg once over 1 to 2 minutes. A repeat dose similar to the initial dose may be given within 2 hours if there is an inadequate response. Following the repeat dose, if there is still an inadequate response within another 2 hours, the last IV dose may be raised by 20 to 40 mg until there is an effective diuresis. Single doses exceeding 200 mg are rarely necessary.

Continuous IV infusion: 0.1 mg/kg as an initial bolus dose, followed by 0.1 mg/kg/hour doubled every 2

hours to a maximum of 0.4 mg/kg/hour.

Infants and Children: IM or IV: 1 to 2 mg/kg/dose every 6 to 12 hours

IV: 20 to 100 mg every 1 to 2 hours over 1 to 2 minutes.

Renal Dose Adjustments: If increasing azotemia and oliguria occur during treatment of severe progressive renal disease, furosemide should be discontinued. Liver Dose Adjustments: Patients with cirrhosis and ascites should be given smaller doses of furosemide due to the risk of altered electrolyte balance, which can lead to hepatic encephalopathy.

# CONTRAINDICATIONS:

Pronounced hyponatremia or hypovolemia and anuria.

# PRECAUTIONS:

Caution when there are losses of potassium (vomiting, diarrhea)! A pronounced hypokalemia demands to be treated (potassium sparing diuretics, potassium substitution). For men with prostate hyperplasia there is a risk of urinary retention.

# INTERACTIONS:

Analgesics reduce natriuretic action of furosemide. Antagonises hypoglycaemic agents and drugs used for gout. Hyperglycaemia with antihypertensive agent diazoxide. Antagonises muscle relaxants. Increased risk of ototoxicity when used with aminoglycosides especially in renal impairment. May enhance nephrotoxicity of cephalosporins. Effects of antihypertensives enhanced. Action antagonised by corticosteroids. Phenytoin and indometacin may reduce effects of furosemide.

# ADVERSE DRUG REACTIONS:

Fluid and electrolyte imbalance. Rashes, photosensitivity, nausea, diarrhoea, blurred vision, dizziness, headache, hypotension. Bone marrow depression (rare), hepatic dysfunction. Hyperglycaemia, glycosuria, ototoxicity. Potentially Fatal: Rarely, sudden death and cardiac arrest. Hypokalaemia and magnesium depletion can cause cardiac arrhythmias.

# 65. FOSPHENYTOIN Inj 75 mg, 2 ml vial

#### SALIENT ACTIONS:

Fosphenytoin is converted to phenytoin in the body. It modulates voltage-dependent Na channels of neurons.

# INDICATION & DOSAGE REGIMENS:

# 1. Tonic-clonic status epilepticus

Adult: As Phenytoin sodium equivalents (PSE): Loading dose: 15 mg/kg, given via IV infusion at a rate of 100-150 mg/minute. Maintenance: Initially, 4-5 mg PSE/kg/day by IM inj or IV infusion at a rate of 50-100 mg PSE/minute; subsequent doses depend on patient's response and trough-plasma phenytoin levels.

Child: ≥5 yr: As Phenytoin sodium equivalents (PSE): Loading dose: 15 mg/kg, given via IV infusion at a rate of 2-3 mg/kg/minute. Maintenance: Initially, 4-5 mg/kg/day by IM inj or IV infusion at a rate of 1-2 mg/kg/minute;

subsequent doses depend on patient's response and trough-plasma phenytoin levels.

#### 2. Seizures

Adult: Except status epilepticus: As Phenytoin sodium equivalents (PSE): Loading dose: 10-15 mg/kg, given via IM inj or IV infusion at a rate of 50-100 mg/minute. Maintenance: Initially, 4-5 mg/kg/day by IM inj or IV infusion at a rate of 50-100 mg/minute; subsequent doses depend on patient's response and trough-plasma phenytoin levels.

Child: ≥5 yr: As Phenytoin sodium equivalents (PSE): Loading dose: 10-15 mg/kg, given via IM inj or IV infusion at a rate of 1-2 mg/kg/minute. Maintenance: Initially, 4-5 mg/kg/day by IM inj or IV infusion at a rate of 1-2 mg/kg/minute; subsequent doses depend on patient's response and trough-plasma phenytoin levels. **Renal impairment:** Dose reduction or slower infusion may be needed.

Hepatic impairment: Dose reduction or slower infusion may be needed.

Special Populations: Reduce dose or rate by 10-25% in elderly patients, with renal or hepatic impairment or those with hypoalbuminaemia.

#### CONTRAINDICATIONS:

Porphyria; sinus bradycardia; SA block; 2nd- and 3rd-degree heart block; Stokes-Adams syndrome; pregnancy, lactation.

#### PRECAUTIONS:

Hepatic or renal impairment; hypoalbuminaemia; elderly; patients requiring phosphate restriction; resuscitation facilities must be available. Monitor ECG, BP and respiratory function during infusion; observe patient for at least 30 minutes after infusion. IV infusion rate should not exceed 150 mg PSE/minute in adults or 3 mg PSE/kg/minute in children ≥5 yr.

#### INTERACTIONS:

Concurrent use may affect the efficacy of anticoagulants, corticosteroids, coumarin, digitoxin, doxycycline, oestrogens, furosemide, oral contraceptives, rifampin, quinidine, theophylline and vitamin D. Amiodarone, chloramphenicol, chlordiazepoxide, cimetidine, diazepam, dicumarol, disulfiram, oestrogens, ethosuximide, fluoxetine, H<sub>2</sub>-antagonists, halothane, isoniazid, methylphenidate, phenothiazines, phenylbutazone, salicylates, succinimides, sulfonamides, tolbutamide and trazodone may increase the plasma levels of phenytoin. Carbamazepine and reserpine may reduce serum levels of phenytoin. TCAs may increase the risk of seizures in susceptible patients.

#### ADVERSE DRUG REACTIONS:

Burning, itching and paraesthesia in the groin area following IV admin; asystole, ventricular fibrillation, hypotension, bradycardia, heart block.

Potentially Fatal: Severe CV reactions.

# 66. GENTAMICIN Inj 40 mg, 2 ml vial

#### SALIENT ACTIONS:

Gentamicin is an aminoglycoside that binds to 30s and 50s ribosomal subunits of susceptible bacteria disrupting protein synthesis, thus rendering the bacterial cell membrane defective

# INDICATION & DOSAGE REGIMENS:

Potent and broader spectrum of action. Effective against pseudomonas. Proteus, E.coli, klebsiella, enterobacter and serratia. Critically ill-prevent respiratory infection. Immunocompromised patients (burns, those receiving anticancer drugs and neutropenic patients) Patients on respirators, post tracheostomy, implants. Post operative pneumonias. Patients in ICCU

Adult: 3-5 mg/kg/day, given in divided doses every 8 hr for 7-10 days. Child: ≤2 wk: 3 mg/kg every 12 hr; 2 wk-12 yr: 2 mg/kg every 8 hr.

For Prophylaxis of surgical infections: Adult: 120 mg before induction of anaesthesia, in combination with penicillin, vancomycin or teicoplanin.

Renal impairment: Haemodialysis: Administer dose after dialysis session and monitor levels.

Special Populations: Renal impairment: Increase the interval between doses keeping serum creatinine levels as a guide. In patients on dialysis an 8 hr dialysis reduces serum levels of gentamicin by 50%. At the end of each session give 1-1.7 mg/kg for adults and 2 mg/kg for children. For IV use, each dose of gentamicin diluted with 50-100 mL of IV fluids given over 20 min. Duration 7-10 days.

#### CONTRAINDICATIONS:

History of hypersensitivity to aminoglycoside; pregnancy; hepatic impairment, perforated ear drum.

#### PRECAUTIONS:

Concurrent use of neuromuscular blocking agents; myasthenia gravis, parkinsonism; conditions predisposing to ototoxicity and nephrotoxicity; lactation. Monitor plasma concentrations of gentamicin in patients receiving high doses or prolonged courses, in infants, elderly, patients with renal impairment, cystic fibrosis or significant obesity. Monitor auditory and renal functions.

#### INTERACTIONS:

Synergistic with ampicillin, benzylpenicillin and other  $\beta$ -lactam antibiotics. Increased risk of severe respiratory depression when used concurrently with anaesthetics or opioids. May reduce renal clearance of zalcitabine and induce hypocalcaemia when used with biphosphonates. Not to be used with agalsidase alfa or beta as it may inhibit  $\alpha$ -galactosidase activity.

Potentially Fatal: Increased incidence of ototoxicity when combined with ethacrynic acid and furosemide. Cephalosporins, ciclosporin, cisplatin, vancomycin, hydrocortisone and indometacin potentiate nephrotoxicity. Potentiates neuromuscular blocking agents.

# ADVERSE DRUG REACTIONS:

Dizziness or vertigo; acute renal failure, interstitial nephritis, acute tubular necrosis; electrolyte imbalances; transient elevation of serum bilirubin and aminotransferases; purpura; nausea, vomiting; convulsions, mental depression, hallucinations. Atrophy or rat necrosis at inj sites.

Potentially Fatal: Nephrotoxicity, ototoxicity and neuromuscular blockade (may unmask or aggravate myasthaenia gravis).

# 67. GLYCOPYRROLATE Inj 0.2 mg, 1 ml ampoule

#### **SALIENT ACTIONS:**

Glycopyrronium bromide is a quarternary ammonium antimuscarinic. It blocks acetylcholine at parasympathomimetic sites and induces smooth muscle relaxation. It also reduces gastric acid secretions and controls pharyngeal, tracheal and bronchial secretions. It antagonises muscarinic symptoms such as bronchorrhoea, bronchospasm, bradycardia and intestinal hypermotility induced by anticholinesterases.

#### INDICATION & DOSAGE REGIMENS:

#### Intravenous

#### 1. Reversal of neuromuscular blockade

Adult: 200 mcg for each 1 mg of neostigmine or 5 mg of pyridostigmine. Alternatively, 5-15 mcg/kg with 50mcg/kg neostigmine with 25-70 mcg/kg of neostigmine or 0.1-0.3 mg/kg of pyridostigmine. Child: 10 mcg/kg with 50 mcg/kg neostigmine.

# Parenteral

# 2. Peptic ulcer

Adult: 0.1-0.2 mg 3-4 times daily via IM/IV admin.

#### CONTRAINDICATIONS:

Hypersensitivity. Glaucoma; obstructive uropathy; obstructive GI diseases; intestinal atony; paralytic ileus; pyloric stenosis; myasthenia gravis. Unstable CV status in acute haemorrhage. Injectable not recommended in new borns ≤1 mth if benzyl alcohol is present in the preparation.

#### PRECAUTIONS:

Pregnancy, lactation. CV disease, hyperthyroidism, hepatic or renal impairment. Enlarged prostate, diarrhoea, fever. May cause ileus or megacolon in patients with ulcerative colitis. Children and elderly.

# INTERACTIONS:

Decreases levodopa effects. Effects may be enhanced by using drugs with antimuscarinic properties or MAOIs concurrently. May antagonise the GI effects of cisapride, metoclopramide and dompeidone.

Potentially Fatal: IV admin in the presence of cyclopropane anesth can result in ventricular arrhythmias.

Click to view more glycopyrronium bromide Drug Interactions

#### ADVERSE DRUG REACTIONS:

Xerostomia; loss of taste, nausea, vomiting, constipation, reduced sweating; urinary hesitancy and retention; blurred vision; cycloplegia; increased ocular tension; tachycardia; palpitation; headache, anxiety, bloated feeling, impotence, skin reactions. *Potentially Fatal:* Severe anaphylaxis.

# 68. GRANISETRON(INJ)

#### SALIENT ACTIONS:

Selective 5-HT<sub>3</sub> receptor antagonist.

#### INDICATIONS:

Prevention of nausea and vomiting associated with chemotherapy (including high-dose cisplatin). Prevention and treatment of post-op nausea and vomiting.

#### DOSAGE REGIMENS:

# Usual Adult Dose for Nausea/Vomiting - Chemotherapy Induced

IV: 10 mcg/kg over 5 minutes, beginning 30 minutes before initiation of chemotherapy.

# Usual Adult Dose for Nausea/Vomiting - Postoperative

Prevention and Treatment

IV: 1 mg undiluted over 30 seconds, given before induction of anesthesia, or immediately before reversal of anesthesia; or give after surgery.

#### CONTRAINDICATIONS:

Concomitant apomorphine.

#### PRECAUTIONS:

Abdominal surgery. May mask progressive ileus and/or gastric distention. Pre-existing arrhythmias or cardiac conduction disorders. Cardiac disease, concomitant cardio-toxic chemotherapy or electrolyte abnormalities: increased risk of QT prolongation. Pregnancy (Cat.B). Nursing mothers.

#### INTERACTIONS:

Caution with drugs that affect CYP450 or prolong the QT interval.

## ADVERSE EFFECTS:

Headache, asthenia, diarrhea, constipation; QT prolongation.

# HALOPERIDOL Inj 5mg, 1ml ampoule

#### SAILENT ACTIONS:

Haloperidol blocks postsynaptic dopamine  $D_1$  and  $D_2$  receptors in the mesolimbic system and decreases the release of hypothalamic and hypophyseal hormones. It produces calmness and reduces aggressiveness with disappearance of hallucinations and delusions.

#### INDICATION:

- 1. Intractable hiccup
- 2. Acute psychosis
- 3. Nausea and vomiting
- 4. Restlessness and confusion
- 5. Severe tics
- 6. Tourette's syndrome

# DOSAGE RGIMENS:

# 1. Intractable hiccup

Adult: 1.5 mg tid, adjust according to response.

# 2. Acute psychosis

**Adult:** Doses range from 2-10 mg, may be given every hr or at intervals of 4-8 hr, until symptoms are controlled. Max: 18 mg/day. For emergency control of severely disturbed patients: Up to 18 mg may be given IV/IM.

# 3. Nausea and vomiting

**Adult:** 0.5-2 mg daily. In palliative care, 1.5 mg 1-2 times daily via oral admin or 2.5-10 mg over 24 hr by SC infusion (via a syringe driver).

#### Subcutaneous

#### 4. Restlessness and confusion

Adult: 5-15 mg via SC infusion over 24 hr.

# **CONTRAINDICATIONS:**

Severe toxic CNS depression; preexisting coma; Parkinson's disease; lactation

#### PRECAUTION:

Parkinsonism; epilepsy, allergy, angle-closure glaucoma, benign prostatic hyperplasia; severe cardiac or hepatic disease; extremes in temp (hot and cold weather); presence of acute infections or leucopenia; hyperthyroidism; pregnancy, elderly, children. Patients receiving anticoagulants. Discontinue upon signs of neurological toxicity in patients taking haloperidol and lithium

# INTERACTION:

Carbamazepine and rifampicin reduce plasma concentrations. Symptoms of CNS depression may be enhanced by CNS depressants e.g. alcohol, hypnotics, general anaesthetics, anxiolytics and opioids. May reduce antihypertensive action of guanethidine. May increase risk of arrhythmia when used with drugs that prolong QT interval or diuretics that can cause electrolyte imbalance. May increase plasma levels of haloperidol when used with clozapine or chlorpromazine.

Potentially Fatal: Increases lithium blood levels and may predispose to neuroleptic malignant syndrome.

# ADVERSE DRUG REACTIONS:

Tardive dyskinesia; extrapyramidal reactions. Anxiety, drowsiness, depression, anorexia, transient tachycardia, postural hypotension, leukopenia; anticholinergic side effects.

Potentially Fatal: Neuroleptic malignant syndrome

# 69. HAEMOPHILUS TYPE B CONJUGATE VACCINE

# SALIENT ACTIONS:

Haemophilus influenzae type B (Hib) is a bacteria that can cause serious illness, including breathing problems or meningitis. Hib infection usually affects children and can be fatal.

Haemophilus B conjugate (PRP-T) vaccine is used to prevent this disease in children, and is sometimes combined with vaccines to protect against other diseases. This vaccine is given to children between the ages of 2 months and 18 months old.

# INDICATIONS:

all children receive one of the conjugate vaccines licensed for infant use (HbOC or PRP-OMP), beginning routinely at 2 months of age

Asplenia

- Indicated for adults with functional or anatomic asplenia (including sickle cell disease) or are undergoing elective splenectomy
- One dose of HIB vaccine should be administered if HIB vaccine not previously received
- HIB vaccination should be given ≥14 days before splenectomy

# Complement deficiency

- Indicated for adults with persistent complement component deficiencies
- One dose of HIB vaccine should be administered if HIB vaccine not previously received

# Post-HSCT Recipients

- Recipients of a hematopoietic stem cell transplant (HSCT) should be vaccinated with a 3-dose regimen 6 to 12 months after a successful transplant, regardless of vaccination history
- At least 4 weeks should separate doses

# DOSAGE REGIMENS:

10mcg Haemophilus b

# CONTRAINDICATIONS & PRECAUTIONS:

Conjugate vaccines that contain either diphtheria toxoid or protein should not be considered as an immunizing agent against diphtheria; no changes in the schedule for administering DTP are recommended. A conjugate vaccine that contains meningococcal protein should not be considered as an immunizing agent against meningococcal disease.

#### INTERACTIONS:

N/A

# ADVERSE EFFECTS:

- · fussiness, irritability, crying for an hour or longer; or
- high fever (within a few hours or a few days after the vaccine).
- vomiting, loss of appetite;
- diarrhea: or
- · pain, swelling, or redness where the shot was given

### 70. HEPARIN 5000IU/ML INJ

#### SALIENT ACTIONS:

Heparin sodium 5000iu injection is an anticoagulant that prevents the formation of harmful blood clots.

#### INDICATIONS:

Heparin Sodium 5000IU Injection is used in the treatment and prevention of deep vein thrombosis, pulmonary embolism, unstable angina and heart attack.

#### DOSAGE REGIMENS:

Prophylaxis of deep vein thrombosis and pulmonary embolism

Adults:

2 hours pre-operatively:

5,000 units subcutaneously

followed by:

5,000 units subcutaneously every 8-12 hours, for 7-10 days or until the patient is fully

ambulant.

During pregnancy:

5,000 - 10,000 units every 12 hours, subcutaneously, adjusted according to APTT or

anti-Xa assay.

Elderly:

Dosage reduction and monitoring of APTT may be advisable.

No dosage recommendations.

Treatment of deep vein thrombosis and pulmonary embolism:

Adults:

Loading dose: 5,000 units intravenously (10,000 units may be required in severe pulmonary embolism)

Maintenance: 1,000-2,000 units/hour by intravenous infusion, or 10,000-20,000 units 12 hourly subcutaneously. or 5,000-10,000 units 4-hourly by intravenous injection.

Elderly:

Dosage reduction may be advisable.

Children and small adults:

Loading dose: 50 units/kg intravenously

Maintenance: 15-25 units/kg/hour by intravenous infusion, or 250 units/kg 12 hourly subcutaneously

or 100 units/kg 4-hourly by intravenous injection

Treatment of unstable angina pectoris and acute peripheral arterial occlusion:

Adults:

Loading dose: 5,000 units intravenously

Maintenance: 1,000-2,000 units/hour by intravenous infusion,

or 5,000-10,000 units 4-hourly by intravenous injection.

Elderly:

Dosage reduction may be advisable.

Children and small adults:

Loading dose: 50 units/kg intravenously

Maintenance: 15-25 units/kg/hour by intravenous infusion.

or 100 units/kg 4-hourly by intravenous injection

Prophylaxis of mural thrombosis following myocardial infarction

Adults:

12,500 units 12 hourly subcutaneously for at least 10 days.

Dosage reduction may be advisable

In extracorporea! circulation and haemodialysis

Adults:

Cardiopulmonary bypass:

Initially 300 units/kg intravenously, adjusted thereafter to maintain the activated clotting time (ACT) in the range 400-500 seconds.

Haemodialysis and haemofiltration:

Initially 1,000-5,000 units,

Maintenance: 1,000-2,000 units/hour, adjusted to maintain clotting time >40 minutes.

# CONTRAINDICATIONS:

Patients who consume large amounts of alcohol, who are sensitive to the drug, who are actively bleeding or who have haemophilia or other bleeding disorders, severe liver disease (including oesophageal varices), purpura, severe hypertension, active tuberculosis or increased capillary permeability.

Patients with present or previous thrombocytopenia. The rare occurrence of skin necrosis in patients receiving heparin contra-indicates the further use of heparin either by subcutaneous or intravenous routes because of the risk of thrombocytopenia

#### PRECAUTIONS:

Platelet counts should be measured in patients receiving heparin treatment for longer than 5 days and the treatment should be stopped immediately in those who develop thrombocytopenia.

In patients with advanced renal or hepatic disease, a reduction in dosage may be necessary. The risk of bleeding is increased with severe renal impairment and in the elderly (particularly elderly women).

Although heparin hypersensitivity is rare, it is advisable to give a trial dose of 1,000 I.U. in patients with a history of allergy. Caution should be exercised in patients with known hypersensitivity to low molecular weight heparins.

# INTERACTIONS:

Analgesics: Drugs that interfere with platelet aggregation eg. aspirin and other NSAIDs should be used with care. Increased risk of haemorrhage with ketorolac (avoid concomitant use even with low-dose heparin). Anticoagulants, platelet inhibitors, etc: Increased risk of bleeding with oral anticoagulants, epoprostenol, clopidogrel, ticlopidine, streptokinase, dipyridamole, dextran solutions, or any other drug which may interfere with coagulation.

Cephalosporins: Some cephalosporins, e.g. cefaclor, cefixime and ceftriaxone, can affect the coagulation process and may therefore increase the risk of haemorrhage when used concurrently with heparin. ACE inhibitors: Hyperkalaemia may occur with concomitant use.

Nitrates: Reduced activity of heparin has been reported with simultaneous intravenous glyceryl trinitrate infusion.

Probenecid: May increase the anticoagulant effects of heparin.

#### ADVERSE EFFECTS:

Bleeding, Injection site reaction.

Adrenal insufficiency secondary to adrenal haemorrhage has been associated with heparin (rarely). Thrombocytopenia

Hypersensitivity reactions to heparin

# 71. HEPATITIS A (FREEZE DRIED LIVE ATTENUATED VACCINE)

#### SALIENT ACTIONS:

The product can induce immunity against hepatitis A virus in recipients following immunization. It is used to prevent hepatitis A

# INDICATIONS:

Hepatitis A susceptible individuals above the age of 18 months.

#### DOSAGE REGIMENS:

Inject 1.0ml s.c. the reconstituted vaccine at deltoid insertion area of the lateral upper arm.

# CONTRAINDICATIONS:

- 1. Subjects with discomfort, body temperature (subaxillary) over 37.5°C.
- 2. Those with acute infectious disease or other serious diseases.
- 3. Those with immunodeficiency or receiving immunosuppressant.
- 4. Those with a history of allergy.

#### PRECAUTIONS:

- 1. Care should be taken to avoid contacting the vaccine by disinfectant during opening the container and in the course of injection.
- 2.Do not use the vaccine if any leakage of container, foreign matters, or turbidity of content is found.
- 3. The immunization of hepatitis A vaccine should be deferred for at least one month following administration of immunoglobulin.
- 4. Use the vaccine cautiously for pregnant women.

#### INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

A few recipients might have pain, erythema and swelling at the injection site, which could generally at the injection site.

# 72. HEPATITIS B SURFACE ANTIGEN(PURIFIED) 20MCG INJ.1ML SALIENT ACTIONS:

protects from consequent hepatitis B virus attacks

#### INDICATIONS:

Immunization is recommended in persons of all ages, especially those who are, or will be, at increased risk of exposure to hepatitis B virus,

#### DOSAGE REGIMENS:

0.5 ML PER DOSE IN PEDIATRICS.

#### 1 ML PER DOSE IN ADULTS

.The usual immunization regimen consists of 3 doses of vaccine given according to the following schedule: first dose: at elected date; second dose: 1 month later; third dose: 6 months after first dose.All given intramuscularly.

#### CONTRAINDICATIONS:

Hypersensitivity to any component of the vaccine, including yeast, is a contraindication.

This vaccine is contraindicated in patients with previous hypersensitivity to any hepatitis B-containing vaccine.

#### PRECAUTIONS:

N/A

#### INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

Incidence 1% to 10% of Injections:

Nervous System Disorders: Dizziness\*, headache.\*

General Disorders and Administration Site Conditions: Fever (>37.5°C), injection site erythema, injection site induration, injection site swelling.

†Parent or guardian completed forms for children and neonates. Neonatal checklist did not include headache, fatigue, or dizziness.

Incidence <1% of Injections:

shoulder, or neck.

SALIENT ACTIONS:

Infections and Infestations: Upper respiratory tract illnesses.

Blood and Lymphatic System Disorders: Lymphadenopathy.

Metabolism and Nutrition Disorders: Anorexia.

Psychiatric Disorders: Agitation, insomnia.

Nervous System Disorders: Somnolence, tingling.

Vascular Disorders: Flushing, hypotension.

Gastrointestinal Disorders: Abdominal pain/cramps, constipation, diarrhea, nausea, vomiting. Skin and Subcutaneous Tissue Disorders: Erythema, petechiae, pruritus, rash, sweating, urticaria. Musculoskeletal and Connective Tissue Disorders: Arthralgia, back pain, myalgia, pain/stiffness in arm,

General Disorders and Administration Site Conditions: Chills, influenza-like symptoms, injection site ecchymosis, injection site pain, injection site pruritus, irritability, malaise, weakness.

# 73. HUMAN INSULIN Inj 40 IU/ml, 10 ml vial

Insulin lowers blood glucose levels. It regulates carbohydrate, protein and fat metabolism by inhibiting hepatic glucose production and lipolysis, and enhancing peripheral glucose disposal. The various insulin formulations are classified according to their durations of action after SC Inj. They are divided into short-, intermediate-, or long-acting insulin. Soluble insulin (also known as 'neutral insulin' or 'regular insulin') is a short-acting preparation. To extend the duration of action of insulin, preparations are formulated as suspensions in 2 methods. The 1st method involves complexing insulin with a protein so that it is slowly released, e.g. protamine zinc insulin (contains an excess of protamine) and isophane insulin (or NPH insulin which contains equal amounts of protamine and insulin). An alternative method is particle size modification e.g. insulin zinc suspensions. While all the formulations can be admin by SC inj, most by IM inj, only soluble insulin can be admin by IV. Compared to SC inj, IM admin usually has a faster onset of action, with a shorter duration of action.

Onset: 0.5-1 hr (short-acting e.g. soluble insulin); 2 hr (intermediate-acting e.g. biphasic insulin, isophane insulin, amorphous insulin zinc suspensions); 2-3 hr (mixed-insulin Zn suspension); 4 hr (long-acting e.g. insulin zinc suspensions, protamine zinc insulins).

**Duration:** 6-8 hr (short-acting e.g. soluble insulin); 24 hr (intermediate-acting e.g. biphasic insulin, isophane insulin, amorphous insulin zinc suspensions); 30 hr (mixed-insulin Zn suspension); 36 hr (long-acting e.g. insulin zinc suspensions, protamine zinc insulins).

#### INDICATIONS:

Diabetes mellitus Diabetic ketoacidosis, renal impairment, hepatic impairment,

#### DOSE REGIMENS:

#### Intramuscular

#### 1. Diabetic ketoacidosis

*Adult:* As soluble insulin, initial loading dose of 20 units, followed by 6 units/hr until blood glucose drops to 10 mmol/l, when the dose is given 2 hrly.

# Intravenous

# 2. Diabetic ketoacidosis

Adult and child: As soluble insulin, given in concentration of 1 unit/ml using an infusion pump: Initially infuse at a rate of 6 units/hr, double or quadruple the rate if blood glucose concentration do not decrease by about 5 mmol/l/hr. If blood glucose concentrations have decreased to 10 mmol/l, reduce the infusion rate to 3 units/hr and continue with 5% glucose to prevent hypoglycaemia, until the patient can eat orally. Do not stop the insulin infusion before SC insulin is started. Ensure adequate fluid replacement and include potassium chloride in the infusion to prevent insulin-induced hypokalaemia.

#### Subcutaneous

**Diabetes mellitus**: Admin according to requirements; inject into thighs, upper arms, buttocks, or abdomen.

Renal and hepatic impairment: Dose reduction may be needed

#### CONTRAINDICATION:

Hypoglycemia

# PRECAUTIONS:

Pregnancy (insulin requirements tend to fall during the 1st trimester, increase during the 2nd and 3rd) and lactation. Regular monitoring of HbA1c and blood glucose concentrations.

#### INTERACTIONS:

Possible absence of hypoglycaemic warning symptoms with β-blockers. Decreased hypoglycaemic effect with corticosteroids, danazol, diazoxide, diuretics, glucagon, isoniazid, phenothiazine derivatives, somatropin, sympathomimetic agents, thyroid hormones, oestrogens, progestins (e.g. in oral contraceptives), protease inhibitors and atypical antipsychotic (e.g. olanzapine and clozapine). Increased hypoglycaemic effect with oral antidiabetic agents, ACE inhibitors, disopyramide, fibrates, fluoxetine, MAOIs, pentoxifylline, propoxyphene, salicylates and sulfonamide antibiotics. Decreased insulin resistance with octreotide and lanreotide. Increased risk of wt gain and peripheral oedema with pioglitazone, rosiglitazone. Decreased effect of sermorelin.

# ADVERSE DRUG REACTIONS:

Hypoglycaemia, insulin resistance, lipoatrophy, hypokalaemia, blurred vision.

# 74. HYALURONIDASE Inj 1500 IU/ampoule SALIENT ACTIONS:

Hyaluronidase is an enzyme which reduces the viscosity of ground substance, thus making the tissues more permeable to injected fluids. It facilitates distribution and absorption of locally injected substances. It also promotes resorption of excess fluids and extravasated blood in the tissues

#### INDICATIONS:

Adjunct in hypodermoclysis, . Aid in dispersal of extravasated fluids or blood , Aid in diffusion of local anesth in ophthalmology

# DOSAGE REGIMENS:

Adult: Parenteral

Adjunct in hypodermoclysis 1,500 u for every 500-1,000 mL of fluid for SC administration. Facilitate SC/IM inj 1,500 u added directly into the inj. Aid in dispersal of extravasated fluids or blood 1,500 u into the affected area.

Aid in diffusion of local anesth in ophthalmology 15 u/mL of local anesth soln.

# CONTRAINDICATIONS:

Hypersensitivity, malignancy. Direct application to the cornea, reduction of swelling of bites or stings. Inj into or around infected area. IV admin; unexplained premature labour.

#### PRECAUTIONS:

Impaired renal function. Infants, elderly. Patients with infections. Pregnancy, lactation.

#### INTERACTIONS:

Action potentiated by urokinase especially in the treatment of MI. May increase absorption and toxicity of local anaesthetics. Heparin, salicylates and NSAIDs may inhibit the spreading action and efficacy of hyaluronidase

#### ADVERSE DRUG REACTIONS:

Urticaria, occasional severe allergy.

Potentially Fatal: Hypersensitivity and anaphylaxis

# 75. HYDROCORTISONE Inj 100mg/vial

#### SALIENT ACTIONS:

Hydrocortisone is a corticosteroid used for its anti-inflammatory and immunosuppressive effects. Its anti-inflammatory action is due to the suppression of migration of polymorphonuclear leukocytes and reversal of increased capillary permeability. It may also be used as replacement therapy in adrenocortical insufficiency.

#### INDICATIONS:

Replacement therapy in adrenocortical insufficiency, As supplement in adrenal insufficiency during minor surgery undergeneral anaesthesia, As supplement in adrenal insufficiency during moderate or major surgery, Acute adrenocortical insufficiency, Soft tissue inflammation

Joint inflammations, Joint inflammations, Corticosteroid-responsive dermatoses

#### DOSAGE REGIMENS:

#### Intravenous

1. Acute adrenocortical insufficiency, Adult: 100-500 mg 3-4 times/24 hr according to the severity of the condition and patient response. Fluids and electrolytes should be administered as needed to correct any metabolic disorder. Doses may also be given via IM inj but the response may be slower.

*Child:* <1 yr: 25 mg; 1-5 yr: 50 mg; 6-12 yr: 100 mg. Fluids and electrolytes should be administered as needed to correct any metabolic disorder. Doses may also be given via IM inj but the response may be slower. *Injection* 

#### 2. Soft tissue inflammation

Adult: As Na phosphate or Na succinate esters: 100-200 mg as local inj.

Intra-articular

#### 3. Joint inflammations

Adult: As acetate: 5-50 mg depending on size of affected joint.

### CONTRAINDICATIONS:

Viral/fungal infections, tubercular or syphilitic lesions, bacterial infections unless used in conjunction with appropriate chemotherapy

#### PRECAUTIONS:

CHF, hypertension, DM, epilepsy, elderly, patients on prolonged therapy. Gradual withdrawal, pregnancy and lactation.

#### INTERACTIONS:

Thiazides may enhance hyperglycaemia and hypokalaemia caused by corticosteroids. Increased incidence of peptic ulcer or GI bleeding with concurrent NSAIDs admin. Response to anticoagulants altered. Dose of antidiabetics and antihypertensives needs to be increased. Decreases serum conc of salicylates and antimuscarinic agents. Ethanol may enhance gastric mucosal irritation. Reduced efficacy with concurrent use ofcarbamazepine, phenytoin, primidone, barbiturates and rifampicin. Mutual inhibition of metabolism between ciclosporin and corticosteroids increase plasma conc of both drugs. Enhanced effect in women taking oestrogens or oral contraceptives

# ADVERSE DRUG REACTIONS:

Sodium and fluid retention. Potassium and calcium depletion. Muscle wasting, weakness, osteoporosis. GI disturbances and bleeding. Increased appetite and delayed wound healing. Bruising, striae, hirsutism, acne, flushing. Raised intracranial pressure, headache, depression, psychosis, menstrual irregularities. Hyperglycaemia, glycosuria, DM, obesity, moon-face, buffalo hump. Suppression of pituitary-adrenocortical system. Growth retardation in childn (prolonged therapy). Increased susceptibility for infection. Topical use: Dermal atrophy, local irritation, folliculitis, hypertrichosis. Inhaled corticosteroids: May cause hoarseness, candidiasis of mouth and throat. Topical application to the eye: Can produce corneal ulcers, raised IOP and

reduced visual function. Intralesional injection: Local hypopigmentation of deeply pigmented skin. Intraarticular injection: Joint damage, fibrosis esp in load bearing joints.

Potentially Fatal: Abrupt withdrawal leading to acute adrenal insufficiency. Rapid IV Inj may cause CV collapse.

# 76. HYOSCINE BUTYLBROMIDE Inj 20 mg, 1ml ampoule

#### **SALIENT ACTIONS:**

Hyoscine competitively blocks muscarinic receptors and has central and peripheral actions. It relaxes smooth muscle and reduces gastric and intestinal motility.

Onset: Oral, IM: 0.5-1 hr; IV: 10 min. Duration: Oral, IM: 4-6 hr; IV: 2 hr.

# INDICATIONS & DOSAGE REGIMENS:

*IV/IM* Genito-urinary spasm; GI tract spasm As butylbromide: 20 mg, repeat 30 mins later if needed. Max: 100 mg/day. *IM/SC* Anesth premed As hydrobromide: 0.2-0.6 mg 30-60 mins before induction of anesth. *SC* CONTRAINDICATIONS:

Narrow-angle glaucoma, acute haemorrhage, paralytic ileus, tachycardia due to cardiac insufficiency, myasthenia gravis

#### PRECAUTIONS:

Hepatic/renal disease, pyloric stenosis, urinary retention, prostatic hyperplasia, psychosis, seizure disorders, ulcerative colitis, coronary artery disease, tachyarrhythmias, heart failure, hypertension. Elderly, children, pregnancy, lactation.

#### INTERACTIONS:

Additive sedative effects with alcohol or other CNS depressants. Reduced effects with acetylcholinesterase inhibitors (donepezil, galantamine, rivastigmine, tacrine). *Potentially Fatal:* Effect potentiated by other anticholinergic drugs and TCAs.

#### ADVERSE DRUG REACTIONS:

Flushing, postural hypotension, tachycardia, fibrillation. Rarely psychotic reactions. Dizziness, drowsiness, fatigue, headache, memory loss. Dry skin, erythema, increased sensitivity to light, rash. Bloatedness, constipation, dry throat, dysphagia, nausea, vomiting, xerostomia. Dysuria, urinary retention. Tremor, weakness. Impaired accommodation, blurred vision, cycloplegia, dryness, narrow-angle glaucoma, increased intraocular pain, itching, photophobia, pupil dilation. Dry nose. Decreased diaphoresis, heat intolerance. Ophthalmic: Somnolence, dermatitis, oedema, exudate, follicular conjunctivitis, increased IOP, local irritation, photophobia, vascular and respiratory congestion. *Potentially Fatal:* CNS depression, coma, circulatory and respiratory failure.

# 77. HYDROXYPROPYL METHYLCELLULOSE 2% W/V INJ

#### **SALIENT ACTIONS:**

Hydroxypropylmethylcellulose belongs to a class of medicines called eye lubricants or artificial tears. It is available as eye drops. It is used to soothe irritation, burning and discomfort of dry eye conditions(deficient tear production, infrequent blinking, smoke, wind, pollution, extended use of computer screen or television, medical treatment, dry atmospheric conditions). It may also be used to aid insertion and increase comfort of hard contact lenses

# INDICATIONS:

It is used in the treatment of dry eye disease.

# DOSAGE REGIMENS:

For anterior segment surgery, 2% hydroxypropyl methylcellulose should be injected carefully into the anterior chamber by using a 20 gauge or smaller cannula.

#### CONTRAINDICATIONS:

N/A

#### PRECAUTIONS:

There may be transient increased intraocular pressure following surgery because of pre-existing glaucoma or due to the surgery itself.

# INTERACTIONS:

N/A

# ADVERSE EFFECTS:

Signs of potential side effects, especially a transient increase in intraocular pressure (asymptomatic), corneal edema or decompensation, hypopyon, or iritis.

# 78. HYDROXYPROGESTERONE CAPROATE INJ SALIENT ACTIONS:

Hydroxyprogesterone is a form of progestin, a manmade form of a female hormone called progesterone. Hydroxyprogesterone is a potent, long-acting, progestational steroid ester which transforms proliferative endothelium into secretory endothelium, induces mammary gland duct development, and inhibits the production and/or release of gonadotropic hormone

Hydroxyprogesterone is used to lower the risk of premature birth in a woman who has already had one premature baby. This medication will not stop premature labor that has already begun.

#### INDICATIONS:

Hydroxyprogesterone Caproate Injection, USP is indicated in non-pregnant women: for the treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV); in the management of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer; as a test for endogenous estrogen production and for the production of secretory endometrium and desquamation.

#### DOSAGE REGIMENS:

Production of secretory endometrium and desquamation - Patients currently on estrogen therapy: 375 mg Hydroxyprogesterone Caproate Injection

# CONTRAINDICATIONS:

Hydroxyprogesterone caproate is contraindicated in patients with known or suspected carcinoma of the breast, other hormone-sensitive cancer, or history of these conditions; undiagnosed abnormal vaginal bleeding; liver dysfunction or disease; missed abortion, and in those with a history of hypersensitivity to the drug. Hydroxyprogesterone caproate is also contraindicated as a diagnostic test for pregnancy and in patients with current or history of thrombotic or thromboembolic disorders.

#### PRECAUTIONS:

Hydroxyprogesterone is not for use in women who are pregnant with more than one baby (twins, triplets, etc). INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

- swelling, oozing, bleeding, or worsening pain where the injection was given;
- · jaundice (yellowing of the skin or eyes);
- · symptoms of depression (sleep problems, weakness, mood changes);
- · swelling in your hands, ankles, or feet;
- signs of a stroke--sudden numbness or weakness (especially on one side of the body), sudden severe headache, slurred speech, problems with vision or balance;
- · signs of a blood clot in your leg--pain, swelling, warmth, or redness in one or both legs; or
- increased blood pressure--severe headache, blurred vision, pounding in your neck or ears, nosebleed, anxiety.

# 79. IMIPENEM Inj 500mg /vial

# SALIENT ACTIONS:

Imipenem is a potent inhibitor of bacterial cell wall synthesis and is bactericidal against a broad spectrum of pathogens. It is resistant to degradation by bacterial β-lactamases. Cilastatin is an inhibitor of dehydropeptidase I, an enzyme found in the brush border of the renal tubules. It is given as the sodium salt with imipenem to prevent its renal metabolism and protect against nephrotoxic effects.).

#### INDICATIONS:

Broad spectrum B lactum antibiotic. Effective against Gram +ve cocci, enterobacter, pseudomonas, anaerobes ,B. fragilis, clostridium difficile, penicillinase producing staphylococci, prophylaxis of surgical infections, mild to moderate susceptible infections

#### DOSAGE REGIMENS:

#### Intravenous:

#### Susceptible infections

Adult: In terms of imipenem, 1-2 g daily in divided doses every 6-8 hr, given via IV infusion. Doses 250 or 500 rng are infused over 20-30 minutes, and doses of 750 mg or 1 g over 40-60 minutes.

Child: >40 kg: same as adult dose. >3 mth and <40 kg: 15-25 mg/kg every 6 hr by IV infusion. Up to 90 mg/kg may be given to older children with cystic fibrosis. Neonates and infants <3 mth: 4 wk-3 mth, 25 mg/kg every 6

hr; 1-4 wk, 25 mg/kg every 8 hr; up to 1 wk, 25 mg/kg every 12 hr.

Max Dosage: Adults and children >40 kg: 4 g/day or 50 mg/kg. Children <40 kg: 2 g/day.

**Prophylaxis of surgical infections**; *Adult:* In terms of imipenem, 1 g given on induction of anaesthesia, followed by 1 g 3 hr later, with additional doses of 500 mg at 8 and 16 hr after induction if necessary. *Intramuscular* 

Mild to moderate susceptible infections

Adult: In terms of imipenem, 500 mg or 750 mg every 12 hr.

Intramuscular

Uncomplicated gonorrhoea

Adult: In terms of imipenem: A single 500 mg dose may be used.

CONTRAINDICATIONS:

Hypersensitivity.

PRECAUTIONS:

Caution when used in patients with known hypersensitivity to other  $\beta$ -lactams due to possibility of cross-sensitivity. CNS disorders such as epilepsy; renal, hepatic impairment; pregnancy, lactation

INTERACTIONS:

Concurrent admin with probenecid may increase the half-life of cilastatin. Increased risk of generalised seizures when used concurrently with ganciclovir

ADVERSE DRUG REACTIONS:

Skin rashes, urticaria, eosinophilia, fever, nausea, vomiting, diarrhoea, tooth or tongue discoloration and altered taste. Erythema multiforme, exfoliative dermatitis. Pain and thrombophlebitis may occur at the inj site.

# 80. INACTIVATED INFLUENZA VACCINE

#### SALIENT ACTIONS:

The inactivated influenza vaccine is made of killed influenza viruses. It protects against viruses that cause influenza, often called the flu. The vaccine does not protect against other viruses or bacteria that cause colds or stomach flu.

# INDICATIONS:

Active immunisation against influenza.

#### DOSAGE REGIMENS:

Adult: IM/SC 0.5 mL as a single dose.

#### CONTRAINDICATIONS:

Known hypersensitivity to egg products. Anaphylactic reaction to a previous dose containing the same antigens.

PRECAUTIONS:

Postpone vaccination in patients with active infection or acute febrile illness. Pregnancy

# INTERACTIONS:

Immunosuppressants, antineoplastics or high doses of corticosteroids may reduce response to vaccines. Increased antibody response with aldesleukin and aspirin. May possibly increase anticoagulant effects of warfarin.

# ADVERSE EFFECTS:

Inj site soreness, fever, malaise, myalgia, headache, GI disturbances, lymphadenitis, oculorespiratory syndrome.

#### 81. IOHEXOL INJ

### SALIENT ACTIONS:

Iohexol is a nonionic radiopaque contrast agent.

## INDICATIONS:

IOHEXOL is indicated for intrathecal administration in adults including myelography (lumbar, thoracic, cervical, total columnar) and in contrast enhancement for computerized tomography (myelography, cisternography, ventriculography). IOHEXOL is indicated for intrathecal administration in children including myelography (lumbar, thoracic, cervical, total columnar) and in contrast enhancement for computerized tomography (myelography, cisternography).

#### DOSAGE REGIMENS:

N/A

#### CONTRAINDICATIONS:

For intrathecal use

• Bleeding, subarachnoid (increased risk of meningeal irritation or arachnoiditis

Epilepsy, history of (myelographic procedure may increase risk of seizures <sup>{49}</sup>)

Infection, local or systemic, significant

Multiple sclerosis

For intravascular use:

Hyperthyroidism(administration of iohexol may precipitate thyroid storm)

- Pheochromocytoma
- · For cerebral arteriography:

Arteriosclerosis

#### PRECAUTIONS:

Patients sensitive to iodine or other iodinated contrast media may be sensitive to iohexol also Cholecystographic agents, oral (may increase the risk of renal toxicity when closely followed by intravascular iohexol, especially in patients with hepatic function impairment

#### INTERACTIONS:

Antidepressants, tricyclic or CNS stimulation-producing medications or

Monoamine oxidase (MAO) inhibitors, including furazolidone, procarbazine, and selegiline or Phenothiazines or Trimeprazine

#### ADVERSE EFFECTS:

#### With intrathecal or intravascular administration

Bronchospasm or pulmonary edema (severe wheezing or troubled breathing (36) (39)) severe hypotension (unusual tiredness or weakness (38) (39) (71))

#### With intravascular administration

Cardiotoxic effects, with ventricular tachycardia or fibrillation (fast or irregular heartbeat {01} {39} {40} {71})

# 82. IRON PREPRATION( FERRIC CARBOXYMALTOSE) INJ

SALIENT ACTIONS:

It is a colloidal iron hydroxide in complex with carboxymaltose, a carbohydrate polymer that releases iron; replaces iron stores found in hemoglobin, myoglobin, and enzymes; works to transport oxygen via hemoglobin **INDICATIONS:** 50mg/ml Injection is used in the treatment of iron deficiency anemia and anemia due to chronic kidney disease.

#### DOSAGE REGIMENS:

≥50 kg: 750 mg IV once, follow 7 days later with second 750 mg dose; not to exceed cumulative dose of 1500 mg per course

<50 kg: 15 mg/kg IV once, follow 7 days later with second dose; not to exceed 1500 cumulative dose per course

# CONTRAINDICATIONS:

Hypersensitivity

#### PRECAUTIONS:

Only administer when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions

# INTERACTIONS:

The absorption of oral iron is reduced when administered concomitantly with parenteral iron preparations. Therefore, if required, oral iron therapy should not be started for at least 5 days after the last injection of DEERIC CARBOXYMALTOSE

#### ADVERSE EFFECTS:

Nausea, Flushing (sense of warmth in the face, ears, neck and trunk), Increased blood pressure, Dizziness, Decreased phosphate level in blood, Injection site reaction.

#### 83. ISOXSUPRINE HYDROCHLORIDE INJ 5MG/ML

# SALIENT ACTIONS:

It is  $\beta$ -Adrenergic receptor stimulant.

#### INDICATIONS:

- 1. For the relief of symptoms associated with cerebral vascular insufficiency
- In Peripheral vascular disease of arteriosclerosis obliterans, thromboangitis obliterans (Buerger's Disease) and Raynaud's disease.
- 3. As a tocolytic

# DOSAGE REGIMENS:

#### Usual adult dose

Labor (premature) inhibitor

Intramuscular, 5 to 10 mg two or three times a day.

# CONTRAINDICATIONS:

current abnormal bleeding, recent childbirth.

# PRECAUTIONS:

N/A

#### INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

hypotension, tachycardia, chest pain, nausea, vomiting, dizziness, abdominal distress, and severe rash. If rash appears, the drug should be discontinued.

#### 84. KETAMINE Inj 50 mg, 2ml ampoule

#### SALIENT ACTIONS:

Ketamine has a direct action on the cortex and limbic system. It produces a cataleptic-like state wherein the patient is withdrawn from the surrounding environment.

# INDICATIONS & DOSAGE REGIMENS:

#### Intravenous

# Induction of anaesthesia

**Adult:** 1-4.5 mg/kg as IV inj. Surgical anaesthesia is produced within 30 sec of the end of inj. Usual dose to produce 5-10 minutes of anaesthesia: 2 mg/kg over 60 seconds. Alternatively, 1-2 mg/kg infused at 0.5 mg/kg/minute; may use with diazepam to prevent emergence reactions.

**Child:** 1-4.5 mg/kg as IV Inj. Surgical anaesthesia is produced within 30 sec of the end of inj and lasts for 5-10 min if 2 mg/kg is given over 60 sec. Alternatively, 0.5-2 mg/kg as IV infusion. Maintenance: Achieve with 10-45 mcg/kg/min; titrate infusion rate according to response.

#### Intramuscular

# Induction of anaesthesia

Adult: 6.5-13 mg/kg. Usual dose to produce 12-25 minutes of anesthesia: 10 mg/kg.

Incompatibility: May form precipitates with barbiturates; do not inject in the same syringe.

# CONTRAINDICATIONS:

Hypertension, history of cerebrovascular accident. Eye injury, raised ocular and intracranial pressure. Psychotic disorders.

#### PRECAUTIONS:

Minimise verbal and tactile stimulation during recovery period. Chronic alcoholic and alcohol-intoxicated patients. Preanaesthetic elevated CSF pressure. Dependence and tolerance may develop. May impair ability to drive or operate machinery. Monitor cardiac function in patients with hypertension or cardiac decompensation. Pregnancy and lactation.

# INTERACTIONS:

May increase effects of nondepolarising muscle relaxants. May reduce hypnotic effect of thiopental. Prolonged recovery time with barbiturates/narcotics. Reduced cardiac output, BP and pulse rate withhalothane. Increased risk of hypertension and tachycardia with thyroidhormones. Seizures and tachycardia may occur when used with theophyllines.

# ADVERSE DRUG REACTIONS:

Emergence reactions e.g. vivid dreams, hallucinations, confusion, irrational behaviour. Increased muscle tone sometimes resembling seizures. Temporary hypertension and tachycardia. Hypotension, bradycardia. arrhythmias. Respiratory depression, apnoea, laryngospasm, diplopia, nystagmus, nausea, vomiting, lachrymation, hypersalivation, raised intraocular and CSF pressure, skin rash and pain at inj site.

# 85. KETOROLAC TROMETHAMINE 30MG/ML INJ

#### SALIENT ACTIONS:

Ketorolac tromethamine IS a nonsteroidal anti-inflammatory drug (NSAID)

#### INDICATIONS:

Ketorolac is used for the short-term treatment of moderate to severe pain.

#### DOSAGE REGIMENS:

The recommended total daily dose of ketorolac tromethamine tablets (maximum 40 mg) is significantly lower than for ketorolac tromethamineIV/IM (maximum 120 mg)

#### CONTRAINDICATIONS:

peptic ulcers, gastrointestinal bleeding, and/or perforation advanced renal impairment

Hypersensitivity

The use of ketorolac tromethamine in labor and delivery is CONTRAINDICATED because it may adversely affect fetal circulation and inhibit uterine contractions.

The use of ketorolac tromethamine is CONTRAINDICATED in nursing mothers because of the potential adverse effects of prostaglandin-inhibiting drugs on neonates.

Ketorolac tromethamine is CONTRAINDICATED in patients currently receiving ASA or NSAIDs because of the cumulative risk of inducing serious NSAID-related side effects

### PRECAUTIONS:

Ketorolac tromethamine should be used with caution in patients with impaired hepatic function. caution should be used when hemostasis is critical

#### INTERACTIONS:

Some products that may interact with this drug include: aliskiren, ACE inhibitors (such as captopril, lisinopril), angiotensin II receptor blockers (such as valsartan, losartan), corticosteroids (such as prednisone), methotrexate, probenecid, other medications that may affect the kidneys (including cidofovir), "water pills" (diuretics such as furosemide).

#### ADVERSE EFFECTS:

Pain at the injection site, dizziness, drowsiness, headache, or upset stomach

#### 86. LABETALOL INJ 4ML

SALIENT ACTIONS: Beta-Blockers

# INDICATIONS & DOSAGE REGIMENS:

IV Emergency treatment of HTN 20 mg injected slowly for at least 2 min; followed by 40-80 mg dose every 10 min. Max: 200 mg. Patient should remain supine during and 3 hr after the procedure. HTN in pregnancy Start infusion at a rate of 20 mg/hr, then doubled every 30 min until a satisfactory response is achieved or a dose of 160 mg/hr is reached. HTN after MI Initiate infusion at a rate of 15 mg/hr, then increase gradually until a favourable response is obtained or a dose of 120 mg/hr is reached. Hypotensive anaesth Initial: 10-20 mg, increase at 5-10 mg increments if satisfactory hypotension is not achieved after 5 min.

#### CONTRAINDICATIONS:

Obstructive airway disease (e.g. bronchial asthma), 2nd and 3rd degree heart block, cardiogenic shock, conditions w/ severe or prolonged hypotension, uncompensated heart failure, severe bradycardia.

#### PRECAUTIONS:

Patients w/ phaeochromocytoma, inadequate cardiac function and well-compensated heart failure, DM, nonallergic bronchospasm.Patients undergoing major surgery involving general anaesth.May mask symptoms of hypoglycaemia. Avoid abrupt withdrawal as it may exacerbate angina. Hepatic impairment.Elderly, pregnancy and lactation. Monitoring Parameters Monitor LFT periodically and BP.

# INTERACTIONS:

Synergistic hypotensive effect w/ halothane.Increased absolute bioavailability w/ cimetidine.Decreased absolute bioavailability w/ glutethimide.Additive hypotensive effect w/ nitroglycerin.Increased incidence of tremor w/ TCAs.Increased risk of bradycardia and heart block w/ Ca channel blocker (e.g. verapamil, diltiazem).

### ADVERSE EFFECTS:

Intraoperative floppy iris syndrome, orthostatic hypotension, bradycardia, syncope, paraesthesia, dizziness, dyspnoea, fatigue, vertigo, headache, nasal stuffiness, diarrhoea, abdominal pain, male sexual dysfunction, dyspepsia, nausea, vomiting, flatulence, constipation, taste disturbances, scalp tingling, tremor, muscle weakness, urinary retention, hepatitis, jaundice, rash, increased transaminases, nightmares, claudication. Potentially Fatal: Hepatic injury.

#### 87. LEVETIRACETAM IP 100MG INJ

#### SALIENT ACTIONS:

The exact mechanism by which levetiracetam acts to treat epilepsy is unknown. However, the drug binds to a

synaptic vesicle glycoprotein, SV2A, [26] and inhibits presynaptic calcium channels [27] reducing neurotransmitter release and acting as a neuromodulator. This is believed to impede impulse conduction across synapses.

#### INDICATIONS:

Seizure that affects the entire brain

Partial onset fits

Involuntary muscle jerk in people with epilepsy.

#### DOSAGE REGIMENS:

Dosing for Partial Onset Seizures:

Adults 16 Years and Older Initiate treatment with a daily dose of 1000 mg/day, given as twice-daily dosing (500 mg twice daily). Additional dosing increments may be given (1000 mg/day additional every 2 weeks) to a maximum recommended daily dose of 3000 mg. There is no evidence that doses greater than 3000 mg/day confer additional benefit.

#### Pediatric Patients

# I Month to < 6 Months

Initiate treatment with a daily dose of 14 mg/kg in 2 divided doses (7 mg/kg twice daily). Increase the daily dose every 2 weeks by increments of 14 mg/kg to the recommended daily dose of 42 mg/kg (21 mg/kg twice daily). In the clinical trial, the mean daily dose was 35 mg/kg in this age group. The effectiveness of lower doses has not been studied.

# 6 Months to < 4 Years:

Initiate treatment with a daily dose of 20 mg/kg in 2 divided doses (10 mg/kg twice daily). Increase the daily dose in 2 weeks by an increment of 20 mg/kg to the recommended daily dose of 50 mg/kg (25 mg/kg twice daily). If a patient cannot tolerate a daily dose of 50 mg/kg, the daily dose may be reduced. In the clinical trial, the mean daily dose was 47 mg/kg in this age group.

# 4 Years to < 16 Years

Initiate treatment with a daily dose of 20 mg/kg in 2 divided doses (10 mg/kg twice daily). Increase the daily dose every 2 weeks by increments of 20 mg/kg to the recommended daily dose of 60 mg/kg (30 mg/kg twice daily). If a patient cannot tolerate a daily dose of 60 mg/kg, the daily dose may be reduced. In the clinical trial, the mean daily dose was 44 mg/kg. The maximum daily dose was 3000 mg/day.

For Levetiracetam tablet dosing in pediatric patients weighing 20 to 40 kg, initiate treatment with a daily dose of 500 mg given as twice daily dosing (250 mg twice daily). Increase the daily dose every 2 weeks by increments of 500 mg to a maximum recommended daily dose of 1500 mg (750 mg twice daily).

For Levetiracetam tablet dosing in pediatric patients weighing more than 40 kg, initiate treatment with a daily dose of 1000 mg/day given as twice daily dosing (500 mg twice daily). Increase the daily dose every 2 weeks by increments of 1000 mg/day to a maximum recommended daily dose of 3000 mg (1500 mg twice daily).

Levetiracetam Oral Solution Weight-Based Dosing Calculation For Pediatric Patients

The following calculation should be used to determine the appropriate daily dose of oral solution for pediatric

Total daily dose (mL/day) = Daily dose (mg/kg/day) x patient weight (kg)

# 100 mg/mL

Dosing for Myoclonic Seizures in Patients 12 Years of Age and Older with Juvenile Myoclonic Epilepsy Initiate treatment with a dose of 1000 mg/day, given as twice-daily dosing (500 mg twice daily). Increase the dosage by 1000 mg/day every 2 weeks to the recommended daily dose of 3000 mg. The effectiveness of doses lower than 3000 mg/day has not been studied.

# Dosing for Primary Generalized Tonic-Clonic Seizures

# Adults 16 Years and Older

Initiate treatment with a dose of 1000 mg/day, given as twice-daily dosing (500 mg twice daily). Increase dosage by 1000 mg/day every 2 weeks to the recommended daily dose of 3000 mg. The effectiveness of doses lower than 3000 mg/day has not been adequately studied.

# Pediatric Patients Ages 6 to < 16 Years

Initiate treatment with a daily dose of 20 mg/kg in 2 divided doses (10 mg/kg twice daily). Increase the daily dose every 2 weeks by increments of 20 mg/kg to the recommended daily dose of 60 mg/kg (30 mg/kg twice daily). The effectiveness of doses lower than 60 mg/kg/day has not been adequately studied. Patients with body weight ≤20 kg should be dosed with oral solution. Patients with body weight above 20 kg can be dosed with either tablets or oral solution .Only whole tablets should be administered.

Dosage Adjustments in Adult Patients with Renal Impairment

Levetiracetam dosing must be individualized according to the patient's renal function status. Recommended dosage adjustments for adults are shown in Table 1. In order to calculate the dose recommended for patients with renal impairment, creatinine clearance adjusted for body surface area must be calculated. To do this an estimate of the patient's creatinine clearance (CLcr) in mL/min must first be calculated using the following formula:

#### CONTRAINDICATIONS:

Levetiracetam tablets are contraindicated in patients with a hypersensitivity to Levetiracetam. Reactions have included anaphylaxis and angioedema.

#### PRECAUTIONS AND ADVERSE EFFECTS:

# Behavioral Abnormalities and Psychotic Symptoms

Levetiracetam may cause behavioral abnormalities and psychotic symptoms. Patients treated with Levetiracetam should be monitored for psychiatric signs and symptoms.

#### Suicidal Behavior and Ideation

Antiepileptic drugs (AEDs), including Levetiracetam, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

# Somnolence and Fatigue

Levetiracetam may cause somnolence and fatigue. Patients should be monitored for these signs and symptoms.

# Anaphylaxis and Angioedema

Levetiracetam can cause anaphylaxis or angioedema after the first dose or at any time during treatment.

#### Serious Dermatological Reactions

Serious dermatological reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in both pediatric and adult pat Coordination Difficulties

Levetiracetam may cause coordination difficulties.

# Withdrawal Seizures

Antiepileptic drugs, including Levetiracetam, should be withdrawn gradually to minimize the potential of increased seizure frequency.

#### Hematologic Abnormalities

Levetiracetam can cause hematologic abnormalities. Hematologic abnormalities occurred in clinical trials and included decreases in red blood cell (RBC) counts, hemoglobin, and hematocrit, and increases in eosinophil counts. Decreased white blood cell (WBC) and neutrophil counts also occurred in clinical trials.

#### **Blood Pressure Increases**

#### INTERACTIONS:

No significant pharmacokinetic interactions were observed between levetiracetam or its major metabolite and concomitant medications via human liver cytochrome P450 isoforms, epoxide hydrolase, UDP-glucuronidation enzymes, P-glycoprotein, or renal tubular secretion.

# 88. LEUCOVORIN CALCIUM INJECTION LP

#### SALIENT ACTIONS:

Folinic Acid (also known as 5-formyl tetrahydrofolic acid or leucovorin) is the 5-formyl derivative of tetrahydrofolic acid, a necessary co-factor in the body. Commercially available leucovorin is composed of a 1:1 racemic mixture of the dextrorotary and levorotary isomers, while levoleucovorin contains only the pharmacologically active levo-isomer. In vitro, the levo-isomer has been shown to be rapidly converted to the biologically available methyl-tetrahydrofolate form while the dextro form is slowly excreted by the kidneys. Despite this difference in activity, the two commercially available forms have been shown to be

pharmacokinetically identical and may be used interchangeably with limited differences in efficacy or side effects (Kovoor et al, 2009).

As folate analogs, leucovorin and levoleucovorin are both used to counteract the toxic effects of folic acid antagonists, such as methotrexate, which act by inhibiting the enzyme dihydrofolate reductase (DHFR). They are indicated for use as rescue therapy following use of high-dose methotrexate in the treatment of osteosarcoma or for diminishing the toxicity associated with inadvertent overdosage of folic acid antagonists. Folic acid is an essential B vitamin required by the body for the synthesis of purines, pyrimidines, and methionine before incorporation into DNA or protein. However, in order to function in this role, it must first be reduced by the enzyme dihydrofolate reductase (DHFR) into the cofactors dihydrofolate (DHF) and tetrahydrofolate (THF). This important pathway, which is required for de novo synthesis of nucleic acids and amino acids, is disrupted when high-dose methotrexate is used for cancer therapy. As methotrexate functions as a DHFR inhibitor to prevent DNA synthesis in rapidly dividing cells, it also prevents the formation of DHF and THF. This results in a deficiency of coenzymes and a resultant buildup of toxic substances that are responsible for numerous adverse side effects associated with methotrexate therapy. As levoleucovorin and leucovorin are analogs of tetrahydrofolate (THF), they are able to bypass DHFR reduction and act as a cellular replacement for the co-factor THF, thereby preventing these toxic side effects.

#### INDICATIONS:

Injectable forms are indicated for use in the treatment of megaloblastic anemias due to folic acid deficiency when oral therapy is not feasible and for use in combination with 5-fluorouracil to prolong survival in the palliative treatment of patients with advanced colorectal cancer. For the treatment of osteosarcoma (after high dose methotrexate therapy).

#### DOSAGE REGIMENS:

# 1) Advanced Colorectal Cancer

Either of the following two regimens is recommended:

- 1. Leucovorin is administered at 200 mg/m2 by slow intravenous injection over a minimum of 3 minutes, followed by 5-fluorouracil at 370 mg/m2 by intravenous injection.
- 2. Leucovorin is administered at 20 mg/m<sup>2</sup> by intravenous injection followed by 5-fluorouracil at 425 mg/m<sup>2</sup> by intravenous injection.

# 2) Leucovorin Rescue After High-Dose Methotrexate Therapy

The recommendations for leucovorin rescue are based on a methotrexate dose of 12 to 15 grams/m2administered by intravenous infusion over 4 hours (see methotrexate package insert for full prescribing information).4 Leucovorin rescue at a dose of 15 mg (approximately 10 mg/m2) every 6 hours for 10 doses starts 24 hours after the beginning of the methotrexate infusion. In the presence of gastrointestinal toxicity, nausea or vomiting, leucovorin should be administered parenterally. Do not administer leucovorin intrathecally.

### 3)Impaired Methotrexate Elimination or Inadvertent Overdosage

Leucovorin rescue should begin as soon as possible after an inadvertent overdosage and within 24 hours of methotrexate administration when there is a delayed excretion Leucovorin 10 mg/m2 should be administered IM, IV, or PO every 6 hours until the serum methotrexate level is less than 10-8 M. In the presence of gastrointestinal toxicity, nausea, or vomiting, leucovorin should be administered parenterally. Do not administer leucovorin intrathecally.

# 4)Megaloblastic Anemia Due to Folic Acid Deficiency

Up to 1 mg daily

### CONTRAINDICATIONS:

Leucovorin is improper therapy for pernicious anemia and other megaloblastic anemias secondary to the lack of vitamin B12. A hematologic remission may occur while neurologic manifestations continue to progress.

#### PRECAUTIONS:

#### General

Parenteral administration is preferable to oral dosing if there is a possibility that the patient may vomit and not absorb the leucovorin. Leucovorin has no effect on non-hematologic toxicities of methotrexate such as the nephrotoxicity resulting from drug and/or metabolite precipitation in the kidney.

Since leucovorin enhances the toxicity of fluorouracil, leucovorin/5-fluorouracil combination therapy for advanced colorectal cancer should be administered under the supervision of a physician experienced in the use of antimetabolite cancer chemotherapy. Particular care should be taken in the treatment of elderly or debilitated colorectal cancer patients, as these patients may be at increased risk of severe toxicity.

## Laboratory Tests

Patients being treated with the leucovorin/5-fluorouracil combination should have a CBC with differential and platelets prior to each treatment. During the first two courses a CBC with differential and platelets has to be repeated weekly and thereafter once each cycle at the time of anticipated WBC nadir. Electrolytes and liver function tests should be performed prior to each treatment for the first three cycles then prior to every other cycle.

Dosage modifications of fluorouracil should be instituted. If no toxicity occurs, the 5-fluorouracil dose may increase 10%. Treatment should be deferred until WBCs are 4,000/mm3 and platelets 130,000/mm3. If blood counts do not reach these levels within two weeks, treatment should be discontinued. Patients should be followed up with physical examination prior to each treatment course and appropriate radiological examination as needed. Treatment should be discontinued when there is clear evidence of tumor progression.

#### INTERACTIONS:

Folic acid in large amounts may counteract the antiepileptic effect of phenobarbital, phenytoin and primidone, and increase the frequency of seizures in susceptible pediatric patients. Preliminary animal and human studies have shown that small quantities of systemically administered leucovorin enter the CSF primarily as 5-methyltetrahydrofolate and, in humans, remain 1 to 3 orders of magnitude lower than the usual methotrexate concentrations following intrathecal administration. However, high doses of leucovorin may reduce the efficacy of intrathecally administered methotrexate.

Leucovorin may enhance the toxicity of 5-fluorouracil

#### ADVERSE EFFECTS:

Allergic sensitization, including anaphylactoid reactions and urticaria, has been reported following the administration of both oral and parenteral leucovorin.

# 89. LIGNOCAINE Inj 2%/30 ml vial(local anaesthesia), 2%/ 50 ml vial (cardiac), 4%/30ml (topical) SALIENT ACTIONS:

Lidocaine is an amide type local anaesthetic. It stabilises the neuronal membrane and inhibits sodium ion movements, which are necessary for conduction of impulses. In the heart, lidocaine reduces phase 4 depolarization and automaticity. Duration of action potential and effective refractory period are also reduced.

## INDICATION & DOSAGEREGIMENS:

## Intravenous/ Parenteral

1. Pulseless ventricular fibrillation or ventricular tachycardia: As hydrochloride: 1-1.5 mg/kg repeated as necessary. Max total: 3 mg/kg. For ventricular arrhythmias in more stable patients: Usual loading dose: 50-100 mg as an IV inj at 25-50 mg/minute, may repeat once or twice up to a max of 200-300 mg in 1 hr, followed by 1-4 mg/minute via continuous IV infusion. May need to reduce dose if the infusion is longer than 24 hr. 2. Intravenous regional anaesthesia:50-300 mg (10-60 ml) of a 0.5% solution without adrenaline; max dose: 4 mg/kg. Sympathetic nerve block: As hydrochloride: 50 mg (5 ml) of a 1% solution for cervical block or 50-100 mg (5-10 ml) of a 1% solution for lumbar block. Percutaneous infiltration anaesthesia: Adult: As hydrochloride: 5-300 mg (1-60 ml of a 0.5% solution or 0.5-30 ml of a 1% solution). Peripheral nerve block: As hydrochloride: For brachial plexus block: 225-300 mg (15-20 ml) of a 1.5% solution; for intercostal nerve block: 30 mg (3 ml) of a 1% solution; for paracervical block: 100 mg (10 ml) of a 1% solution on each side, repeated not more frequently than every 90 minutes; for paravertebral block: 30-50 mg (3-5 ml) of a 1% solution; for pudendal block: 100 mg (10 ml) as a 1% solution on each side; for retrobulbar block: 120-200 mg (3-5 ml) of a 4% solution.3. Pupil dilatation during phacoemulsification cataract surgery: As a 1% ophthalmic preservative-free solution (often used in combination with phenylephrine and cyclopentolate). To be injected into the anterior chamber of the eye at the beginning of the procedure.4.Surface anaesthesia: For pain: 3 00 mg (15 ml) of 2% solution rinsed and ejected for mouth and throat pain; or gargled and swallowed if necessary for pharyngeal pain. Not to be used more frequently than every 3 hr. Max (topical oral solution): 2.4 g/day. Before bronchoscopy, bronchography, laryngoscopy, oesophagoscopy, endotracheal intubation, and biopsy in the mouth and throat: 40-300 mg (1-7.5 ml) of 4% solution. For dentistry and otorhinolaryngology procedures: 10-50 mg of 10% solution sprayed to mucous membrane.5. Epidural anaesthesia: As hydrochloride: 2-3 ml solution administered for each dermatome to be anaesthesized. Recommended doses are: lumbar epidural 250-300 mg (25-30 ml of a 1% solution) for analgesia and 225-300 mg (15-20 ml of a 1.5% solution) or 200-300 mg (10-15 ml of a 2% solution) for anaesthesia; for thoracic epidural: 200-300 mg of a 1% solution. For obstetric caudal analgesia, up to 300 mg (30 ml of a 0.5% or 1% solution); for surgical caudal analgesia: 225-300 mg (15-20 ml of a 1.5% solution). 6.Spinal anaesthesia: Adult: As hyperbaric solution of 1.5% or 5% lidocaine in 7.5% glucose solution. Normal vaginal delivery: 50 mg (1 ml) of a 5% solution or 9-15

mg (0.6-1 ml) of a 1.5% solution. Caesarian operation: Up to 75 mg (1.5 ml) of a 5% solution. Other surgical procedures: 75-100 mg (1.5-2 ml).7. Surface anaesthesia: Adult: As 2% gel: Female: 60-100 mg inserted into the urethra several minutes before examination. Male: 100-200 mg before catheterisation and 600 mg before sounding or cystoscopy. 8. Emergency treatment of ventricular arrhythmias: Adult: As hydrochloride: 300 mg injected into the deltoid muscle, repeat after 60-90 minutes if necessary.

## CONTRAINDICATIONS:

Heart block, second or third degree (without pacemaker), Severe sinoatrial block (without pacemaker), Serious adverse drug reaction to lidocaine or amide local anaesthetics, Concurrent treatment with quinidine, flecainide, disopyramide, procainamide (Class I antiarrhythmic agents), Prior use of Amiodarone, Hypotension not due to Arrhythmia, Bradycardia, Accelerated idioventricular rhythm, Pacemaker, Porphyria, especially acute porphyria (AIP); lidocaine is known to be porphyrogenic although similar drugs (e.g. bupivacaine, tetracaine) are known to be safe.

#### PRECAUTIONS:

Hepatic or renal impairment; CHF and following cardiac surgery; bradycardia; respiratory depression; porphyria; elderly or debilitated patients; pregnancy.

#### INTERACTIONS:

Additive cardiac effects with IV phenytoin. Effects antagonized by hypokalaemia caused by acetazolamide, loop diuretics and thiazides. Dose requirements may be increased with long-term use of phenytoin and other enzyme-inducers. Potentially Fatal: Cimetidine and propranolol increase plasma concentration and toxicity. Increased risk of myocardial depression with beta blockers and other antiarrhythmics.

## ADVERSE DRUG REACTIONS:

Dizziness, paraesthesia, drowsiness, confusion, respiratory depression and convulsions. *Potentially Fatal:* Hypotension and bradycardia leading to cardiac arrest; anaphylaxis.

# 90. LORAZEPAM Inj 2mg, 2ml ampoule

## SALIENT ACTIONS:

Lorazepam is a short acting benzodiazepine. Lorazepam enhances the inhibitory effect of GABA on neuronal excitability by modulating GABA<sub>A</sub>receptors.

Onset: Hypnosis: 20-30 min (IM); sedation: 5-20 min (IV); anticonvulsant: 5 min (IV), 30-60 min (oral).

Duration: 6-8 hr.

## INDICATIONS:

Acute Anxiety ,Insomnia associated with anxiety,premedication in surgery,sedation in critical care,prophylaxis of nausea and vomiting associated with cytotoxic therapy,status epilepticus

#### DOSAGE REGIMENS

**Parenteral** Acute anxiety : Adult: 25-30 mcg/kg repeated every 6 hr if necessary. Dose may be given via IV or IM inj. Give IV inj at a rate of not >2 mg/minute into a large vein.

Child: Usual: 50 mcg/kg every 4-8 hr.

### Intravenous

**Status epilepticus** ; *Adult:* 4 mg injected slowly, may repeat once after 10 minutes if seizures recur. Dose should be given at a rate not >2 mg/minute into a large vein.

Child: Neonates and children up to 12 yr: 0.1 mg/kg (max: 4 mg) as a single dose, may repeat once after 10 minutes if needed.

#### Parenteral

**Premedication in surgery;** *Adult:* 50 mcg/kg, to be given 30-45 minutes before the operation if given via IV inj or 1-1.5 hr before operation if given via IM inj.

### Intravenous

**Sedation in critical care** *Adult*;: 0.02-0.06 mg/kg every 2-6 hr as inj or 0.01-0.1 mg/kg/hr as continuous IV infusion.

Child: ≥2 mth: 0.025-0.05 mg/kg (max 2 mg) every 2-4 hr as intermittent IV infusion or 0.025 mg/kg/hr (to a max of 2 mg/hr) as continuous IV infusion.

## CONTRAINDICATIONS:

Severe hepatic impairment; respiratory depression; acute narrow-angle glaucoma; pregnancy and lactation **PRECAUTIONS**:

Hepatic and renal dysfunction; pulmonary insufficiency; myasthenia gravis; may impair ability to drive or operate machinery; elderly o

#### INTERACTION:

Potentiation of CNS depression produced by alcohol; general anaesthetics; narcotic analgesics; TCAs; MAOIs; phenothiazines; antipsychotics; barbiturates; scopolamine.

r debilitated patients.

## ADVERSE DRUG REACTIONS:

Drowsiness, headache, dizziness, confusion; blurred vision; nausea; weakness; unsteadiness. *Potentially Fatal:* Respiratory depression.

# 91. MAGNESIUM SULPHATE Inj 50 %, W/V, 2ml ampoule

## **SALIENT ACTIONS:**

Oral: Magnesium sulfate increases peristaltic activity by causing osmotic retention of fluids, thus resulting in bowel evacuation. Parenteral: Magnesium sulfate decreases levels of acetylcholine in motor nerve terminals. It also acts on the myocardium by decreasing the rate of SA node impulse formation and prolonging the conduction time.

Onset: Oral: 1-2 hr. IM: 1 hr. IV: Immediate.

Duration: IM: 3-4 hr. IV: 30 min.

INDICATION & DOSAGE REGIMENS:

**Parenteral** 

Hypomagnesaemia

Adult: IM admin: For mild deficiency: 1 g (8.12 mEq or 2 mL of the 50% solution) every 6 hr for 4 doses or based on serum magnesium levels. For severe deficiency: 2 mEq (0.5 mL of the 50% solution)/kg or up to 250 mg/kg within a 4-hr period if needed. IV admin: For symptomatic deficiency: 1-2 g over 5-60 minutes followed by maintenance infusion at 0.5-1 g/hr to correct the deficiency. For severe hypomagnesemia: 1-2 g/hr for 3-6 hr, then 0.5-1 g/hr as needed based on serum magnesium levels.

#### Intravenous

## Torsades de pointes

*Adult:* With pulses: Loading dose of 1-2 g diluted in 50-100 ml of 5% dextrose inj over 5-60 minutes, followed by maintenance infusion at 0.5-1 g/hr as needed. Pulseless: 1-2 g diluted in 10 ml of 5% dextrose inj and given over 5-20 minutes.

## Eclampsia

Adult: Typical loading dose: 4-5 g over 10-15 minutes, followed by either a continuous infusion of 1 g/hr (for at least 24 hr after the last seizure) or deep IM doses of 4-5 g into alternate buttocks every 4 hr (for at least 24 hr after the last seizure). If seizure recurs, an additional IV dose of 2-4 g may be given. Continue therapy until paroxysms cease. A serum magnesium level of 6 mg/100 mL is considered optimal for seizure control. Not to exceed 30-40 g per 24 hr.

## Muscle stimulating effects of barium poisoning

Adult: 1-2 g administered IV.

## Reduction of cerebral oedema.

Adult: 2.5 g (25 ml of a 10% solution) administered IV.

Special Populations: Reduce dose in patients with renal impairment.

#### CONTRAINDICATIONS:

Parenteral: Heart block, severe renal impairment, myocardial damage.

#### PRECAUTIONS:

Renal impairment, myasthaenia gravis, digitalised patients; pregnancy. Monitor serum-magnesium concentrations

### ADVERSE DRUG REACTIONS:

Parenteral: Hypermagnesaemia characterised by nausea, vomiting, flushing, thirst, hypotension, drowsiness, confusion, slurred speech, double vision, bradycardia, muscle weakness. Hypocalcaemia; paralytic ileus.

## INTERACTIONS:

Oral: Decreases absorption of tetracyclines and biphosphonates. Additive neuromuscular blocking effects with aminoglycosides, digitalis glycosides. Additive effects with nifedipine and CNS depressants

# 92. MEPHENTERMINE SULPHATE Inj 30 mg, 10 ml vial

### SALIENT ACTIONS:

Mephentermine sulfate is a sympathomimetic amine that acts indirectly by releasing norepinephrine. Cardiac contraction is enhanced, and cardiac output and systolic and diastolic pressures are usually increased. The

pressor response also involves peripheral vasoconstriction. The change in heart rate is variable, depending on the degree of vagal tone; large doses can depress the heart. In some cases the net vascular effect may be vasodilation, which appears not to involve beta-adrenergic receptors. Coronary blood flow is increased, forearm blood flow is reduced, and venous tone is increased. Marked mucosal vasoconstriction can be produced by local application of the drug. CNS effects may occur with large doses of mephentermine. The main effect of therapeutic doses of mephentermine is cardiac stimulation. A pressor response occurs almost immediately and persists for 15 to 30 minutes following intravenous injection of therapeutic doses of mephentermine sulfate. Pressor activity occurs within 5 to 15 minutes following intramuscular administration and persists for 1 to 4 hours.

#### INDICATIONS:

Maintenance of BP in hypotensive.

Hypotension secondary to spinal anesth in obstetric patients

## DOSAGE REGIMENS:

*Adult: IV* Maintenance of BP in hypotensive states 30-45 mg as single dose, repeated as necessary or followed by IV infusion of 0.1% mephentermine in 5% dextrose, rate and duration of administration will depend on patient's response.

Hypotension secondary to spinal anesth in obstetric patients 15 mg as a single dose, repeat if needed.

## CONTRAINDICATIONS:

Hypotension caused by phenothiazines. Hypertension. Phaeochromocytom

## PRECAUTIONS:

Patient on MAOIs. For shock due to loss of blood or fluid, give fluid replacement therapy primarily, CVS disease, hypertension, hyperthyroidism, chronic illnesses. Lactation, pregnancy

### INTERACTIONS:

Antagonises effect of hypotensive agents. Severe hypertension with MAOIs and possibly TCAs. Additive vasoconstricting effects with ergot alkaloids, oxytocin.

Potentially Fatal: Risk of arrhythmia in patients undergoing anesthesia with cyclopropane and halothane

## ADVERSE DRUG REACTIONS:

Drowsiness, incoherence, hallucinations, convulsions, tachycardia. Fear, anxiety, restlessness, tremor, insomnia, confusion, irritability and psychosis. Nausea, vomiting, reduced appetite, urinary retention, dyspnoea, weakness. *Potentially Fatal:* AV block, CNS stimulation. Cerebral haemorrhage and pulmonary oedema, ventricular arrhythmias.

# 93. METOPROLOL Inj 1 mg/ml, 5ml ampoule SALIENT ACTIONS:

Selective  $\beta_1$  receptor blocker used in treatment of several diseases of the cardiovascular system, especially hypertension. The active substance metoprolol is employed either as *metoprolol succinate* or *metoprolol tartrate* (where 100 mg metoprolol tartrate corresponds to 95 mg metoprolol succinate). The tartrate is an immediate-release and the succinate is an extended-release formulation.

# INDICATIONS & DOSAGE REGIMENS:

#### Adult: IV

- Emergency treatment of cardiac arrhythmias Initial: ≤5 mg at a rate of 1-2 mg/min; repeat at 5-min intervals if needed up to a total of 10-15 mg. Maintenance via oral therapy: ≤50 mg 3 times/day 4-6 hr after IV regimen.
- Prevention or control of arrhythmias on induction of anesth 2-4 mg as slow inj; repeat as needed. Max total: 10 mg.
- Adjunct in the early management of acute MI Administer w/in 12 hr of the onset of chest pain, 5 mg at 2min intervals to a total of 15 mg, if tolerated. After 15 mins, initiate oral therapy at 50 mg 6 hrly for 2 days for

# CONTRAINDICATIONS:

2nd or 3rd degree AV block; sick sinus syndrome; decompensated heart failure; clinically relevant sinus bradycardia. Severe peripheral arterial circulatory disorders. Cardiogenic shock. Asthma. Phaeochromocytoma (without α-blockade), systolic BP <100 mmHg. Metabolic acidosis. Pregnancy (2nd and 3rd trimesters PRECAUTIONS:

Compensated heart failure, bronchospastic disease, hepatic impairment, AV conduction disorders, bradycardia, peripheral arterial circulatory disorders. An α-blocker should be given concurrently in patients with phaeochromocytoma. May mask signs of acute hypoglycaemia. May mask symptoms of hyperthyroidism.

Caution when used in patients with history of cardiac failure or those with minimal cardiac reserve. Avoid using anaesthetic agents that may depress the myocardium. May impair ability to drive or operate machinery. Myasthenia gravis; history of psychiatric disorder. Lactation. Avoid abrupt drug withdrawal INTERACTIONS:

Additive effect with catecholamine-depleting drugs e.g. reserpine and MAOIs. May antagonise  $\beta_1$ -adrenergic stimulating effects of sympathomimetics. Additive negative effects on SA or AV nodal conduction with cardiac glycosides, nondihydropyridine calcium-channel blockers. Increased oral bioavailability with aluminium/magnesium-containing antacids. Paradoxical response to epinephrine may occur. Increased plasma concentrations with CYP2D6 inhibitors (e.g. bupropion, cimetidine, diphenhydramine, fluoxetine, hydroxycholoquine, paroxetine, propafenone, quinidine, ritonavir, terbinafine, thioridazine). Increased risk of hypotension and heart failure with myocardial depressant general anaesthetics (e.g. diethyl ether). Risk of pulmonary hypertension with vasodilators e.g. hydralazine in uraemic patients. Reduced plasma levels with rifampicin. May increase negative inotropic and negative dromotropic effect of anti-arrhythmic drugs e.g. quinidine and amiodarone. Propafenone may increase serum levels of metoprolol. Concurrent use with indomethacinmay reduce the antihypertensive efficacy of  $\beta$ -blocker. May reduce clearance of lidocaine. May increase effects of hypoglycaemics. Efficacy may be reduced by isoprenaline. Concurrent use with digoxin may lead to additive bradycardia.

Potentially Fatal: Additive or synergistic effects with verapamil; increased oral bioavailability with verapamil. Exacerbation of rebound hypertension during abrupt clonidine withdrawal.

# ADVERSE DRUG REACTIONS:

Bradycardia, hypotension, arterial insufficiency, chest pain, CHF, oedema, palpitation, syncope, gangrene; dizziness, fatigue depression, confusion, headache, insomnia, short-term memory loss, nightmares, somnolence; pruritus, rash, increased psoriasis, reversible alopecia; sexual dysfunction/impotence, Peyronie's disease; diarrhoea, constipation, flatulence, GI pain, heartburn, nausea, xerostomia; agranulocytosis (rare); musculoskeletal pain; blurred vision, dry eyes, oculomucocutaneous syndromtinnitus; dyspnoea, bronchospasm, wheezing, rhinitis; cold extremities.

# 94. MEROPENEM Inj 500mg and 1gm/vial SALIENT ACTIONS:

Meropenem is bactericidal except against *Listeria monocytogenes* where it is bacteriostatic. It inhibits bacterial wall synthesis like other beta-lactam antibiotics. In contrast to other beta-lactams, it is highly resistant to degradation by beta-lactamases or cephalosporinases. Resistance generally arises due to mutations in penicillin binding proteins, production of metallo-beta-lactamases, or resistance to diffusion across the bacterial outer membrane. Unlike imipenem, it is stable to dehydropeptidase-1 and can therefore be given without cilastatin **INDICATIONS & DOSAGE REGIMENS:** 

## Adult:

IV

- Susceptible infections 0.5-1 g 8 hrly.
- 2. Meningitis 2 g 8 hrly.
- 3. Cystic fibrosis Up to 2 g 8 hrly.
- 4. Skin infections 500 mg 8 hrly.
- 5. Diabetic foot; Intra-abdominal infections 1 g 8 hrly.

# **CONTRAINDICATIONS:**

Hypersensitivity.

## PRECAUTIONS:

History of hypersensitivity to carbapenem, pencillins or other  $\beta$ -iactam antibiotics; infants <3 mth; renal insufficiency; neurological disorders; pregnancy, lactation. Not recommended for use in MRSA Interaction: Serum levels may be increased by probenecid. May reduce serum valproic acid levels; subtherapeutic levels may be reached in some patients

## ADVERSE DRUG REACTIONS:

Diarrhoea, nausea, vomiting, abdominal pain; headache; constipation; rash, pruritus, uticaria; apnoea; phlebitis, thrombophlebitis, swelling and pain at inj site; disturbances in LFTs (may cause increases in serum transaminases, alkaline phosphatase, lactic dehydrogenase). Rarely: erythema multiforme; eosinophilia, thrombocytopenia, leucopenia, neutropenia; seizures and CNS effects reported in patients with underlying CNS disorders or renal impairment.

Potentially Fatal: Anaphylaxis; pseudomembranous colitis; Stevens-Johnsons syndrome

# 95. METHYLERGOTAMINE Inj 0.2 mg, 1ml ampoule SALIENT ACTIONS:

Methylergometrine is an ergot alkaloid, which directly stimulates contractions of uterine and vascular smooth muscle.

Onset: 5-15 min (oral); 2-5 min (IM); immediate (IV). Duration: ≥3 hr (oral/IM); 45 min (IV).

# INDICATIONS & DOSAGE REGIMENS:

Intramuscular

Treatment and prophylaxis of postpartum and postabortal haemorrhage

Adult: 200 mcg. May repeat every 2-4 hr. Max: 5 doses.

Intravenous

Treatment and prophylaxis of postpartum and postabortal haemorrhage

Adult: As an emergency measure: 200 mcg by slow inj over at least 1 minute, may repeat every 2-4 hr, up to a max of 5 doses.

# CONTRAINDICATIONS:

Hypertension, eclamptic or previously hypertensive patients, heart disease, venoatrial shunts, mitral valve stenosis, obliterative vascular disease. Do not use in cases of threatened spontaneous abortion. Pregnancy

## PRECAUTIONS:

Captivation of the placenta may occur if given during the 2nd or 3rd stage of labour prior to delivery of the placenta; use in this situation should only be done by a qualified personnel. Avoid prolonged use. Caution in patients with sepsis, hepatic or renal impairment. Lactation

## INTERACTIONS:

Possible increase in serum levels and risk of severe vasoconstrictive effects with potent CYP3A4 inhibitors e.g. erythromycin, troleandomycin, clarithromycin, ritonavir, indinavir, nelfinavir, delavirdine, ketoconazole, itra conazole, voriconazole) and less potent CYP3A4 inhibitors (e.g.saquinavir, nefazodone, fluconazole, fluoxetine, fluoxamine, zileuton

# ADVERSE DRUG REACTIONS:

Headache, dizziness, hallucinations; tinnitus; nausea, vomiting, foul taste, diarrhoea; hypertension, temporary chest pain, palpitations, bradycardia; nasal congestion, dyspnoea; diaphoresis; thrombophlebitis; haematuria; water intoxication; leg cramps; allergic reactions.

Potentially Fatal: Shock

# 96. METHYLPREDNISOLONE SODIUM SUCCINATE Inj 1gm/vial SALIENT ACTIONS:

This can help control a wide number of disease states, characterised by excessive inflammation. They include severe allergic reactions, inflammation of the lungs in asthma and inflammation of the joints in arthritis. Methylprednisolone also decreases the numbers of white blood cells circulating in the blood. This, along with the decrease in inflammatory chemicals, can prevent the rejection of organ transplants, as it prevents the body from attacking foreign tissue. Methylprednisolone is used in much higher doses than the levels of corticosteroids produced naturally by the body, and as such, the usual actions of corticosteroids become exaggerated and can be observed as side effects of this medicine

# INDICATIONS & DOSAGE REGIMENS:

Adult:

IV

- 1. Status asthmaticus As Na succinate: Loading dose: 2 mg/kg, then 0.5-1 mg/kg 6 hrly for up to 5 days.
- Acute spinal cord injury As Na succinate: 30 mg/kg, followed in 45 mins by a continuo of 5.4 mg/kg/hr for 23 hr.

3. Lupus nephritis As Na succinate: High-dose "pulse" therapy: 1 g/day for 3 days.

4. Aplastic anaemia As Na succinate: 1 mg/kg/day or 40 mg/day (whichever dose is higher) for 4 days. Thereafter, change to PO and continue until day 10 or till symptoms of serum sickness resolve, then rapidly reduce over approx 2 wk.

5. Pneumocystis (carinii) jirovecipneumonia in patients with AIDS As Na succinate: 30 mg twice daily for 5 days, then 30 mg once daily for 5 days, then 15 mg once daily for 11 days.

6. Life-threatening shock As Na succinate: Initial: 30 mg/kg, repeat 4-6 hrly if needed.

Anti-inflammatory or immunosuppresive *IV/IM* as Na succinate: 10-40 mg via IV inj, may repeat via IV/IM inj at intervals based on clinical response. Up to 30 mg/kg may be used if needed; may repeat 4-6 hrly for 48 hr. *IM* As Na succinate: 10-80 once daily. As acetate: 10-80 mg every 1-2 wkly. *Intra-articular:* As acetate: Large

joints: 20-80 mg; Small joints: 4-10 mg. Give doses us infusion1-5 wkly. *Intralesional:* As acetate: 20-60 mg 1-5 wkly.

## CONTRAINDICATIONS:

Serious infections except septic shock or tuberculous meningitis; viral, fungal and tubercular skin lesions; admin of live virus vaccines. Preparations containing benzyl alcohol preservative are contraindicated in infants.

#### PRECAUTIONS:

including family history (glucose regulation altered), osteoporosis especially post-menopausal women (associated with increased bone loss and osteoporotic fractures), glaucoma including family history (risk of increased intraocular pressure), corneal perforation, severe affective disorders (particularly if history of steroid-induced psychosis), epilepsy, GI disease (perforation risk), thyroid disease (changes in thyroid status may necessitate dosage adjustments), history of steroid myopathy. Pregnancy and lactation. Avoid abrupt withdrawal after a prolonged period of use. When applied topically to large areas, broken skin, or under occlusive dressings, may cause systemic effects.

## INTERACTIONS:

Decreases effect of anticholinesterases in myasthenia gravis. May decrease the hypoglycaemic effects of antidiabetic agents. Decreases serum concentrations of salicylates. Increased hypokalemic effects of potassium-depleting diuretics (thiazides or furosemide), amphotericin B, bronchodilator therapy with xanthines or  $\beta_2$  agonists. Increase incidence of GI bleeding and ulceration with NSAIDs. May increase the anticoagulant effects of warfarin. Decreased levels/effects with CYP3A4 inducers viz.

nafcillin, nevirapine, phenobarbital, phenytoin, and rifamycins). Increased levels/effects with CYP3A4 inhibitors (azole antifungals, clarithromycin, diclofenac, oxycycline, erythromycin, imatinib, isoniazid, nefazodone, nicardipine, propofol, protease inhibitors, quinidine, telithromycin, and verapamil). May decrease the effects of vaccines (dead organism) or increase the risk of vaccinal infection (live organism). Antacids and bile sequestrants may decrease the absorption of corticosteroids. Increased hypokalemic effects of potassium-depleting diuretics (thiazides or furosemide), amphotericin B, bronchodilator therapy with xanthines or  $\beta_2$  agonists. Increase incidence of GI bleeding and ulceration with NSAIDs.

## ADVERSE DRUG REACTIONS:

Oedema, hypertension, arrhythmia; CNS, endocrine, metabolic and GI effects; hirsutism, acne, skin atrophy, bruising, hyperpigmentation; transient leukocytosis; arthralgia, muscle weakness, osteoporosis, fractures, cataracts, glaucoma; infections, hypersensitivity reactions, avascular necrosis, secondary malignancy, intractable hiccups.

# 97. MENADIONE SODIUM BISULPHITE 1ML INJ

# SALIENT ACTIONS:

Menadione is a synthetic lipid-soluble vitamin K analogue. It is an essential cofactor in the hepatic synthesis of prothrombin (factor II) and other blood clotting factors (factors VII, IX, X and proteins C and S), and in the function of proteins important for bone development (e.g. osteocalcin).

Absorption: Requires bile for absorption from the GI tract.

Distribution: Accumulates in the liver; does not appear to cross the placenta.

#### INDICATIONS& DOSAGE REGIMENS:

Oral

## Vitamin K deficiency

Adult: 10 mg every 6 hr.

Oral

## Severe hypoprothrombinaemia

Adult: 10 mg 34 times daily.

Intravenous

## Vitamin K deficiency

Adult: 0.03 mcg/kg/day.

Child: Infants: 1-5 mcg/kg/day.

Intramuscular

# Severe hypoprothrombinaemia

Adult: 2.5-10 mg daily.

# PRECAUTIONS:

Pregnancy, G6PD deficiency, vitamin E deficiency. Neonates, premature infants. Hepatic impairment. Monitor prothrombin time.

## INTERACTIONS:

Decreases effects of oral anticoagulants.

## ADVERSE EFFECTS:

Facial flushing, sweating, chest constriction/pain, dyspnoea, cyanosis, CV collapse. IM: Severe shock-like reactions, phlebitis, inj site reactions.

Potentially Fatal: Anaphylaxis.

# 98. METHOTREXATE 50 MG INJECTION

## SALIENT ACTIONS:

Methotrexate is a folic acid antagonist that inhibits DNA synthesis. It irreversibly binds to dihydrofolate reductase, inhibiting the formation of reduced folates, and thymidylate synthesase, resulting in inhibition of purine and thymidylic acid synthesis.

# INDICATIONS & DOSAGE:

- 1. Burkitt's lymphoma: Adult: 10-25 mg daily for 4-8 days, repeated after 7-10 days.
- 2. Acute lymphoblastic leukaemia: Adult: Maintenance: 15 mg/m2 once or twice wkly, with other agents.
- 3. Choriocarcinoma: Adult: 15-30 mg daily for 5 days, repeat after an interval of ≥1 wk for 3-5 courses.
- 4. Mycosis fungoides: Adult: 2.5-10 mg daily to induce remission.
- 5. Psoriasis: Adult: 10-25 mg wkly as a single dose, adjust subsequent doses based on response.
- 6. Rheumatoid arthritis: Adult: 7.5 mg once wkly, adjust by response. Not more than 20 mg/wk.
- 7. Crohn's disease: Adult: 12.5-22.5 mg once wkly for up to 1 yr.

Hepatic impairment: Bilirubin 3.1-5 mg/dl: Administer 75% of dose; Bilirubin >5 mg/dl: Avoid use.

Should be taken on an empty stomach. (Avoid taking w/ milk-rich products.)

# CONTRAINDICATIONS:

Severe renal or hepatic impairment, pre-existing profound bone marrow suppression in patients with psoriasis or rheumatoid arthritis, alcoholic liver disease, AIDS, pre-existing blood dyscrasias, pregnancy (in patients with psoriasis or rheumatoid arthritis), breast-feeding.

## PRECAUTIONS:

Pregnancy Category (US FDA) – X.Special precaution: Hepatic or renal impairment, bone marrow depression, elderly, neonates, Ulcerative disorders of the GI tract. Monitor haematological, renal and hepatic function, and GI toxicity regularly.

## INTERACTIONS:

Decreased effectiveness with folic acid and its derivatives. Increased toxicity with NSAIDs and salicylates; probenecid; some penicillins; aminoglycosides neomycin and paromomycin; sulfafurazole and sulfamethoxazole; co-trimoxazole or trimethoprim; cisplatin; ciclosporin; etretinate. Synergistic enhancement of effects with fluorouracil. Increased bioavailability of mercaptopurine. Reduces serum-valproate concentrations. Reduced serum concentrations with colestyramine. Increased serum concentrations with omeprazole.

## ADVERSE EFFECTS:

Ulceration of the mouth and GI disturbances (stomatitis and diarrhoea), bone marrow depression, hepatotoxicity, renal failure, skin reactions, alopecia, ocular irritation, arachnoiditis in intrathecal use, megaloblastic anaemia, osteoporosis, precipitation of diabetes, arthralgias, necrosis of soft tissue and bone, anaphylaxis, impaired fertility. *Potentially Fatal:* interstitial lung disease; neurotoxicity.

# 99. METHYLENE BLUE USP 10MG INJ

# SALIENT ACTIONS:

Methylene Blue Injection is a sterile solution of Phenothiazin-5-ium, 3, 7-bis (dimethylamino)-, chloride, trihydrate. Each mL contains methylene blue, 10 mg in water for injection q.s. pH adjusted with hydrochloric acid and/or sodium hydroxide when necessary. Methylene blue will produce two opposite actions on hemoglobin. Low concentrations will convert methemoglobin to hemoglobin. High concentrations convert the ferrous iron of reduced hemoglobin to ferric iron which results in the formation of methemoglobin. Methylene blue is metabolized in the body to leukomethylene blue which is excreted primarily in the urine. Some unchanged drug is also excreted in the urine

## INDICATIONS:

Drug induced methemoglobinemia.

## Contraindications

Methylene blue can cause fetal harm when administered to a pregnant woman. An association exists between the use of methylene blue in amniocentesis and atresia of the ileum and jejunum, ileal occlusions and other

adverse effects in the neonate. (2, 3) Methylene blue is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

Intraspinal and subcutaneous injections are contraindicated.

Methylene blue is contraindicated in patients with a known hypersensitivity to the drug.

**Dosage and Administration** 

0.1 to 0.2 mL per kg body weight (0.045 to 0.09 mL per pound body weight). Inject methylene blue intravenously very slowly over a period of several minutes.

Methylene blue must be injected intravenously very slowly over a period of several minutes to prevent local high concentration of the compound from producing additional methemoglobin. Do not exceed recommended dosage.

Parenteral drug products should be inspected visually for particulate matter and discoloration, whenever solution and container permit.

## INTERACTIONS:

Methylene blue may interact with any drug that acts as a serotonin reuptake inhibitor (SRI) including, amongst others, selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), norepinephrine-dopamine reuptake inhibitors (NDRIs), triptans and ergot alkaloids; such combinations may have the consequence of potentially fatal serotonin toxicity (serotonin syndrome). Methylene blue should not be co-administered with any drug that acts as an SRI.

# PRECAUTIONS:

Methylene blue should not be given by subcutaneous or intrathecal injection.

Methylene blue is a potent monoamine oxidase inhibitor: Methylene blue has been demonstrated to be a potent monoamine oxidase inhibitor (MAOI) and may cause potentially fatal serotonin toxicity (serotonin syndrome) when combined with serotonin reuptake inhibitors (SRIs)

Serotonin toxicity is characterized by development of neuromuscular hyperactivity (tremor, clonus, myoclonus and hyperreflexia, and, in the advanced stage, pyramidal rigidity); autonomic hyperactivity (diaphoresis, fever, tachycardia, tachypnoea, and mydriasis); and altered mental status (agitation, excitement, and in the advanced stage, confusion). If methylene blue is judged to be indicated, SRIs must be ceased, prior to treatment/procedure/surgery.

Pregnancy Category X

Glucose-6-Phosphate Dehydrogenase Deficiency (G6PD Deficiency): Methylene blue should be avoided in patients with G6PD deficiency due to the risk of paradoxical methemoglobinemia and hemolysis. Renal Failure: Methylene blue should be used with caution in patients with severe renal impairment Methylene blue must be injected intravenously very slowly over a period of several minutes to prevent local high concentration of the compound from producing additional methemoglobin. Do not exceed recommended dosage.

Large intravenous doses of methylene blue produce nausea, abdominal and precordial pain, dizziness, headache, profuse sweating, mental confusion and the formation of methemoglobin.

## 100. METOCLOPRAMIDE HCL 5MG INJ

#### SALIENT ACTIONS:

Metoclopramide enhances the motility of the upper GI tract and increases gastric emptying without affecting gastric, biliary or pancreatic secretions. It increases duodenal peristalsis which decreases intestinal transit time, and increases lower oesophageal sphincter tone. It is also a potent central dopamine-receptor antagonist and may also have serotonin-receptor (5-HT3) antagonist properties.

## INDICATIONS & DOSAGE REGIMENS:

Intravenous

Intubation of the small intestine, Premedication for radiologic examination of the upper gastrointestinal tract

Adult: 10 mg as a single dose by slow inj over 1-2 min.

Child: <6 yr 0.1 mg/kg as a single dose; 6-14 yr 2.5-5 mg as a single dose.

Imravenous

Prophylaxis of chemotherapy-induced nausea and vomiting

Adult: For highly emetogenic drugs/regimens: Initially, 2 mg/kg by slow inj over at least 15 min, 30 min before chemotherapy. Repeat 2 hrly for 2 doses, then 3 hrly for 3 doses. For less emetogenic drugs/regimens: 1 mg/kg may be used. Max duration: 5 days.

Parenteral

Diabetic gastric stasis

Adult: 10 mg 4 times daily by IM inj or slow IV inj over 1-2 min for up to 10 days. Convert to oral admin when symptoms subside sufficiently.

Parenteral

Prophylaxis of postoperative nausea and vomiting

Adult: 10 mg as a single dose by IM or slow IV inj over at least 3 min.

Child: 1-3 yr 10-14 kg: 1 mg tid; >3-5 yr 15-19 kg: 2 mg tid; >5-9 yr 20-29 kg: 2.5 mg tid; >9-18 yr 30-60 kg: 5 mg tid. Max duration: 48 hr.

CONTRAINDICATIONS:

GI hemorrhage, mechanical obstruction and perforation; phaeochromocytoma; history of seizures.

PRECAUTIONS:

Pregnancy Category (US FDA)- B.Special precaution: Adjust dose in patients with renal impairment: 150 mg/day orally or 25 mg for parenteral administration. Exclude malignancy before treating gastric ulcer. Renal and hepatic impairment. Infants, pregnancy and lactation.

Renal Impairment

Intravenous:

Intubation of the small intestine, Premedication for radiologic examination of the upper gastrointestinal

CrCl (mL/min)	Dosage
<40	Reduce dose by 50%.

Parenteral:

Prophylaxis of postoperative nausea and vomiting

CrCl (mL/min)	Dosage	
≤15	Reduce dose by 75%.	
16-60	Reduce dose by 50%.	

Hepatic	Parenteral:
Impairment	Prophylaxis of postoperative nausea and vomiting Severe: Reduce dose by 50%.

## INTERACTIONS:

Increased sedative effects with CNS depressants.GI effects antagonised by antimuscarinics and opioids. Reduces absorption of digoxin. Increases absorption of ciclosporin, levodopa, aspirin, paracetamol. Interferes with hypoprolactinaemic effect of bromocriptine. Inhibits serum cholinesterase and prolongs neuromuscular blockade produced by suxamethonium and mivacurium. Potentially Fatal: Serotonin syndrome with sertraline (SSRI).

## ADVERSE EFFECTS:

Extrapyramidal symptoms, restlessness, drowsiness, anxiety, diarrhoea, hypotension, hypertension, headache, depression aganulocytosis, methaemoglobinaemia, hypersensitivity reactions (e.g. bronchospasm, rash), galactorrhoea or related disorders, transient increase in plasma aldosterone levels. Potentially Fatal: Neuroleptic malignant syndrome; cardiac conduction disorders may occur with IV dosage form

# 101. MILRINONE LACTATE 1MG IN.I

# SALIENT ACTIONS:

Description: Milrinone is a selective phosphodiesterase III inhibitor with positive inotropic and vasodilator activity. It selectively inhibits cyclic adenosine monophosphate (cAMP) phosphodiesterase activity in cardiac and vascular muscles resulting in increased intracellular concentrations of cAMP. It also acts directly on vascular smooth muscle.

Onset: IV: 5-15 minutes.

Pharmacokinetics:

Distribution: Protein binding: About 70%. Volume of distribution at steady-state: 0.32-0.45 L/kg.

Metabolism: About 12% metabolised hepatically.

Excretion: Eliminated via urine (85% as unchanged drug). Elimination half life: About 2.5 h

## INDICATIONS:

Acutely decompensated heart failure.

## **DOSAGE REGIMENS:**

Adult: IV Loading dose: 50 mcg/kg then continuous maintenance infusion of 0.375-0.75 mcg/kg/min. Adjust according to response. Max:1.13 mcg/kg/day

# .Intravenous

Acutely decompensated heart failure, Short-term management of severe heart failure

**Adult:** Initially, a loading dose of 50 mcg/kg by slow IV injection over 10 min then continuous maintenance infusion of 0.375-0.75 mcg/kg/min. Adjust according to haemodynamics and clinical response. Max dose 1.13 mcg/kg/day.

Child: Initial loading dose of 75 mcg/kg by IV injection over 10-60 min followed by continuous infusion of 0.5-0.75 mcg/kg/min.

Reconstitution

Use 0.45% sodium chloride, 0.9% sodium chloride or 5% dextrose inj as diluents.

#### **CONTRAINDICATIONS:**

Heart valve stenosis, acute myocardial infarction.

## PRECAUTIONS:

Severe obstructive aortic or pulmonary valvular disease, hypertrophic cardiomyopathy, atrial flutter or fibrillation. Monitor blood pressure, heart rate, ECG, fluid and electrolyte balance. Pregnancy and lactation. Use for >48 hr.

## INTERACTIONS:

Potentially Fatal: Avoid anagrelide due the potential for increased inotropic effects.

## ADVERSE EFFECTS:

Angina-like chest pain, headache, hypokalaemia, tremor, thrombocytopenia, bronchospasm.

Potentially Fatal: Supraventricular and ventricular arrhythmias; hypotension.

# 102. MIDAZOLAM Inj 1mg, 5 ml vial

## SALIENT ACTIONS:

Midazolam is a short-acting benzodiazepine. It exerts sedative and hypnotic, muscle relaxant, anxiolytic and anticonvulsant actions. While the probable anxiolytic action might be as a result of the drug's ability to increase glycine inhibitory neurotransmitter level, the hypnotic/anaesthetic action may be due to the occupation of the benzodiazepine and GABA receptors leading to membrane hyperpolarisation and neuronal inhibition, and further interfering with the re-uptake of GABA at the synapses.

# INDICATIONS & DOSAGE REGIMENS:

## IV

- Sedation for dental and minor surgical procedures Initial: Up to 2.5 mg given 5-10 mins before procedure. Repeat after at least 2 mins if needed. Usual total: 3.5-5 mg. Max total: 7.5 mg.
- Induction of anesth 150-200 mcg/kg in premedicated patients and at least 300 mcg/kg for those who have not received premed. Resistant cases: Up to 600 mcg/kg.
- 3. Sedation in critical care Initial: 30-300 mcg/kg. Maintenance: 20-200 mcg/kg/hr.

## IM

1. Premedication in surgical procedures 70-80 mcg/kg 20-60 mins pre-op by deep inj

#### CONTRAINDICATIONS:

Acute narrow-angle glaucoma; coma or patients in shock; acute alcohol intoxication; intrathecal and epidural admin. Acute pulmonary insufficiency or marked neuromuscular respiratory weakness including unstable myasthenia gravis; severe respiratory depression

## PRECAUTIONS:

Paediatric patients with cardiovascular instability; chronic renal failure; open-angle glaucoma; cardiac disease; respiratory disease; myasthenia gravis; neonates; history of drug or alcohol abuse; elderly and debilitated (reduce dose); avoid prolonged use or abrupt withdrawal; hepatic impairment; severe fluid or electrolyte disturbances. May impair ability to drive or operate machinery; titrate dose carefully; monitor for early signs of hypoventilation, airway obstruction, or apnea. Pregnancy, lactation

## INTERACTIONS:

Increased CNS depression with alcohol, opioids, barbiturates, other sedatives and anaesthetics. Increased respiratory depression with opiates, phenobarbital, other benzodiazepines. Plasma concentrations increased by CYP3A4 inhibitors such

as cimetidine, erythromycin, clarithromycin, diltiazem, verapamil, ketoconazole and itraconazole, antiretroviral agents, quinupristin with dalfopristin. Midazolam concentration decreased byphenytoin, carbamazepine, phenobarbital, rifampicin. Halothane, thiopental requirements may be reduced during concurrent use

# ADVERSE DRUG REACTIONS:

Physical and psychological dependence with withdrawal symptoms; decreased tidal volume and respiration rate; apnoea; headache; hiccup; nausea, increased appetite, vomiting; cough; oversedation; seizure-like activity (paediatrics); paradoxical reactions; kernicterus; nystagmus; skin rash, pruritus; reduced alertness, confusion, euphoria, hallucinations, fatigue, dizziness, ataxia, post-operative sedation, anterograde amnesia; jaundice; cardiac arrest, heart rate changes, thrombosis; anaphylaxis; laryngospasm, bronchospasm. Potentially Fatal: Respiratory depression, respiratory arrest; hypotension.

# 103. MENAPHTHONE SODIUMBISULPHITE Inj 10 mg, 1ml ampoule SALIENT ACTIONS:

IT is a synthetic lipid-soluble vitamin K analogue. It is an essential cofactor in the hepatic synthesis of prothrombin (factor II) and other blood clotting factors (factors VII, IX, X and proteins C and S), and in the function of proteins important for bone development (e.g. osteocalcin).

# INDICATION & DOSAGE REGIMENS:

Intravenous

# Vitamin K deficiency

Adult: 0.03 mcg/kg/day.

Child: Infants: 1-5 mcg/kg/day.

Intramuscular

## Severe hypoprothrombinaemia

Adult: 2.5-10 mg daily.

## PRECAUTIONS:

Pregnancy. G6PD deficiency, vitamin E deficiency. Neonates, premature infants. Hepatic impairment. Monitor prothrombin time.

## INTERACTIONS:

Decreases effects of oral anticoagulants.

# ADVERSE DRUG REACTIONS:

Facial flushing, sweating, chest constriction/pain, dyspnoea, cyanosis, CV collapse. IM: Severe shock-like reactions, phlebitis, inj site reactions.

Potentially Fatal: Anaphylaxis.

# 104. MORPHINE INJ IP 10MG/ML

## SALIENT ACTIONS:

Morphine is a phenanthrene derivative which acts mainly on the CNS and smooth muscles. It binds to opiate receptors in the CNS altering pain perception and response. Analgesia, euphoria and dependence are thought to be due to its action at the mu-1 receptors while resp depression and inhibition of intestinal movements are due to action at the mu-2 receptors. Spinal analgesia is mediated by morphine agonist action at the K receptor.

# INDICATIONS & DOSAGE REGIMENS:

Intravenous

# Pain associated with myocardial infarction

Adult: 5-10 mg at 1-2 mg/min followed by a further 5-10 mg as necessary.

Elderly: Half of the usual adult dose.

Renal impairment: Dosage may need to be reduced.

Hepatic impairment: Dosage may need to be reduced.

Incompatibility: Aciclovir Na, chlorpromazine HCl, doxorubicin, fluorouracil, furosemide, haloperidol, heparin Na, pethidine HCl, prochloeperazine edisilate, promethazine HCl, ranitidine HCl, tetracycline, aminophylline, amobarbital Na, cefepime HCl, chlorothiazide Na, floxacillin Na, gallium nitrate, meperidine HCl, meperidine, Na, methicillin, Na, minocycline HCl, pentobarbital Na, phenobarbital Na, phenytoin Na, sargramostim, Na bicarbonate, thiopental Na, Na iodide.

Intravenous

Acute pulmonary oedema

Adult: 5-10 mg via slow inj at 2 mg/min. Elderly: Half of the usual adult dose.

**Renal impairment:** Dosage may need to be reduced. **Hepatic impairment:** Dosage may need to be reduced.

*Incompatibility:* Aciclovir Na, chlorpromazine HCl, doxorubicin, fluorouracil, furosemide, haloperidol, heparin Na, pethidine HCl, prochloeperazine edisilate, promethazine HCl, ranitidine HCl, tetracycline, aminophylline, amobarbital Na, cefepime HCl, chlorothiazide Na, floxacillin Na, gallium nitrate, meperidine HCl, meperidine, Na, methicillin, Na, minocycline HCl, pentobarbital Na, phenobarbital Na, phenytoin Na, sargramostim, Na bicarbonate, thiopental Na, Na iodide.

Parenteral

Moderate to severe pain

Adult: IM/SC: 5-20 mg; 2.5-10 mg via slow IV inj over 4-5 min w/ patient in recumbent position or a starting dose of 1-2 mg/hr via continuous IV infusion (max: 100 mg/day; 4 g/day in cancer patients). Doses may be adjusted according to severity of pain and patient's response.

**Renal impairment:** Dosage may need to be reduced. **Hepatic impairment:** Dosage may need to be reduced.

Incompatibility: Aciclovir Na, chlorpromazine HCl, doxorubicin, fluorouracil, furosemide, haloperidol, heparin Na, pethidine HCl, prochloeperazine edisilate, promethazine HCl, ranitidine HCl, tetracycline, aminophylline, amobarbital Na, cefepime HCl, chlorothiazide Na, floxacillin Na, gallium nitrate, meperidine HCl, meperidine, Na, methicillin, Na, minocycline HCl, pentobarbital Na, phenobarbital Na, phenytoin Na, sargramostim, Na bicarbonate, thiopental Na, Na iodide.

Intraspinal

Moderate to severe pain

Adult: Initially, 5 mg epidural inj; after 1 hr, additional doses of 1-2 mg may be given up to a total dose of 10 mg/24 hr if pain relief is unsatisfactory. A dose of 20-30 mg daily may be required in some patients. Liposomal inj: 10-20 mg depending on the type of surgery.

Renal impairment: Dosage may need to be reduced.

Hepatic impairment: Dosage may need to be reduced.

Incompatibility: Aciclovir Na, chlorpromazine HCl, doxorubicin, fluorouracil, furosemide, haloperidol, heparin Na, pethidine HCl, prochloeperazine edisilate, promethazine HCl, ranitidine HCl, tetracycline, aminophylline, amobarbital Na, cefepime HCl, chlorothiazide Na, floxacillin Na, gallium nitrate, meperidine HCl, meperidine, Na, methicillin, Na, minocycline HCl, pentobarbital Na, phenobarbital Na, phenytoin Na, sargramostim, Na bicarbonate, thiopental Na, Na iodide.

Intrathecal

Moderate to severe pain

Adult: 0.2-1 mg once daily or 1-10 mg daily for patients w/ opioid tolerance. Some patients may require a dose of up to 20 mg daily.

Renal impairment: Dosage may need to be reduced. Hepatic impairment: Dosage may need to be reduced.

Incompatibility: Aciclovir Na, chlorpromazine HCl, doxorubicin, fluorouracil, furosemide, haloperidol, heparin Na, pethidine HCl, prochloeperazine edisilate, promethazine HCl, ranitidine HCl, tetracycline, aminophylline, amobarbital Na, cefepime HCl, chlorothiazide Na, floxacillin Na, gallium nitrate, meperidine HCl, meperidine, Na, methicillin, Na, minocycline HCl, pentobarbital Na, phenobarbital Na, phenytoin Na, sargramostim, Na bicarbonate, thiopental Na, Na iodide.

Parenteral

Premedication in surgery

Adult: IM/SC: Up to 10 mg given 60-90 min before operation.

Renal impairment: Dosage may need to be reduced. Hepatic impairment: Dosage may need to be reduced.

Incompatibility: Aciclovir Na, chlorpromazine HCl, doxorubicin, fluorouracil, furosemide, haloperidol, heparin Na, pethidine HCl, prochloeperazine edisilate, promethazine HCl, ranitidine HCl, tetracycline, aminophylline, amobarbital Na, cefepime HCl, chlorothiazide Na, floxacillin Na, gallium nitrate, meperidine HCl, meperidine, Na, methicillin, Na, minocycline HCl, pentobarbital Na, phenobarbital Na, phenytoin Na, sargramostim, Na bicarbonate, thiopental Na, Na iodide.

Rectal

Severe pain

Adult: 10-20 mg 4 hrly. Dosage may be increased as required.

## CONTRAINDICATIONS:

Resp depression, obstructive airway disease, delayed gastric emptying, acute abdomen, heart failure secondary to chronic lung disease, known or suspected paralytic ileus, phaeochromocytoma. Concurrent admin w/ MAOI or w/in 2 wk after treatment.

#### PRECAUTIONS:

Patient w/ impaired resp function, severe bronchial asthma, convulsive disorders, acute alcoholism, delirium tremens, raised intracranial pressure, hypotension w/ hypovolaemia, cardiac arrhythmias, severe cor pulmonale, history of substance abuse, diseases of the biliary tract, pancreatitis, inflammatory bowel disorders, prostatic hypertrophy, adrenocortical insufficiency, toxic psychoses. Opioid dependent patients. Renal and hepatic impairment. Pregnancy and lactation. *Patient Counselling* May impair ability to drive or operate machinery. *Monitoring Parameters* Monitor efficacy of pain control, vital signs, and mental status; signs of drug abuse, addiction, or diversion; signs or symptoms of hypogonadism or hypoadrenalism.

#### INTERACTIONS:

Additive depressant effects w/ other CNS depressants (e.g. sedatives, hypnotics, general anaesth, phenothiazines, other tranquilisers). May enhance the neuromuscular blocking action of skeletal muscle relaxants. Reduced analgesic effect w/ mixed agonist/antagonist opioid analgesics (e.g. pentazocine, nalbuphine, buprenorphine). Increased plasma concentrations w/ cimetidine. May reduce the efficacy of diuretics by inducing the release of antidiuretic hormone. May delay the absorption of mexiletine. May antagonise the GI effect of cisapride, domperidone and metoclopramide. May produce hyperpyrexia and CNS toxicity w/ dopaminergics.

Potentially Fatal: MAOIs intensify the effect of morphine resulting to severe and even fatal events (e.g. anxiety, confusion, resp depression, sometimes leading to coma).

## ADVERSE EFFECTS:

Nausea, vomiting, constipation, abdominal pain, dry mouth, anorexia, taste disturbance, dyspepsia, resp depression, sedation, dizziness, confusion, insomnia, headache, somnolence, involuntary muscle contractions, hyperhidrosis, rash, pruritus, asthenic conditions, HTN, bronchospasm, seizures, amenorrhoea, rhabdomyolysis, nystagmus.

# 105. NALBUPHINE HCL INJ. 10MG

**SALIENT ACTION:** Nalbuphine is a phenanthrene derivative w/ mixed opioid agonist and antagonist activity (agonist at kappa opiate receptor; partial antagonist at mc receptor). It inhibits the ascending pain pathways, alters the perception of and response to pain by binding to opiate receptors in the CNS. It also produces generalised CNS depression.

## INDICATIONS & DOSAGE REGIMENS:

Parenteral

Moderate to severe pain

Adult: IM/IV/SC: 10-20 mg 3-6 hrly as required. Non-opioid-tolerant patients: Max single dose: 20 mg. Max daily dose: 160 mg.

Renal impairment: Reduce dose. Hepatic impairment: Reduce dose.

Incompatibility: Y-site: Allopurinol, amphotericin B cholesteryl sulfate complex, cefepime, docetaxel, methotrexate, nafcillin, piperacillin/tazobactam, pemetrexed, sargramostim, Na bicarbonate. Syringe: Diazepam, dimenhydrinate, ketorolac, pentobarbital.

Intravenous

Adjunct in balanced anaesthesia

Adult: Induction: 0.3-3 mg/kg over 10-15 min. Maintenance: 0.25-0.5 mg/kg as single admin if required.

Renal impairment: Reduce dose. Hepatic impairment: Reduce dose.

Incompatibility: Y-site: Allopurinol, amphotericin B cholesteryl sulfate complex, cefepime, docetaxel, methotrexate, nafcillin, piperacillin/tazobactam, pemetrexed, sargramostim. Na bicarbonate. Syringe: Diazepam, dimenhydrinate, ketorolac, pentobarbital.

PRECAUTIONS:

Emotionally unstable patients. Patient w/ MI who exhibit nausea and vomiting, history of opiate abuse, impaired

respiration due to other drugs, uraemia, bronchial asthma, severe infection, cyanosis or resp obstruction; about to undergo biliary tract surgery; head injury, intracranial lesions or pre-existing increased intracranial pressure. Renal or hepatic impairment. Pregnancy and lactation. *Patient Counselling* This drug may cause drowsiness and dizziness, if affected, do not drive or operate machinery. *Monitoring Parameters* Monitor relief of pain, resp and mental status, BP.

## DRUG INTERACTIONS:

Additive CNS depressant effects w/ other CNS depressants (e.g. general anaesth, phenothiazines, other tranquilisers, sedatives, hypnotics).

## ADVERSE DRUG REACTIONS:

Sedation, dizziness, vertigo, miosis, headache; depression, restlessness, nervousness, crying, drunkenness, euphoria, floating, hostility, confusion, unusual dreams, faintness, feeling of heaviness, tingling, numbness; nausea, vomiting, dry mouth; bradycardia, tachycardia, HTN, hypotension, pulmonary oedema; itching, burning, urticaria; resp depression, dyspnoea, asthma; speech difficulty, urinary urgency, blurred vision, flushing, warmth, sweatiness, clamminess.

**Potentially Fatal:** Anaphylactic or anaphylactoid and other serious hypersensitivity reactions (e.g. shock, resp distress or arrest, bradycardia, cardiac arrest, hypotension, laryngeal oedema).

## 106. NANDROLONE DECANOATE

## SALIENT ACTION:

Nandrolone is an anabolic steroid. It promotes tissue-building processes and protein anabolism. It also stimulates erythropoeitin production, causing an increase in haemoglobin and RBC volume.

# INDICATIONS & DOSAGE REGIMENS:

Intramuscular

## As anabolic after debilitating illness

Adult: As decanoate: 25-100 mg once every 3-4 wk.

Intramuscular

## Postmenopausal osteoporosis

Adult: As decanoate: 25-100 mg once every 3-4 wk.

Intramuscular

## Metastatic breast cancer

Adult: As decanoate: 25-100 mg once every 3-4 wk.

Intramuscular

## Anaemia of chronic renal failure

Adult: As decanoate: 50-200 mg wkly.

Intramuscular

## Anaemia in chemotherapy patients

**Adult:** 50-150 mg wkly.

#### **CONTRAINDICATIONS:**

Prostatic or breast carcinoma (male); nephrosis, porphyria; infants, pregnancy and lactation.

#### PRECAUTIONS

Monitor diabetic patients carefully. Conditions influenced by oedema (e.g. CV disease, migraine, seizure disorder, renal impairment). Hepatic impairment. Elderly. Discontinue if signs of virilisation in women occur. Monitor skeletal maturation in children.

## **DRUG INTERACTIONS:**

May increase effects of oral anticoagulants, insulin, oral antidiabetic agents, adrenal steroid, adrenocorticotropic hormone (ACTH).

## ADVERSE DRUG REACTIONS:

Male: Postpubertal: Acne, gynaecomastia, bladder irritability, priapism, insomnia, chills, decreased libido, hepatic dysfunction, nausea, diarrhoea, prostatic hyperplasia. Prepubertal: Acne, virilism, chills, insomnia, hyperpigmentation, diarrhoea, nausea. Female: Virilism, hypercalcaemia, nausea, diarrhoea, chills, insomnia, iron deficiency anaemia, hepatic dysfunction.

# 107. N-BUTYL CYANOACRYLATE 0.5ML INJ

#### SALIENT ACTION:

NBCA has unique properties compared to other cyanoacrylates such as octyl cyanoacrylate or isoamyl cyanoacrylate. The polymerized form has excellent tensile strength and is very effective in closing surgical or

wound incisions.

The closure of the wound or cut is quick (about 30 to 45 seconds) and the product has inherently some valuable bacteriostatic properties. The cosmetic outcome of the closure is comparable or generally better than an equivalent suture substitute with least amount of scarring visible after three to six months.

## INDICATIONS & DOSAGE REGIMENS:

Used as tissue adhesives.

In gastroenterology, butyl cyanoacrylate is used to treat bleeding gastric varices, which are dilated veins that occur in the setting of liver cirrhosis or thrombosis of the splenic vein

# 108. NEOSTIGMINE Inj 0.5 mg, 1ml ampoule

## SALIENT ACTIONS:

Neuromuscular Disorder Drugs / Antiglaucoma Preparations, N07AA01 - neostigmine; Belongs to the class of anticholinesterase. Used as parasympathomimetics.

## INDICATION&DOSAGES REGIMENS:

Adult: IV

1. Reversal of nondepolarising neuromuscular blockade As metilsulfate: 50-70 mcg/kg via inj.

IM

2. **Diagnosis of myasthenia gravis** As metilsulfate: 0.02 mg/kg as a single dose. Discontinue all anticholinesterase medications for at least 8 hr prior to administration.

IM/SC

- 3. Myasthenia gravis As metilsulfate: 0.5-2.5 mg at intervals, up to a total dose of 5-20 mg/day.
- 4. Paralytic ileus
- 5. Post-op urinary retention As metilsulfate: 0.5 mg.

## CONTRAINDICATIONS:

Mechanical GI or urinary tract obstruction, peritonitis

#### PRECAUTIONS:

Patients with epilepsy, bronchial asthma, bradycardia, recent MI, hypotension, vagotonia, hyperthyroidism, recent intestinal or bladder surgery, renal impairment, arrhythmias, peptic ulcer. Distinguish cholinergic crisis due to overdosage from myasthenic crisis. Pregnancy and lactation. Atropine should always be available when given by inj.

## INTERACTIONS:

May reduce effects of anticholinergics. May increase effects of cholinergic agonists. Increased risk of bradycardia with digoxin, diltiazem, verapamil or  $\beta$ -blockers without intrinsic sympathomimetic activity. Increased muscle weakness and decreased response to anticholinesterases with corticosteroids. May increase effects of depolarising neuromuscular blockers. Effects may be antagonised by drugs with neuromuscular blocking activity e.g. aminoglycosides, clindamycin, colistin, cyclopropane, halogenated inhalational anaesthetics. Effects may be reduced by quinine, chloroquine, hydroxychloroquine, quinidine, procainamide, propafenone, lithium,  $\beta$ -blockers. Possible additive toxicity with ophthalmic use of anticholinesterases e.g. ecothiopa

## ADVERSE DRUG REACTIONS:

Increased salivation and sweating, nausea and vomiting, abdominal cramps, diarrhoea, allergic reactions, rash (bromide salt), miosis, increased bronchial secretions, bradycardia, bronchospasm, weakness, muscle cramps, fasciculation, hypotension.

Potentially Fatal: Anaphylaxis

## 109. NITROGLYCERINE Inj 5 mg/ml, 5 ml ampoule

## SALIENT ACTIONS:

Anti-Anginal Drugs organic nitrate vasodilators. Used in the treatment of cardiac disease.

COSAE01 - glyceryl trinitrate; Belongs to the class of muscle relaxants. Used in the topical treatment for the treatment of hemorrhoids and anal fissures also.

## INDICATION&DOSAGE REGIMENS:

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- 1. Unstable angina Initial: 5-10 mcg/min. Usual: 10-200 mcg/min.
- 2. Heart failure Initial: 5-25 mcg/min.
- 3 Acute MI
- 4. Induction of hypotension or control of HTN during surgery Initial: 5-25 mcg/min.

Usual: 10-200 mcg/min. Max: 400 mcg/min.

## CONTRAINDICATIONS:

Hypersensitivity. Severe hypotension, heart failure marked anaemia, hypertrophic obstructive cardiomyopathy, cerebral haemorrhage or head trauma, low cardiac output secondary to hypovolaemia, inferior MI with right ventricular involvement, raised intracranial pressure. Concomitant use with phosphodiesterase type-5 inhibitors. **PRECAUTIONS**:

Severe hepatic or renal impairment, hypothyroidism, malnutrition, hypothermia. Cerebrovascular disease, lung disease or cor pulmonale. Pregnancy, lactation, glaucoma, mitral valve prolapse, cardiac tamponade, syncope. Gradual withdrawal in patients who have received prolonged high dose infusions. Avoid prolonged excessive hypotension. Nitrate-free interval is recommended in patients on continuous treatment with nitrates to reduce risk of tolerance

## INTERACTIONS:

Enhances bioavailability of dihydroergotamine. Glyceryl trinitrate infusion may prolong pancuronium-induced neuromuscular blockade. May reduce the efficacy of heparin, alteplase and noradrenaline when used together. Efficacy of buccal and sublingual preparations may be reduced by drugs that can cause dry mouth due to decreased dissolution. Aspirin and other NSAIDs may reduce the therapeutic response to glyceryl trinitrate. *Potentially Fatal:* Orthostatic hypotension may be produced by combined use of calcium channel blockers, antihypertensives, phenothiazines and TCAs. Alcohol may cause severe hypotension and collapse.

#### ADVERSE DRUG REACTIONS:

Facial flushing, dizziness, tachycardia, throbbing headache and tolerance. Large doses can cause vomiting, restlessness, hypotension, syncope, rarely cyanosis and methaemoglobinaemia, impaired respiration, bradycardia. IV admin: IV preparation contains substantial quantities of alcohol and alcohol intoxication can occur. Sublingual Tabs/Spray: Dry mouth, localised burning sensation. Topical: Contact dermatitis, erythema, local irritation. Transdermal patches: Contact dermatitis, metal-containing patches should be removed before cardioversion, defibrillation, diathermy. Buccal tablets: Delayed dissolution, may be swallowed by mistake. *Potentially Fatal:* Hypotension, paradoxical bradycardia, impaired respiration, syncope and collapse

# 110. NORADRENALINE BITARTRATE Inj 2mg, 2 ml ampoule SALIENT ACTIONS:

Vasoconstrictor C01CA03 - norepinephrine; Belongs to the class of adrenergic and dopaminergic cardiac stimulants excluding glycosides. Used in the treatment of heart failure.

## INDICATION&DOSAGE REGIMENS:

Adult: IV Acute hypotensive states Initial: 8-12 mcg/min, up to 8-30 mcg/min in refractory shock. Adjust according to BP response. Maintenance: 2-4 mcg/min. Injection Upper GI haemorrhage Instill 8 mg in 100 mL of 0.9% sodium chloride soln through a nasogastric tube hrly for 6-8 hr, Then 2 hrly for 4-6 hr. Withdraw drug gradually

## CONTRAINDICATIONS:

Hypertension. Pregnancy. Patients with peripheral or mesenteric vascular thrombosis unless necessary as a life-saving procedure

## PRECAUTIONS:

Not a substitute for replacement of blood, plasma, fluids, and/or electrolytes; correct volume depletion prior to admin. Identify and correct hypoxia, hypercapnia and acidosis prior to or during admin. Avoid extravasation as tissue necrosis may occur. Avoid inj into leg veins, especially in elderly or those with occlusive vascular diseases, arteriosclerosis, DM or Buerger's disease. Hypertensive or hyperthyroid patients. In conjunction with local anaesthetics, do not use in fingers, toes, ears, nose or genitalia. Lactation

#### INTERACTIONS:

Not a substitute for replacement of blood, plasma, fluids, and/or electrolytes; correct volume depletion prior to admin. Identify and correct hypoxia, hypercapnia and acidosis prior to or during admin. Avoid extravasation as tissue necrosis may occur. Avoid inj into leg veins, especially in elderly or those with occlusive vascular diseases, arteriosclerosis. DM or Buerger's disease. Hypertensive or hyperthyroid patients. In conjunction with local anaesthetics, do not use in fingers, toes, ears, nose or genitalia. Lactation

## ADVERSE DRUG REACTIONS:

Bradycardia, arrhythmias, anxiety, skin necrosis (with extravasation), dyspnoea, respiratory difficulty

# 111. OCTERIOTIDE Inj 50 mg, 1ml ampoule

## SALIENT ACTIONS:

Trophic Hormones & Related Synthetic Drugs H01CB02 - octreotide; Belongs to the class of antigrowth hormone. Used in hypothalamic hormone preparations

# INDICATIONS & DOSAGE REGIMENS:

#### Adult: IV

1. Variceal haemorrhage in patients w/ cirrhosis 25 mcg/hr for 48 hr (up to 5 days in patients at high risk of re-bleeding).

## IM

2. **Acromegaly**Following initial control w/ SC therapy: *Depot* Initial: 20 mg 4 wkly. Adjust if required after 3 mth to 10-30 mg 4 wkly. Max: 40 mg 4 wkly.

## IM/SC

- 3. **Secretory neoplasms** As SC: Initial: 50 mcg 1-2 times/day, up to 600 mcg/day in 2-4 divided doses based on response. Maintenance: *Depot* 10-30 mg 4 wkly via IM inj.
- Acromegaly Initial: 50 mcg 3 times/day, increase if needed. Usual dose: 100-200 mcg 3 times/day. Max: 500 mcg 3 times/day.
- 5. Prevention of complications following pancreatic surgery 100 mcg 3 times/day of a rapid-acting preparation for 7 days, starting at least 1 hr pre-op.
- 6. **HIV-associated diarrhoea** Initial: 100 mcg 3 times/day. If symptoms are not controlled after 1 wk, increase to 250 mcg 3 times/day.
- Secretory neoplasms Initial: 50 mcg 1-2 times/day, up to 600 mcg/day doses based on response in 2-4 divided

## CONTRAINDICATIONS:

PRECAUTION: Renal disease; risk of gall bladder disease; DM; hypothyroidism. Pregnancy, lactation, children, elderly. Monitor levels of vitamin B12 during long term therapy.

#### INTERACTIONS:

Dosage adjustment of concurrent therapy may be necessary with calcium channel blockers, oral hypoglycaemics,  $\beta$ -blockers, diuretics. May increase concentration of bromocriptine.

Potentially Fatal: Requirements of insulin may be reduced requiring careful blood-glucose monitoring. Reduction in ciclosporin bioavailability and efficacy.

Click to view more octreotide Drug Interactions.

## ADVERSE DRUG REACTIONS:

Local pain, stinging, tingling at site of inj; anorexia, nausea, vomiting, abdominal pain, bloating, flatulence, loose stools, steatorrhoea; biliary tract abnormalities. Hypoglycaemia and hyperglycaemia, hypothyroidism, cardiac conduction abnormalitles, pancreatitis.

# 112. ONDENSETRONE Inj 2mg, 2ml ampoule, Tab 4 mg, Syrup 2mg/ml, 30 ml bottle SALIENT ACTIONS:

Antiemetics / Supportive Care Therapy. Belongs to the class of serotonin (5HT3) antagonists. Used for the prevention of nausea and vomiting

## INDICATION & DOSAGE REGIMENS:

## IV/IM

- Nausea and vomiting associated w/ highly-emetogenic cancer chemotherapy 8 mg as a single dose immediately before treatment.
- 2. Prophylaxis of post-op nausea and vomiting 4 mg as a single dose at induction of anesth.
- 3. Post-op nausea and vomiting 4 mg as a single dose.

## Rectal

- 4. Nausea and vomiting associated w/ cancer chemotherapy As supp: 16 mg 1-2 hr before treatment.
- 5. Prevent delayed emesis following chemotherapy As supp: 16 mg once daily for up to 5 days after end of a course of chemotherapy, dose immediately before treatment.
- 6. Prophylaxis of post-op nausea and vomiting 4 mg as a single dose at induction of anesth.
- 7. Post-op nausea and vomiting 4 mg as a single dose.
- 8. Nausea and vomiting associated w/ cancer chemotherapy As supp: 16 mg 1-2 hr before treatment.
- 9. Prevent delayed emesis following chemotherapy As supp: 16 mg once daily for up to 5 days after end of a course of chemotherapy

#### CONTRAINDICATIONS:

Use with apomorphine (profound hypotension).

#### PRECAUTIONS:

May cause QT prolongation; caution when used in cardiac diseases, patients who are on medications that can prolong QT or patients with electrolyte abnormalities. Severe hepatic impairment. May mask progressive ileus and/or gastric distension. Pregnancy, lactation

## INTERACTIONS:

Rifampicin and other CYP3A4 inducers reduce levels/effects of ondansetron.

Potentially Fatal: Concurrent use may increase the hypotensive effect of apomorphine; avoid concurrent use.

## ADVERSE DRUG REACTIONS:

Headache, malaise/fatigue, constipation; drowsiness, fever, dizziness, anxiety, cold sensation; pruritus, rash; diarrhoea; gynaecological disorder, urinary retention; elevated transaminase; local inj site reaction (pain, redness, burning); paresthesia; hypoxia. Rarely: Anaphylaxis, angina, bronchospasm, ECG changes, extrapyramidal symptoms, grand mal seizure, hypokalaemia, tachycardia, vascular occlusive events.

# 113. OXYTOCIN Inj 5 IU, 1ml ampoule SALIENT ACTIONS:

Oxytocin synthetic, acts on the smooth muscle of the uterus to stimulate contractions; response depends on the uterine threshold of excitability. It exerts a selective action on the smooth musculature of the uterus, particularly toward the end of pregnancy, during labor and immediately following delivery. Oxytocin stimulates rhythmic contractions of the uterus, increases the frequency of existing contractions and raises the tone of the uterine musculature. Synthetic oxytocin elicits only slight pressor and antidiuretic activity due to the absence of vasopressin. (Hypertension has been observed resulting from concomitant use of oxytocics and continuous caudal block anesthesia).

#### INDICATIONS & DOSAGE REGIMENS:

Induction of Labor: I.V. infusion (drip method) is the only acceptable method of administration for the induction or stimulation of labor. Accurate control of the rate of infusion flow is essential. An infusion pump or other such device and frequent monitoring of strength of contractions and fetal heart rate are necessary for the safe administration of oxytocin for the induction or stimulation of labor. If uterine contractions become too powerful, the infusion can be abruptly stopped, and oxytocic stimulation of the uterine musculature will soon wane. The initial dose should be no more than 1 to 4 mU/min=0.1 to 0.4 mL/min=2 to 8 drops/min. The dose may be increased in increments of no more than 1 to 2 mU/min=0.1 to 0.2 mL/min=2 to 4 drops/min., until a contraction pattern has been established, which is similar to normal labor, to a maximum of 20 mU/min=2 mL/min=40 drops/min, provided fetal heart rate, resting uterine tone and the frequency, duration and force of contractions are carefully monitored. The oxytocin infusion should be discontinued immediately in the event of uterine hyperactivity or fetal distress. If regular contractions are not established after the infusion of 500 mL (=5 IU oxytocin), the attempt to induce labor should be broken off; it can generally be repeated on the following day. Once labor is initiated, the infusion rate is adjusted (usually reduced) according to need. I.V. infusion should be administered only when strictly medically indicated, rather than for convenience.

## Stimulation of Labor: I.V. infusion (as above). Cases

As adjunctive therapy in the management of incomplete or inevitable abortion. Postpartum: To produce uterine contractions during the third stage of labor and to control postpartum bleeding and hemorrhage.

## CONTRAINDICATIONS:

Significant cephalopelvic disproportion. Severe toxemia. Malpresentation or malposition of the fetus or placenta previa. Prematurity or unripe cervix. Predisposition to uterine rupture (grand multiparity, overdistention of the uterus, previous cesarean section or other surgery involving the uterus). Hypertonic labor patterns. Prolonged use in uterine inertia. Factors predisposing to thromboplastin or anniotic fluid embolism (prolonged retention of dead fetus, abruptio placentae). Serious medical and obstetric conditions and any conditions in which fetal distress already occurs. Inability of physician to be in attendance. Hypersensitivity to oxytocin.

#### PRECAUTIONS:

1. Use only under close medical/obstetrical supervision. 2. Never administer i.v. undiluted oxytocin, or use inhigh concentrations. 3. Oxytocin must not be used by more than one route simultaneously, e.g., parenteral and buccal, or parenteral and nasal. When given for induction and stimulation of labor, Oxytocin Injection, USP must only be used as i.v. drip infusion, and not by i.m., nor by direct i.v. injection. Careful monitoring (blood pressure, fetal heart rate, possible tocometry) is vital, in order to adjust dosage according to the individual response: if uterine activity interferes at any time with fetal heart rate, the infusion should be discontinued. In

patients with cardiovascular disorders, the infusion volume should be kept low by using a more concentrated solution. All patients receiving i.v. oxytocin must be under continuous observation by trained personnel. Overstimulation of the uterus by improper administration can be hazardous to both mother and fetus. Even with proper administration and adequate supervision, hypertonic contractions can occur in patients whose uteri are hypersensitive to oxytocin.

## DRUG INTERACTIONS:

Cyclopropane anesthesia-risk of arrhythmias, vasoconstrictor drug - severe hypertension, Prostaglandin E2 acts synergistically with oxytocin results in a substantial reduction in the quantity of oxytocin required.

# ADVERSE DRUG REACTIONS:

Water intoxication with headaches and nausea has been reported after prolonged or too rapid i.v. infusion of oxytocin. Premature ventricular contractions, fetal bradycardia and cardiac arrhythmia have been noted. Hypotension, tachycardia and ECG changes have been observed following i.v. administration of concentrated solutions. Anxiety, dyspnea, precordial pain, edema, cyanosis or reddening of the skin and cardiovascular spasm and collapse have occurred on rare occasions. Rarely anaphylactoic reactions. Overdosage may give rise to slowing of fetal heart, meconium staining of the amniotic fluid and asphyxia; hypertonic contractions, uterine rupture, retention of the placenta, postpartum uterine inertia

# 114. OXYTETRACYCLIN Inj 50 mg/ml, 30 ml vial SALIENT ACTION:

Oxytetracycline works by interfering with the ability of bacteria to produce proteins that are essential to them. Without these proteins the bacteria cannot grow, multiply and increase in numbers. Oxytetracycline therefore stops the spread of the infection and the remaining bacteria are killed by the immune system or eventually die. Oxytetracycline is a broad spectrum antibiotic that is active against a wide variety of bacteria. However, some strains of bacteria have developed resistance to this antibiotic, which has reduced its effectiveness for treating some types of infection. Oxytetracycline is still used to treat infections caused by chlamydia (eg the chest infection psittacosis, the eye infection trachoma, and the genital infection urethritis) and infections caused by mycoplasma organisms (eg pneumonia). Tetracycline can be used to treat flare-ups of chronic bronchitis, due to its activity against the bacteria usually responsible, *Haemophilus influenzae*. Oxytetracycline is also used to treat other rarer infections, such as those caused by a group of micro-organisms called rickettsiae (eg Q fever, Rocky mountain spotted fever) and those caused by Brucella bacteria (brucellosis). Oxytetracycline is also used to treat acne, as it is active against the bacteria associated with acne, *Propionebacterium acnes*.

## INDICATIONS:

Acne vulgaris. Chronic inflammatory disorder of the facial skin (acne rosacea). Bacterial infections of the lungs, eg bronchitis, pneumonia. Infections caused by chlamydia (eg the chest infection psittacosis, the eye infection trachoma, and sexually-transmitted chlamydia). Bacterial infections of the urinary tract. Syphillis. Gonorrhoea. Infections caused by mycoplasma organisms (eg pneumonia or genital infections). Infections caused by Rickettsiae micro-organisms transmitted by lice, fleas, ticks and mites, eg Rocky Mountain spotted fever, typhus group, Q fever and Coxiella endocarditis and tick fevers. Infections caused by Borrelia recurrentis (relapsing fever). Infection caused by Brucella bacteria (brucellosis). Leptospirosis (Weil's disease). Disease caused by a bacterium found in soil and water (melioidosis). Cholera. Bubonic plague. Gas gangrene.

# CONTRAINDICATIONS:

Children under 12 years of age. Decreased kidney function. Pregnancy. Breastfeeding. Hereditary blood disorders called porphyrias

## INTERACTIONS:

aluminium salts, antacids for heartburn and indigestion containing aluminium, bismuth, calcium or magnesium calcium supplements and dairy products, iron preparations, eg ferrous sulphate (oxytetracycline also reduces the absorption of iron from the gut), kaolin, magnesium salts, quinapril tablets that contain magnesium carbonate, eg Accupro brand ranitidine bismuth citrate, sucralfate, tripotassium dicitrato-bismuthate, zinc salts (oxytetracycline also reduces the absorption of zinc from the gut)

# ADVERSE DRUG REACTIONS:

Nausea and vomiting. Diarrhoea. Loss of appetite. Difficulty or pain when swallowing (dysphagia). Inflammation or ulceration of the foodpipe (tablets should be swallowed whole with plenty of fluid while sitting or standing to avoid this). Overgrowth of the yeast Candida, which may cause infection such as thrush (see warning section above). Skin reactions such as rash and itch. Abnormal reaction of the skin to light, usually a rash (photosensitivity - see warning section above). Inflammation of the bowel (colitis) - see warning section above. Inflammation of the pancreas (pancreatitis). Raised pressure within the skull (consult your doctor if you

get a severe persistant headache, or double or blurred vision while taking this medicine). Liver disorders (consult your doctor if you experience yellowing of your skin or eyes (jaundice) while taking this medicine). Blood disorders (consult your doctor if you experience bruising, sore throat, fever or infections while taking this medicine).

# 115. OXALIPLATIN 50MG INJ

## SALIENT ACTIONS:

Oxaliplatin, a platinum-containing complex similar to cisplatin, is an alkylating agent. After intracellular hydrolysis, the platinum compound binds to DNA forming cross-links which inhibit DNA replication and transcription, resulting in cell death.

## INDICATIONS & DOSAGE REGIMENS:

Intravenous

#### Advanced colorectal cancer

*Adult:* In combination with fluorouracil/leucovorin: 85 mg/m<sup>2</sup> every 2 wk until disease progression or unacceptable toxicity. Dose to be given by IV infusion over 2-6 hr, dissolved in 250-500 ml of glucose 5%, . After recovery from toxicity, reduce dose to 65 mg/m<sup>2</sup>. Administer before fluoropyrimidines.

Renal impairment: Dose adjustment may be needed.

**Reconstitution:** Reconstitute with 10 ml (for 50 mg vial) or 20 ml (for 100 mg vial) water for inj or 5% dextrose inj. Reconstituted solution must be further diluted with 250-500 ml of 5% dextrose inj before admin.

Incompatibility: Admixture incompatibility: Alkaline medications or media.

Intravenous

## Adjuvant therapy in stage III colon cancer

Adult: In combination with fluorouracil/leucovorin: 85 mg/m<sup>2</sup> every 2 wk for 12 cycles. Dose to be given by IV infusion over 2-6 hr, dissolved in 250-500 ml of glucose 5%, every 2 wk; given for 12 cycles. After recovery from toxicity, reduce dose to 75 mg/m<sup>2</sup>. Administer before fluoropyrimidines.

Renal impairment: Dose adjustment may be needed.

**Reconstitution:** Reconstitute with 10 ml (for 50 mg vial) or 20 ml (for 100 mg vial) water for inj or 5% dextrose inj. Reconstituted solution must be further diluted with 250-500 ml of 5% dextrose inj before admin.

Incompatibility: Admixture incompatibility: Alkaline medications or media.

## CONTRAINDICATIONS:

Pregnancy. Peripheral neuropathy with functional impairment. Severe renal impairment.

### PRECAUTIONS:

Should be administered under the supervision of an experienced cancer chemotherapy physician. Use appropriate precautions for handling and disposal. Monitor neurological status and dose should be reduced if symptoms are prolonged or severe. Monitor blood counts during treatment and courses should not be repeated until blood counts have recovered. Caution in elderly, moderate degrees of renal impairment. Avoid using aluminum-containing needles or IV admin sets that may come into contact with oxaliplatin as aluminum has been reported to cause degradation of platinum compounds. Lactation.

#### DRUG INTERACTIONS:

May decrease plasma levels of digoxin. May increase risk of toxicity with nephrotoxic drugs. When administered as sequential infusions, taxane derivatives (docetaxel, paclitaxel) should be administered before oxaliplatin to limit myelosuppression and enhance efficacy.

## ADVERSE DRUG REACTIONS:

Fatigue, fever, pain, headache, insomnia, nausea, diarrheoa, vomiting, abdominal pain, constipation, aporexia, stomatitis, anemia, thrombocytopenia, leukopenia, aspartate and alanine transaminases increased, total bilirubin increased, peripheral neuropathy, back pain, dyspnoea, cough, oedema, chest pain, peripheral oedema, flushing, thromboembolism, dizziness, rash, alopecia, hand-foot syndrome dehydration, hypokalaemia, dyspepsia, taste perversion, flatulence, mucositis, gastroesophageal reflux, dysphagia, dysuria, neutropenia, inj site reaction, rigors, arthralgia, abnormal lacrimation, serum creatinine increased, rhinitis, epistaxis, pharyngitis, pharyngolaryngeal dysesthesia, allergic reactions, hiccup.

Potentially Fatal: Anaphylaxis, pulmonary fibrosis.

# 116. PANTAPRAZOLE Inj 40 mg/ vial, Tab 40 mg

SALIENT ACTIONS:

Belongs to the class of proton pump inhibitors. Used in the treatment of peptic ulcer and gastro-oesophageal reflux disease (GERD)

# INDICATIONS & DOSAGE REGIMENS:

ORAL.

- 1. **Gastro-oesophageal reflux disease:** Adult: 20-40 mg OD in the morning for 4 wk, increased to 8 wk if necessary. Maintenance: 20-40 mg daily, increased to 40 mg each morning if symptoms return.
- 2. **Peptic ulcer:**Adult: 40 mg OD in the morning for 2-4 wk for duodenal ulceration or 4-8 wk for benign gastric ulceration.
- 3. **H.pylori infection:**Adult: Triple therapy: 40 mg bid combined with clarithromycin 500 mg bid and either amoxicillin 1 g bid or metronidazole 400 mg bid.

4. Prophylaxis of NSAID-induced ulcers: Adult: 20 mg daily.

5. Zollinger-Ellison syndrome: Adult: Initially 80 mg daily, adjusted to individual requirements. Up to 240 mg daily may be used if needed. Daily doses >80 mg should be given in 2 divided doses. Hepatic impairment: Doses >40 mg daily have not been studied in hepatically-impaired patients.

IV

Zollinger-Ellison syndrome and other hypersecretory states as sodium salt: 80 mg/day. Max: 240 mg/day in divided doses if rapid control required. GERD; Peptic ulcer as Na salt: 40 mg/day until oral therapy can be resumed.

## CONTRAINDICATIONS:

Lactation

## PRECAUTIONS:

Long-term therapy may lead to bacterial overgrowth in the GI tract. Hepatic impairment; monitor liver function regularly (if enzymes increase, discontinue); pregnancy; not recommended in children <18 yr; long term use may lead to atrophic gastritis.

## INTERACTIONS:

Decreased absorption of ketoconazole and itraconazole; may slightly increase digoxin plasma concentration; may reduce plasma concentration of atazanavir, avoid concomitant use; may enhance anticoagulant effect of coumarins; may cause gastric mucosal irritation with alcohol; may increase levels or effects of: bosentan, dapsone, fluoxetine, glimepiride, glipizide, losartan, montelukast, nateglinide, paclitaxel, phenytoin, warfarin, and zafirlukast; may decrease levels or effects of: aminoglutethimide, carbamazepine, phenytoin, and rifampicin.

## ADVERSE EFFECTS:

Diarrhoea, dizziness, pruritus, skin rashes, GI tract infections, chest pain, headache, nausea, pain, anxiety, hyperglycaemia; malaise or lassitude; myalgia; oedema; insomnia; hyperlipidaemia; flatulence, abdominal pain, constipation, eructation, dyspepsia, rectal disorder; urinary frequency, UTI; abnormalities in liver function; local site reaction; hypertonia, neck pain, weakness; bronchitis, cough, dyspnoea, pharyngitis, rhinitis, sinusitis, upper respiratory tract infection, flu syndrome.

## 117. PACLITAXEL INJ

#### SALIENT ACTIONS:

Paclitaxel promotes microtubule formation by enhancing the action of tubulin dimers, stabilising existing microtubules and preventing their disassembly, thereby disrupting normal cell division in the late  $G_2$  mitotic phase of the cell cycle. This results in the inhibition of cell replication.

# INDICATIONS & DOSAGE REGIMENS:

Intravenous

# Ovarian carcinoma

**Adult:** Primary treatment (in combination with cisplatin or carboplatin): 135 mg/m<sup>2</sup> infused over 24 hr followed by cisplatin and repeated at 3 wk intervals. Secondary treatment (as single agent): 135 or 175 mg/m<sup>2</sup> infused over 3 hr once every 3 wk.

Hepatic impairment: Do not use in severe impairment, increased risk of hepatotoxicity. For detailed dosing recommendations, consult local protocol.

**Reconstitution:** Paclitaxel must be diluted before infusion. It can be diluted in 9.9% sodium chloride inj, 5% dextrose inj, 5% dextrose and 0.9% sodium chloride inj or 5% dextrose in lactated Ringer's inj to a concentration of 0.3-1.2 mg/ml.

*Incompatibility:* Do not prepare, store or administer in PVC containing equipment; macrogol glycerol ricinolate (an excipient) can cause [di-(2-ethylhexyl)phthalate] (DEHP) leaching. Y-site incompatibility: Amphotericin B, amphotericin B cholesteryl sulfate complex, chlorpromazine, doxorubicin liposome, hydroxyzine, methylprednisolone sodium succinate, mitoxantrone. Variable compatibility when admixed with cisplatin.

#### Intravenous

## Breast cancer

Adult: Adjuvant therapy; 2nd line monotherapy or 1st line treatment with trastuzumab: 175 mg/m² infused over 3 hr once every 3 wk for 4 courses; when used with trastuzumab, dose should be given the day after the 1st dose of trastuzumab or immediately after subsequent doses if well-tolerated. 1st line with doxorubicin: 220 mg/m² over 3 hr every 3 wk, dose to be administered 24 hr after doxorubicin.

Hepatic impairment: Do not use in severe impairment, increased risk of hepatotoxicity. For detailed dosing recommendation, consult local protocol.

**Reconstitution:** Paclitaxel must be diluted before infusion. It can be diluted in 0.9% sodium chloride inj, 5% dextrose inj, 5% dextrose and 0.9% sodium chloride inj or 5% dextrose in lactated Ringer's inj to a concentration of 0.3-1.2 mg/ml.

Incompatibility: Do not prepare, store or administer in PVC containing equipment; macrogol glycerol ricinolate (an excipient) can cause [di-(2-ethylhexyl)phthalate] (DEHP) leaching. Y-site incompatibility: Amphotericin B, amphotericin B cholesteryl sulfate complex, chlorpromazine, doxorubicin liposome, hydroxyzine, methylprednisolone sodium succinate, mitoxantrone. Variable compatibility when admixed with cisplatin. Intravenous

# Advanced non-small cell lung cancer

Adult: 135 mg/m<sup>2</sup> over 24 hr or 175 mg/m<sup>2</sup> over 3 hr, followed by cisplatin and repeated at 3 wk intervals. Hepatic impairment: Do not use in severe impairment, increased risk of hepatotoxicity. For detailed dosing recommendation, consult local protocol.

**Reconstitution:** Paclitaxel must be diluted before infusion. It can be diluted in 0.9% sodium chloride inj, 5% dextrose inj, 5% dextrose and 0.9% sodium chloride inj or 5% dextrose in lactated Ringer's inj to a concentration of 0.3-1.2 mg/ml.

Incompatibility: Do not prepare, store or administer in PVC containing equipment; macrogol glycerol ricinolate (an excipient) can cause [di-(2-ethylhexyl)phthalate] (DEHP) leaching. Y-site incompatibility: Amphotericin B, amphotericin B cholesteryl sulfate complex, chlorpromazine, doxorubicin liposome, hydroxyzine, methylprednisolone sodium succinate, mitoxantrone. Variable compatibility when admixed with cisplatin. Intravenous

# AIDS-related Kaposi's sarcoma

Adult: 135 mg/m<sup>2</sup> over 3 hr every 3 wk. Alternatively, 100 mg/m<sup>2</sup> over 3 hr every 2 wk especially in patients with poor performance status.

Hepatic impairment: Do not use in severe impairment, increased risk of hepatotoxicity. For detailed dosing recommendation, consult local protocol.

**Reconstitution:** Paclitaxel must be diluted before infusion. It can be diluted in 0.9% sodium chloride inj, 5% dextrose inj, 5% dextrose and 0.9% sodium chloride inj or 5% dextrose in lactated Ringer's inj to a concentration of 0.3-1.2 mg/ml.

Incompatibility: Do not prepare, store or administer in PVC containing equipment; macrogol glycerol ricinolate (an excipient) can cause [di-(2-ethylhexyl)phthalate] (DEHP) leaching. Y-site incompatibility: Amphotericin B, amphotericin B cholesteryl sulfate complex, chlorpromazine, doxorubicin liposome, hydroxyzine, methylprednisolone sodium succinate, mitoxantrone. Variable compatibility when admixed with cisplatin.

## CONTRAINDICATIONS:

History of hypersensitivity (especially macrogol glycerol ricinolate). Patients with baseline neutropenia of <1500 cells/mm³ (<1000 cells/mm³ for kaposi's sarcoma). Pregnancy and lactation. In kaposi's sarcoma, contraindicated in patients with concurrent, serious, uncontrolled infections.

## PRECAUTIONS:

Bone marrow suppression during therapy. Monitor cardiac function if conduction abnormalities result. Premedicaton (with corticosteroid, antihistamine and histamine H<sub>2</sub>-receptor antagonist) may be required to reduce risk of hypersensitivity reaction. Discontinue, if severe reactions e.g. hypotension, dyspnoea, angioedema or urticaria occur. Caution in patients with moderate hepatic impairment. Monitor for reactions of admin. Safety and efficacy in paediatric patients have not been established. Administer before platinum derivatives (cisplatin, carboplatin) if used in combination. Hazardous agent; use appropriate precautions for handling and disposal.

## **DRUG INTERACTIONS:**

Myelosuppression was more profound when given after cisplatin than with the alternate sequence (e.g., paclitaxel before cisplatin). CYP2C8 inducers e.g. carbamazepine, phenobarbital, phenytoin, rifampicin, rifapentine, and secobarbital may reduce levels or effects. CYP2C8 inhibitors e.g. gemfibrozil, ketoconazole, montelukast, and ritonavir may increase levels or effects. CYP3A4 inducers e.g. aminoglutethimide,

carbamazepine, nafcillin, nevirapine, phenobarbital, phenytoin, and rifamycins may decrease the levels or effects. CYP3A4 inhibitors e.g. azole antifungals, clarithromycin, diclofenac, doxycycline, erythromycin, imatinib, isoniazid, nefazodone, nicardipine, propofol, protease inhibitors, quinidine, telithromycin, and verapamil may increase levels or effects. May increase anthracycline (eg doxorubicin, epirubicin) levels or toxicity; admin of anthracycline at least 24 hr prior to paclitaxel may reduce interaction. May decrease the absorption of cardiac glycosides (may only affect digoxin tablets); levels should be monitored.

## ADVERSE DRUG REACTIONS:

Neutropenia, leukopenia, thrombocytopenia, anaemia, bleeding; hypersensitivity reactions (dyspnoea, flushing, chest pain, tachycardia, rash, hypotension, hypertension); bradycardia, abnormal ECG; neurotoxicity (mainly peripheral neuropathy), myalgia, arthralgia; nausea, vomiting, diarrhoea; severe mucositis, alopecia; rarely hepatic necrosis and encephalopathy, inj site reactions e.g. erythema, tenderness, skin discolouration, swelling; interstitial pneumonitis; infections (mainly UTIs and upper respiratory tract); mucosal inflammation, severe elevation in LFTs (aspartate aminotransferase and alkaline phosphatase).

Potentially Fatal: Infections and infestations leading to death e.g. pneumonia and peritonitis.

# 118. PARACETAMOL Inj 150 mg, 2ml ampoule, Tab 500 mg / 650 mg, Syrup 125 mg/ml, 60 ml botttle SALIENT ACTIONS:

Belong to the class of NSAIDs and act by non selectively inhibiting the COX-1 and COX-2 Ezymes. It has analgesic and antipyretic action and no anti-inflammatory action.

## INDICATIONS & DOSAGE REGIMENS:

#### Tablets:

Mild to moderate pain and fever: Adult: 0.5-1 g 4-6 hrly as necessary. Max: 4 g daily.

Child: Neonate 28-32 wk post menstrual age: 20 mg/kg as a single dose then 10-15 mg/kg 8-12 hrly (max 30 mg/kg daily in divided doses); neonate >32 wk post menstrual age: 20 mg/kg as a single dose then 10-15 mg/kg 6-8 hrly (max 60 mg/kg daily in divided doses); child 1-3 mth: 30 mg 8 hrly (max 60 mg/kg daily in divided doses); 3 mth-1 yr: 60-120 mg 4-6 hrly (max 4 doses in 24 hr); 1-5 yr: 120-250 mg 4-6 hrly (max 4 doses in 24 hr); 6-12 yr: 250-500 mg 4-6 hrly (max 4 doses in 24 hr).

Post-immunization pyrexia: Child: 2-3 mth: Initially, 60 mg repeated 4-6 hrly if necessary.

### Injection:

Adult: Administer over 15 minutes. Wt >50 kg: 1 g 4-6 hrly (max 4 g daily); <50 kg: 15 mg/kg 4-6 hrly (max 60 mg/kg daily). Child: Administer over 15 minutes. Wt <10 kg: 7.5 mg/kg 4-6 hrly (max 30 mg/kg daily); 10-50 kg: 15 mg/kg 4-6 hrly (max 60 mg/kg daily); >50 kg: 1 g 4-6 hrly (max 4 g daily).

## CONTRAINDICATIONS:

Gastro-duodenal ulcer, chronic alcoholic.

## PRECAUTIONS:

Pregnancy Category (US FDA) – B. Renal or hepatic impairment; alcohol-dependent patients; G6PD deficiency INTERACTIONS:

Reduced absorption of cholestyramine within 1 hr of admin. Accelerated absorption with metoclopramide. Decreased effect with barbiturates, carbamazepine, hydantoins, rifampicin and sulfinpyrazone. Paracetamol may increase effect of warfarin.

Potentially Fatal: Paracetamol increases the risk of liver damage in chronic alcoholics. Increased risk of toxicity with other hepatotoxic drugs or drugs which induce microsomal enzymes e.g. barbiturates, carbamazepine, hydantoins, rifampicin and sulfinpyrazone.

## ADVERSE EFFECTS:

Nausea, allergic reactions, skin rashes, acute renal tubular necrosis.

Potentially Fatal: Very rare, blood dyscrasias (e.g. thrombocytopenia, leucopenia, neutropenia, agranulocytosis); liver damage.

# 119. PENTAZOCINE Inj 30 mg, 1ml ampoule

#### SALIENT ACTIONS:

Pentazocine is a benzomorphan derivative with mixed opioid agonist and antagonist actions. It alters perception of and response to pain and produces generalised CNS depression by binding to opiate receptors in the CNS and acting as a partial agonist/antagonist.

## INDICATIONS:

Moderate to severe pain

## DOSAGE REGIMENS:

30-60 mg 3-4 hrly

# CONTRAINDICATIONS:

Head injury; narcotic dependence; respiratory depression; raised intracranial pressure; MI; heart failure; arterial or pulmonary hypertension; porphyria; pregnancy (prolonged use or high doses at term).

#### PRECAUTIONS:

May precipitate withdrawal in narcotic addicts. Impaired respiratory, renal and hepatic function; morbidly obese patients; thyroid dysfunction; prostatic hyperplasia or urinary stricture; biliary tract impairment; adrenal insufficiency (including Addison's disease); abdominal conditions. Elderly or debilitated patients; seizure-prone patients; children and infants (safety and efficacy not established in <1 yr); lactation. May impair ability to drive or operate machinery. Administer IM rather than SC (when frequent inj are needed) and inj sites should be varied.

#### INTERACTIONS:

Depressant affects potentiated by alcohol, CNS depressants; concurrent use with fluoxetine may lead to diaphoresis, ataxia flushing and tremor associated with serotonin syndrome

## ADVERSE EFFECTS:

Physical dependence; sedation, dizziness, euphoria, lightheadedness, alterations of mood; respiratory depression; visual hallucinations, disorientation, confusion; hypertension, tachycardia, circulatory depression; shock; hypotension; nausea, vomiting, constipation; seizures, diaphoresis; rash; blood dyscrasias; local tissue damages (SC), muscle fibrosis (IM).

Potentially Fatal: Respiratory depression, hypotension, circulatory failure, deepening coma, convulsions.

# 120. PANCURONIUM BROMIDE B.P 4MG INJ

#### SALIENT ACTIONS:

Pancuronium blocks neural transmission by competing w/ acetylcholine for cholinergic receptors at the motor end-plate, resulting to skeletal muscles relaxation.

## INDICATIONS & DOSAGE REGIMENS:

Intravenous

# Muscle relaxant in general anaesthesia

*Adult:* Initially, 50-100 mcg/kg by inj, may reduce to 20-60 mcg/kg if given after suxamethonium. Maintenance: 10-20 mcg/kg.

Child: 0-30 days Initially, 30-40 mcg/kg. Maintenance: 10-20 mcg/kg; >1 mth Same as adult dose.

**Renal impairment:** Haemodialysis/peritoneal dialysis patient: Avoid use. Continuous renal replacement therapy: 50% of normal dose

CrCl (ml/min)	Dosage Recommendation Avoid use.	
<10		
10-50	50% of normal dose.	

Incompatibility: Y-site: Diazepam, pantoprazole, thiopental.

Intravenous

## Facilitate endotracheal intubation

Adult: Initially, 50-100 mcg/kg by inj, may reduce to 20-60 mcg/kg if given after suxamethonium. Maintenance: 10-20 mcg/kg.

Child: 0-30 days Initially, 30-40 mcg/kg, Maintenance: 10-20 mcg/kg; >1 mth Same as adult dose.

Renal impairment: Haemodialysis/peritoneal dialysis patient: Avoid use. Continuous renal replacement therapy: 50% of normal dose.

CrCl (ml/min) Dosage Recommendation
<10 Avoid use.
10-50 50% of normal dose.

Incompatibility: Y-site: Diazepam, pantoprazole, thiopental,

Intravenous

# Facilitate mechanical ventilation in intensive care

Adult: 60 mcg/kg every 1-1.5 hr or less frequently.

**Renal impairment:** Haemodialysis/peritoneal dialysis patient: Avoid use. Continuous renal replacement therapy: 50% of normal dose.

CrCl (ml/min) Dosage Recommendation

<10	Avoid use. 50% of normal dose.	
10-50		

Incompatibility: Y-site: Diazepam, pantoprazole, thiopental.

Special Populations: Obese patient: Adjust dose based on ideal body wt.

# PRECAUTIONS:

Patient w/ burn injury, biliary tract disease, pulmonary disease, muscular dystrophies, myasthenia gravis, myasthenic syndrome, electrolyte disturbance, altered pH, dehydration, CV disease, oedema, raised catecholamine concentration and those at risk of HTN. Renal and hepatic impairment. Childn. Pregnancy and lactation. Patient Counselling Not recommended to drive or operate machinery w/in 24 hr after full recovery from neuromuscular effects. Monitoring Parameters Monitor heart rate, BP, assisted ventilation status. DRUG INTERACTIONS:

Increased effect w/ inhalational anaesth, other non-depolarising muscle relaxants, antibiotics (polypeptide and aminoglycoside group), diazepam, propranolol, thiamine (high dose), MAOIs, quinidine, Mg sulfate, protamine, nitroglycerin, narcotic analgesics, diuretics, phenytoin,  $\alpha$  and  $\beta$  adrenergic blockers, imidazoles, norepinephrine and epinephrine and prior suxamethonium. Decreased effect w/ neostigmine, edrophonium, corticosteroids (high dose); KCl, Ca chloride and NaCl; heparin (temporary decrease), azathioprine, theophylline, pyridostigmine, neurolept analgesia and propanidid.

# ADVERSE DRUG REACTIONS:

Tachycardia, HTN, bradycardia, bronchospasm, hypotension, CV collapse, excessive salivation; pain or local skin reactions at inj site. Rarely, hypersensitivity reactions.

Potentially Fatal: Anaphylaxis.

# 121. PHENYTOIN SODIUM Inj 50 mg, 2ml ampoule, Tab 50 mg SALIENT ACTIONS:

Phenytoin is an anticonvulsant agent act by stabilising neuronal membranes and decreasing seizure activity. It can also be used as an antiarrhythmic by extending the effective refractory period and suppressing ventricular pacemaker automaticity, shortening action potential in the heart.

# INDICATIONS & DOSAGE REGIMENS:

ORAL:

Epilepsy: Adult: Initially, 3-4 mg/kg daily as single dose or in divided doses. Alternatively, 150-300 mg daily increased gradually to 600 mg daily if necessary. Maintenance: 200-500 mg daily. Child: Initially, 5 mg/kg daily in 2-3 divided doses. Maintenance: 4-8 mg/kg daily in divided doses. Max dose: 300 mg daily. IV

For Tonic-clonic status epilepticus -10-15 mg/kg. Maintenance: 100 mg 6-8 hrly.

# CONTRAINDICATIONS:

Pregnancy. IV administration in sinus bradycardia, heart block / Stokes-Adams syndrome.

## PRECAUTIONS:

Cardiovascular disease, hepatic impairment; hypoalbuminemia; porphyria, petit mal epilepsy, debilitated patients; elderly, hypotension, heart failure or MI,IV must be given slowly (too rapid admin may cause hypotension, CNS depression, cardiac arrhythmias and impaired heart conduction). May impair ability to drive or operate machinery.

## INTERACTIONS:

Effects of other sedative drugs or ethanol enhanced. Enhances toxic effects of paracetamol, lithium. Increased risk of osteomalacia with acetazolamide. Careful while giving with CYP inducers, inhibitors and substrates. Potentially Fatal: increases hypotensive properties of dopamine and the cardiac depressant properties of lidocaine.

# ADVERSE EFFECTS:

Hypersensitivity, lack of appetite, headache, dizziness, tremor, transient nervousness, insomnia, GI disturbances (e.g. nausea, vomiting, constipation), tenderness and hyperplasia of the gums, acne, hirsutism, coarsening of the facial features, rashes, osteomalacia. Phenytoin toxicity as manifested as a syndrome of cerebellar, vestibular. ocular effects, notably nystagmus, diplopia, slurred speech, and ataxia; also with mental confusion, dyskinesias. exacerbations of seizure frequency, hyperglycaemia.

# 122. PHENIRAMINE MALEATE Inj 22.75 mg/ml, 2 ml ampoule, Tab 25 mg SALIENT ACTIONS:

Pheniramine is an alkylamine derivative with histamine H<sub>1</sub>-receptor antagonist effects. It also has

anticholinergic and moderate sedative effects

## INDICATIONS & DOSAGE REGIMENS:

ORAL

Allergic conditions, Prophylaxis of motion sickness: Take 1st dose at least 30 min before travelling.

Adult: As maleate: Syrup: 15-30 mg bid or tid. Tablet: Up to 45 mg tid. Max: 3 mg/kg/day.

Child: As maleate: 5-10 yr: Half a 45-mg tablet up to tid; >10 yr: Syrup: 15-30 mg bid or tid. Tablet: Up to 45 mg tid. Max: 3 mg/kg/day. Elderly: As maleate: Syrup: 15-30 mg bid or tid. Tablet: Up to 45 mg tid. Max: 3 mg/kg/day. Should be taken with food. (Take after meals.)

IM

20-50 mg intramuscularly

# CONTRAINDICATIONS:

Symptomatic prostatic hypertrophy; neonates and premature infants

## PRECAUTIONS:

May impair ability to drive or operate machinery. Has potential for abuse. Narrow angle glaucoma, asthma or severe CV disease. Antiemetic effect may mask signs of other conditions. Pregnancy and lactation. Elderly.

#### INTERACTIONS:

May mask ototoxicity produced by aminoglycoside antibiotics.

Potentially Fatal: Potentiation of CNS depression by alcohol, sedatives, opioids, barbiturates, hypnotics, narcoleptics. May increase antimuscarinic effect of MAOIs, atropine and TCAs.

### ADVERSE EFFECTS:

Sedation, hypersensitivity reactions. Lassitude, dizziness, tinnitus, inability to concentrate, incoordination, irritability, insomnia and tremors. Urinary retention. Palpitations, headache. Blurred vision, increased intraocular pressure. Muscular weakness. Rarely, blood dyscrasias e.g. agranulocytosis, haemolytic anaemia

# 123. PHENOBARBITONE SODIUM 200MG INJ.1ML

#### SALIENT ACTIONS:

Phenobarbital is a long-acting barbiturate. It depresses the sensory cortex, reduces motor activity, changes cerebellar function and produces drowsiness, sedation and hypnosis. Its anticonvulsant property is exhibited at high doses.

#### INDICATIONS & DOSAGE REGIMENS:

Parenteral

Status epilepticus

Adult: As phenobarbital Na: 200-600 mg. Child: As phenobarbital Na: 100-400 mg.

Elderly: Reduce dose.

Renal impairment: Reduce dose. Severe: Contraindicated. Hepatic impairment: Reduce dose. Severe: Contraindicated.

**Reconstitution:** Dilute w/ most IV infusion soln (e.g. NaCl 0.45% or 0.9%, lactated Ringer's, dextrose 5%, Ringer's).

Incompatibility: Y-site: Pantoprazole, amphotericin B cholesteryl sulfate complex. Syringe: Ranitidine, hydromorphone, sufentanil.

Parenteral

## Emergency management of acute seizures

Adult: As phenobarbital Na: 200-600 mg. Child: As phenobarbital Na: 100-400 mg.

Elderly: Reduce dose.

Renal impairment: Reduce dose. Severe: Contraindicated. Hepatic impairment: Reduce dose. Severe: Contraindicated.

Reconstitution: Dilute w/ most IV infusion soln (e.g. NaCl 0.45% or 0.9%, lactated Ringer's, dextrose 5%,

Ringer's).

\*\*Procompatibility: Y-site: Pantoprazole, amphotericin B cholesteryl sulfate complex. Syringe: Ranitidine,

hydromorphone, sufentanil.

Parenteral

# As a hypnotic

Adult: 100-320 mg. Do not admin for >2 wk for the treatment of insomnia.

Elderly: Reduce dose.

Renal impairment: Reduce dose. Severe: Contraindicated.

Hepatic impairment: Reduce dose. Severe: Contraindicated.

Reconstitution: Dilute w/ most IV infusion soln (e.g. NaCl 0.45% or 0.9%, lactated Ringer's, dextrose 5%,

Ringer's).

Incompatibility: Y-site: Pantoprazole, amphotericin B cholesteryl sulfate complex. Syringe: Ranitidine,

hydromorphone, sufentanil.

Intramuscular

## Preoperative sedation

*Adult:* As phenobarbital Na: 100-200 mg 60-90 min pre-op. *Child:* As phenobarbital Na: 16-100 mg 60-90 min pre-op.

Elderly: Reduce dose.

Renal impairment: Reduce dose. Severe: Contraindicated. Hepatic impairment: Reduce dose. Severe: Contraindicated.

Intravenous

# Preoperative sedation

Child: 1-3 mg/kg pre-op.

Renal impairment: Reduce dose. Severe: Contraindicated. Hepatic impairment: Reduce dose. Severe: Contraindicated.

**Reconstitution:** Dilute w/ most IV infusion soln (e.g. NaCl 0.45% or 0.9%, lactated Ringer's, dextrose 5%, Ringer's).

Incompatibility: Y-site: Pantoprazole, amphotericin B cholesteryl sulfate complex. Syringe: Ranitidine, hydromorphone, sufentanil.

Special Populations: Debilitated patient: Reduce dose.

## CONTRAINDICATIONS:

Severe resp depression, acute intermittent porphyria. Severe renal and hepatic impairment. Intra-arterial and SC admin.

## PRECAUTIONS:

Patient w/ history or sedative/hypnotic addiction; resp disease, depression or suicidal tendencies, hypoadrenalism. Avoid abrupt withdrawal. Mild to moderate renal and hepatic impairment. Elderly or debilitated patient, childn. Pregnancy and lactation. *Patient Counselling* May impair ability to drive or operate machinery. *Monitoring Parameters* Monitor CBC, LFTs, mental status and seizure activity.

# DRUG INTERACTIONS:

May reduce plasma levels of oral anticoagulants (e.g. warfarin, dicoumarol, acenocoumarol, phenprocoumon), corticosteroids, griseofulvin, doxycycline, Na valproate and valproic acid. May increase CNS depressant effect w/ phenytoin, antihistamines, sedative/hypnotics, tranquilisers. May prolong the effect w/ MAOIs. May reduce the effect of estradiol, progesterone, estrone and other steroidal hormones.

## ADVERSE DRUG REACTIONS:

Bradycardia, syncope, hypotension; anxiety, agitation, ataxia, CNS excitation or depression, confusion, dizziness, drowsiness, hallucinations, hangover effect, headache, hyperkinesias; constipation, nausea, vomiting; agranulocytosis, thrombocytopenia, megaloblastic anaemia; oliguria; pain at inj site, thrombophlebitis (w/ IV use); laryngospasm, resp depression, apnoea (esp w/ rapid IV use), hypoventilation; gangrene (w/ unintentional intra-arterial inj).

Potentially Fatal: Stevens-Johnson syndrome, toxic epidermal necrolysis.

# 124. PHOSPHOLIPIDS FRACTION FROM BOVINE LUNG (SURFACTANT)

50 mg/vial

## SALIENT ACTIONS:

It lowers surface tension on alveolar surfaces during respiration and stabilizes alveoli against collapse at resting transpulmonary pressure.

# INDICATIONS & DOSAGES REGIMENS:

Preventive use in premature neonates with a high risk of respiratory Distress Syndrome 5 ml/kg at 27mg of phospholipids/ml which equals to 135 mg phospholipids/kgIntratracheally. As many as 3 subsequent doses within 5 days.

## CONTRAINDICATIONS:

Abnormal liver function tests, Atrial fibrillation, Diabetes, Liver problems, Infants with active pulmonary haemorrhage

#### PRECAUTIONS:

- 1. Intended for intratracheal use only
- 2. Transient bradycardia and decreased oxygen saturation has been noted
- 3. Rales and moist breath sounds may occur transiently after administration
- 4. Breastfeeding
- 5. Pregnancy

## INTERACTIONS:

No known interactions

#### ADVERSE EFFECTS

Patent ductusarteriosus, decreased post dose pulmonary function values, intraventricularhaemorrhages, sepsis, retinopathy of prematurity, bradycardia, convulsions, hypotension, apnoea, hydrocephalus, pneumonia

# 125. PROMETHAZINE HYDROCHLORIDE Inj 25 mg, 2 ml ampoule

## SALIENT ACTIONS:

Promethazine, a phenothiazine derivative, blocks postsynaptic dopaminergic receptors in the brain and has a strong  $\alpha$ -adrenergic blocking effect. It competitively binds to  $H_1$ -receptors.

## INDICATIONS:

Allergic conditions, nausea and vomiting

## DOSAGE REGIMENS:

IV/IM Allergic conditions As HCl: 25-50 mg. Max: 100 mg. Nausea andvomiting As HCl: 12.5-25 mg, May repeat at intervals of not <4 hr. Max: 100 mg/24 hr.

## CONTRAINDICATIONS:

Hypersensitivity, coma, porphyria, cardiac disease, hypokalaemia, intra-arterial or SC inj, neonates and young children, pregnancy, lactation.

## PRECAUTIONS:

Elderly, glaucoma, epilepsy, CVS disease, impaired liver function, asthma, urinary retention, prostatic hyperplasia, pyloroduodenal obstruction. May cause drowsiness. For parenteral admin: Drug must be administered carefully and slowly; incorrect admin can lead to severe tissue injury

#### INTERACTIONS:

Masks ototoxicity of aminoglycoside antibiotics. May enhance the sedative effects of CNS depressants like alcohol, hypnotics, barbiturates and opioids.

Potentially Fatal: Ventricular arrhythmias when used with drugs that prolong QT interval.

## ADVERSE EFFECTS:

CNS depression, paradoxical excitation in childn, dryness of mouth, blurring of vision, retention of urine, constipation, glaucoma, tachycardia, headache, hypotension, tinnitus.

## 126. PILOCARPINE NITRATE Inj 0.5%

## SALIENT ACTIONS:

Pilocarpine nitrate is clear, colorless solution for intracameral administration to induce prompt micsis, directly stimulates cholinergic receptors in the eyes causing pupillary constriction, spasm of accommodation and a transient rise in IOP followed by a fall.

#### INDICATIONS:

It is used as direct acting miotic. To induce miosis during surgery for prompt miosis ( Cataract surgery with I.O.L implant ).

## DOSAGE REGIMENS:

As per opthlologists.

#### CONTRAINDICATIONS:

Angle-closure glaucoma; acute iritis, anterior uveitis; hypersensitivity, pregnancy

## PRECAUTIONS:

Not to be used as injection. Lactation, acute cardiac failure, bronchial asthma, peptic ulcer, hyperthyroidism, GIspasm, urinary tract obstruction, Parkinson's disease, recent MI, hypertension or hypotension. Retinal detachment; corneal or conjunctival damage. Patients with cognitive or psychiatric disorders, renal impairment, biliary tract disorders. Prolonged use may lead to lens opacities. May impair ability to drive or operate machines.

## INTERACTIONS:

Concomitant 2 miotics may increase risk of toxic reactions. Aminoglycosides, clindamycin, colistin,

cyclopropane and halogenated inhalational anaesthetics, quinine, procainamide, lithium and  $\beta$ -blockers may reduce the efficacy of pilacarpine. Concurrent use with  $\beta$ -blockers may lead to bradycardia. May prolong the action of suxamethonium.

Potentially Fatal: Miotic and ocular hypotensive effect antagonised by anticholinergies. Conduction disturbances with β-blockers.

## ADVERSE EFFECTS:

Ocular: Pain and irritation, blurred vision, lachrymation, browache, conjunctival vascular congestion, superficial keratitis, vitreous haemorrhage, increased pupillary block

# 127. PIPERACILLIN SODIUM 4 gm + TAZOBACTAM SODIUM 0.5 gm Inj / vial SALIENT ACTIONS:

Piperacillin has an antimicrobial activity against *K. pneumoniae*, *P. aeruginosa*, *Enterobacteriaceae*. Tazobactam, beta lactamase inhibitor,enhances the activity of piperacillin against beta-lactamase-producing bacteria.

## INDICATIONS:

Nosocomial pneumonia, Severe infections, Renal impairment: For haemodialysis

#### DOSAGE REGIMENS:

1. Nosocomial pneumonia

Adult: Initial dose: 4.5 g (piperacillin 4 g and tazobactam 0.5 g) every 6 hr for 7-14 days. When used empirically, combination with an aminoglycoside or antipseudomonal fluoroquinolone is recommended. May be given via infusion over 30 minutes. If *Pseudomonas aeruginosa* is not isolated, may discontinue aminoglycoside. *Child*: 2-8 mth: 80 mg of piperacillin/kg every 8 hr; ≥9 mth and ≤40 kg: 100 mg of piperacillin/kg every 8 hr.

2. Severe infections

Adult: 3.375 g (piperacillin 3 g and tazobactam 0.375 g) every 6 hr for 7-10 days. May be given via infusion over 30 minutes.

3. Renal impairment: For haemodialysis: admin an additional dose of 0.75 g after each dialysis session on hemodialysis days.

## CONTRAINDICATIONS:

Hypersensitivity.

### PRECAUTIONS:

Pregnancy and lactation, pseudomembranous colitis. Prolonged treatment may increase risk of superinfections. Convulsions or neuromuscular excitability may occur when high doses are used, especially in renally impaired patients.

## INTERACTIONS:

Probenecid prolongs half lives of piperacillin and tazobactam. Increased risk of methotrexate toxicity when used together. *Potentially Fatal:* Interacts with heparin and other oral anticoagulants. Prolongs the neuromuscular blockade of vecuronium and non-depolarizing muscle relaxants.

## ADVERSE EFFECTS:

Diarrhoea, skin rashes, occasionally platelet mediated bleeding, rigors, malaise, ulcerative stomatitis. Inj-site reactions such as pain, erythema, induration and thrombophlebitis.

Potentially Fatal: Serious, anaphylactic reactions.

#### 128. PIRACETAM(NOOTROPIL INJ 15ML)

#### SALIENT ACTIONS:

Piracetam protects the cerebral cortex against hypoxia. It also inhibits platelet aggregation and reduces blood viscosity.

## INDICATIONS & DOSAGE REGIMENS:

Parenteral

As a cognitive enhancer in cerebrocortical insufficiency

Adult: 1-2 g tid via IV/IM admin.

## CONTRAINDICATIONS:

Hepatic and severe renal impairment. Cerebral haemorrhage. Pregnancy and lactation.

#### PRECAUTIONS:

Avoid abrupt withdrawal. Impaired renal function. Cardiac disorders. Haemostatic disorders. Patients who have recently undergone major surgery. Elderly.

#### DRUG INTERACTIONS:

May increase prothrombin time in patients who are on warfarin.

## ADVERSE DRUG REACTIONS:

Hyperkinesia, nervousness, depression, diarrhoea, rashes. CNS stimulation, sleep disturbances, dizziness, excitement, insomnia, somnolence, wt gain.

## 129. PNEUMOCOCCAL POLYSACCHARIDE VACCINE

#### SALIENT ACTIONS:

Pneumococcal polysaccharide vaccine (PPSV23) protects against 23 types of pneumococcal bacteria. It will not prevent all pneumococcal disease.

## INDICATIONS & DOSAGE REGIMENS:

PPSV23 is recommended for:

- All adults 65 years of age and older,
- · Anyone 2 through 64 years of age with certain long-term health problems,
- · Anyone 2 through 64 years of age with a weakened immune system,
- Adults 19 through 64 years of age who smoke cigarettes or have asthma.
- immunosuppression, a missing spleen, sickle cell anaemia or coeliac disease
- chronic liver disease, kidney disease or heart disease
- chronic lung conditions
- chronic brain (neurological) conditions including learning disability
- diabetes
- cochlear implants
- cerebrospinal fluid leaks
- complement disorders (the complement system is an important part of the immune system)

## Adults and children over two years of age

The 23-valent vaccine (e.g., Pneumovax 23) is effective against 23 different pneumococcal capsular types (serotypes 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F and 33F), and so covers 90 percent of the types found in pneumococcal bloodstream infections.

## Young children

Children under the age of two years fail to mount an adequate response to the 23-valent adult vaccine, and instead a 13-valent **Pneumococcal Conjugated Vaccine**(PCV) (e.g. <u>Prevnar 13</u>) must be used. Prevnar 13 is a new vaccine which has replaced Prevnar 7, adding six new serotypes to the vaccine.

## Special risk-groups

Children at special risk (e.g. <u>sickle cell disease</u> and <u>those without a functioning spleen</u>) require additional protection using the 13-valent congugated vaccine, with the then more extensive 23-valent vaccine given after the second year of life:

Vaccination schedule for children at special risk					
Age	2–6 months	7–11 months	12–23 months		
Conjugated vaccine	3× monthly dose	2× monthly dose	2 doses, 2 months apart		
	Further dose in s	econd year of life	,		
23-valent vaccine	Then after 2nd birthday single dose of 23-valent				

#### CONTRAINDICATIONS:

- Anyone who has had a life-threatening allergic reaction to PPSV should not get another dose.
- Anyone who has a severe allergy to any component of PPSV should not receive it. Tell your provider if you
  have any severe allergies.
- Anyone who is moderately or severely ill when the shot is scheduled may be asked to wait until they
  recover before getting the vaccine. Someone with a mild illness can usually be vaccinated.
- Children less than 2 years of age should not receive this vaccine.

There is no evidence that PPSV is harmful to either a pregnant woman or to her fetus. However, as a
precaution, women who need the vaccine should be vaccinated before becoming pregnant, if possible.

## ADVERSE DRUG REACTIONS:

redness, tenderness and/or swelling at the injection site, and a slightly raised temperature.

More severe side effects are infrequent, but can include: swelling in the injected limb; feeling tired, weak, sick

or generally unwell; high temperatures and shivering, sometimes leading to convulsions.

# 130. POLYMYXIN B INJ

They are active against most gram negative bacteria, notably Pseudomonas exceptions are Proteus, Serratia and Neisseria. Both have very similar range of activity, but colistin is more potent on pseudomonas, Salmonella and shigella. Little or no absorption occurs from oral route or even from denuded skin (burn, ulcers).

## INDICATIONS:

Sytemic urinary tract meningeal local and enteric infections caused by gram negative organisms.

# DOSAGE REGIMENS:

Polymyxin B 15,000-25,000 u./kg body wt daily for 7-10 days. Max: 2,000,000 i.u. per day.

## CONTRAINDICATIONS:

Hypersensitivity.

Special precaution: Perforated tympanic membrane, monitor renal functions.

Paediatrics: Use with caution.

Pregnancy: Contraindicated

Lactation: Contraindicated.

Elderly: use with caution.

DRUG INTERACTIONS:

Potentiates nephrotoxicity produced by cephalothin and aminoglycosides. Neuromuscular blockade potentiated by ether anaesthesia, sedatives, muscle relaxants and aminoglycoside antibiotics. Synergy with trimethoprim and useful combination with rifampicin.

## ADVERSE EFFECTS:

Intramuscular injection causes pain, flushing and paresthesias after injection. Nephrotoxi-city, neurological disturbances ototoxicity.

# 131. POLIDOCANOL INJECTION 60MG/2ML

## SALIENT ACTIONS:

Polidocanol is a <u>local anaesthetic</u> and <u>antipruritic</u> component of <u>ointments</u> and bath additives. It relieves itching caused by <u>eczema</u> and dry skin. It is formed by the <u>ethoxylation</u> of <u>dodecanol</u>.

Each mL contains 5 mg (0.5%) or 10 mg (1.0%) polidocanol in water for injection with 5% (v/v) ethanol at pH 6.5-8.0; disodium hydrogen phosphate dihydrate, potassium dihydrogen phosphate are added for pH adjustment.

# INDICATIONS & DOSAGE REGIMENS:

Varicose veins, bleeding due to gastro-duodenal ulcers, superficial venules & telangiectasias, sclerosing agent for bleeding oesophageal varices.

For <u>spider veins</u> (varicose veins ≤ 1 mm in diameter), use Asclera (polidocanol injection) 0.5%. For reticular veins (varicose veins 1 to 3 mm in diameter), use Asclera (polidocanol injection) 1%. Use 0.1 to 0.3 mL per injection and no more than 10 mL per session.

Use a syringe (glass or plastic) with a fine needle (typically, 26- or 30-gauge). Insert the needle tangentially into the vein and inject the solution slowly while the needle is still in the vein. Apply only gentle pressure during injection to prevent vein rupture. After the needle has been removed and the injection site has been covered, apply compression in the form of a stocking or bandage. After the treatment session, encourage the patient to walk for 15 to 20 minutes. Keep the patient under observation to detect any anaphylactic or allergic reaction Maintain compression for 2 to 3 days after treatment of spider veins and for 5 to 7 days for reticular veins. For extensive varicosities, longer compression treatment with compression bandages or a gradient compression stocking of a higher compression class is recommended. Post-treatment compression is necessary to reduce the risk of deep vein thrombosis.

Repeat treatments may be necessary if the extent of the varicose veins requires more than 10 ml. These treatments should be separated by 1 to 2 weeks.

## ADVERSE EFFECTS:

Immune system disorders: Anaphylactic shock, angioedema, urticaria generalized, asthma

Nervous system disorders: Cerebrovascular accident, migraine, paresthesia (local), loss of consciousness,

confusional state, dizziness

Cardiac disorders: Cardiac arrest, palpitations

Vascular disorders. Deep vein thrombosis, pulmonary embolism, syncope vasovagal, circulatory

collapse, vasculitis

Respiratory, thoracic and mediastinal disorders: Dyspnea

Skin and subcutaneous tissue disorders: Skin hyperpigmentation, dermatitis allergic, hypertrichosis (in the area of sclerotherapy)

General disorders and injection site conditions: Injection site necrosis, pyrexia, hot flush

Injury, poisoning and procedural complications: Nerve injury

## INTERACTIONS:

No drug-drug interactions have been studied with Asclera (polidocanol injection)

## PRECAUTIONS:

Anaphylaxis

Severe allergic reactions have been reported following polidocanol use, including anaphylactic reactions, some of them fatal. Severe reactions are more frequent with use of larger volumes ( > 3 mL). The dose of polidocanol should therefore be minimized. Be prepared to treat anaphylaxis appropriately.

Severe adverse local effects, including tissue necrosis, may occur following extravasation; therefore, care should be taken in intravenous needle placement and the smallest effective volume at each injection site should be used. After the injection session is completed, apply compression with a stocking or bandage, and have the patient walk for 15-20 minutes. Keep the patient under supervision during this period to treat any anaphylactic or allergic reaction

Accidental Intra-arterial Injection

Intra-arterial injection can cause severe necrosis, ischemia or gangrene. If this occurs consult a vascular surgeon immediately.

Inadvertent Perivascular Injection

Inadvertent perivascular injection of Asclera (polidocanol injection) can cause pain. If pain is severe, a local anesthetic (without adrenaline) may be injected.

Nonclinical Toxicology

Carcinogenesis, Mutagenesis, Impairment of Fertility

## **CONTRAINDICATIONS:**

Asclera (polidocanol injection) is contraindicated for patients with known allergy (anaphylaxis) to polidocanol and patients with acute thromboembolic diseases.

# 132. POTASSIUM CHLORIDE Inj 150 mg, 10ml ampoule, Syrup 1 gm, 200 ml bottle SALIENT ACTIONS:

Potassium chloride is a major cation of the intracellular fluid. It plays an active role in the conduction of nerve impulses in the heart, brain and skeletal muscle; contraction of cardiac skeletal and smooth muscles; maintenance of normal renal function, acid-base balance, carbohydrate metabolism and gastric secretion.

## INDICATIONS:

Severe acute hypokalaemia

## DOSAGE REGIMENS:

If serum potassium level >2.5 mEq/L, give at a rate not exceeding 10 mEq/hr in a concentration of up to 40 mEq/L. Max dose: 200 mEq/24 hr. If serum potassium level <2 mEq/L, may infuse at a rate of up to 40 mEq/hr. Continuous cardiac monitoring is essential. Max dose: 400 mEq/24 hr.

Max Dosage: 2-3 mmol potassium/kg body wt in 24 hrs.

## CONTRAINDICATIONS:

Hyperchloraemia, severe renal or adrenal insufficiency

#### PRECAUTIONS:

Renal or adrenocortical insufficiency; cardiac disease; acute dehydration; extensive tissue destruction, pregnancy. Ensure adequate urine output; monitor plasma-potassium and other electrolyte concentrations. Discontinue treatment if severe nausea, vomiting or abdominal distress develops

#### INTERACTIONS:

Potassium-sparing diuretics, ACE inhibitors, ciclosporin and potassium-containing drugs. Antimuscarinics delay gastric emptying time consequently increasing risk of GI adverse effects especially of solid oral dosage forms.

## ADVERSE EFFECTS:

Hyperkalaemia, nausea, vomiting, diarrhoea and abdominal cramps, pain or phlebitis, cardiac toxicity

# 133. PROFOFOL Inj 10 mg, 20 ml vial

## SALIENT ACTIONS:

Propofol is a short-acting anaesthetic given for induction and maintenance of general anaesthesia. Onset of action: 30 sec., Duration of action: 3-10 min.

## INDICATIONS:

Induction and maintenance of general anaesthesia

# DOSAGE REGIMENS:

Adult: Induction: 40 mg by inj or infusion every 10 sec. Usual dose: 1.5-2.5 mg/kg. Maintenance: 4-12 mg/kg/hr or intermittent bolus inj of 20-50 mg.

Child: >8 yr: Induction dose of 2.5 mg/kg. Maintenance dose: 9-15 mg/kg/hr by IV infusion or intermittent bolus inj.

# CONTRAINDICATIONS:

Electroconvulsive therapy, obstetrics. Sedation in children ≤16 yr. Pregnancy, lactation.

# PRECAUTIONS:

Paediatrics, elderly, hypovolaemia, epilepsy, lipid disorders, patients with increased intracranial pressure. Avoid rapid bolus doses in high risk patients. Emulsion formulation of propofol 2% should only be used in children >3

# INTERACTIONS:

Reduce dose if given with nitrous oxide or halogenated anaesthetics. Increased sedative, anaesthetic and cardiorespiratory effects when used with other CNS depressants.

# ADVERSE EFFECTS:

Involuntary muscle movements; nausea, vomiting, headache, fever; pain, burning or stinging at inj site. Potentially Fatal: Apnoea, bradycardia, hypotension, convulsions; anaphylaxis.

# 134. PROTAMINE SULPHATE INJ

# SALIENT ACTIONS:

Protamine sulfate is prepared from the sperm or mature testes of salmon or related species and is composed of arginine, proline, serine and valine. It combines w/ strongly acidic heparin to form a stable complex, neutralising the anticoagulant activity of both drugs.

INDICATIONS: Antidote to overdosage with heparin; antidote for heparin in controlled bleeding.

Availability: SOLUTION 5 ml (1%); Injection 5 ml ampoule (10 mg/ml).

DOSAGE REGIMENS: Intravenous injection Heparin overdose, over approximately 10 min; 1 mg neutralizes 80 to 100 units heparin when given within 15 min, if longer time, less protamine needed as heparin is rapidly excreted. 1 ml neutralises the effect of 1000 ml i.u. of circulating heparin; max. single dose 50 mg (5 ml). PRECAUTIONS: If used in excess protamine has an anticoagulant effect; allergic reactions increased in persons at risk including previous treatment with protamine or protamine insulin; fish allergies; men who are infertile or who have had a vasectomy; pregnancy; lactation; children. PRECAUTIONS:

Patient at risk of developing hypersensitivity to protamine (e.g. previous history of procedures such as coronary angioplasty or cardiopulmonary bypass surgery where protamine is frequently used, diabetics using protamine insulin, allergy to fish, vasectomised or infertile males who may have antibodies to protamine). Pregnancy and lactation. Monitoring Parameters Monitor clotting parameters closely esp in prolonged procedures. Monitor aPTT or activated coagulation time, 5-15 min after protamine sulfate admin.

## ADVERSE EFFECTS:

Nausea; vomiting; lassitude; flushing; hypotension; bradycardia; dyspnoea; allergic reactions (including angioedema; anaphylaxis); allergy specially if previous exposure to protamine insulin; fish allergy; infertile or vasectomised men.

# 135. RABIES VACCINE Inj 0.5 ml/vial

# SALIENT ACTIONS:

Rables vaccine is an inactivated virus vaccine that is used for active immunisation against rables. For postexposure immunisation, it is often used in conjunction with rabies immunoglobulins as it takes about 7-10 days for the specific antibodies to develop.

## INDICATIONS:

Active immunisation against rabies

# DOSAGE REGIMENS:

primary immunisation: 5 doses of 1 mL each on days 0, 3, 7, 14 and 28 (patients should also receive rabies immunoglobulin with the 1st dose); patients who have received primary immunisation: 2 doses of 1 mL on days 0 and 3.

CONTRAINDICATIONS:

Confirmed diagnosis of rabies. Postexposure prophylaxis may be started regardless of the length of time from likely exposure, as long as clinical signs of rabies infection are not present

PRECAUTIONS:

Possibility of immune complex reaction 2-21 days after booster doses of HDCV ;symptoms include arthralgia, arthritis, nausea, malaise, angioedema, fever and vomiting. bleeding disorders, anticoagulant treatment, severely immunocompromised patients. Pregnancy and lactation.

INTERACTIONS:

Concurrent use with immunosuppressants may reduce the efficacy of vaccines

ADVERSE EFFECTS:

Headache, dizziness, malaise, abdominal pain, nausea, myalgia. Inj-site reactions such as itching, swelling, pain.

# 136. RANITIDINE Inj 25 mg , 2ml ampoule, Tab 150 mg

SALIENT ACTIONS:

Ranitidine blocks histamine  $H_2$ -receptors in the stomach and prevents histamine-mediated gastric acid secretion. It does not affect pepsin secretion, pentagastrin-stimulated factor secretion or serum gastrin.

# INDICATIONS & DOSAGE REGIMENS:

ORAL

1.Benign gastric and duodenal ulceration- to improve healing: Adult: 300 mg single daily dose at bedtime or 150 mg bid; 300 mg bid for 4 wk Treatment duration: 4-8 wk for benign gastric and duodenal ulceration; up to 8 wk in NSAID-associated ulceration. 2.For prevention of NSAID-associated ulceration: 150 mg bid: Child: 3-12 yr: 2-4 mg/kg (max: 150 mg) bid for 4-8 wk.3.H.pylori infection: Adult: 300 mg once daily or 150 mg bid with amoxicillin 750 mg tid & metronidazole 500 mg tid for 2 wk. Treatment with ranitidine for a further 2 wk. Gastro-oesophageal reflux disease: Adult: 150 mg bid or 300 mg at bedtime for 8 wk, increase to 150 mg four times daily for 12 wk in severe cases. Child: 5-10 mg/kg daily, given in 2 divided doses. 4.Hypersecretory conditions: Adult: 150 mg bid/tid increased to 6 g daily if necessary. 5.Acid aspiration during general anaesthesia: Adult: 150 mg, 2 hr before induction of anaesthesia & an additional dose on the previous evening. Dyspepsia: Adult: 75 mg, repeated if necessary up to 4 doses daily. Max: 2 wk of continuous use at each time. For chronic episodic dyspepsia: 150 mg bid for up to 6 wk.

IV/IM

1.Prophylaxis of acid aspiration during general anaesthesia: 50 mg IV/IM given 45-60 minutes before the induction of anaesthesia. 2.Hypersecretory conditions: 1 mg/kg/hr IV infusion, may increase by increments of 0.5 mg/kg/hr starting after 4 hr if necessary. 3.Stress ulceration of upper gastrointestinal tract: 50 mg by slow IV Inj as priming dose followed by 125-250 mcg/kg/hr as continuous IV infusion then transfer to oral dose of 150 mg bid once oral feeding is resumed. *Renal impairment:* Dosage reduction is required in severe renal impairment.

## CONTRAINDICATIONS:

Porphyria.

PRECAUTIONS:

Exclude malignancy before treating gastric ulcer. Renal and hepatic impairment. Infants, pregnancy and lactation.

INTERACTIONS:

Antacids may interfere with absorption. May decrease the GI absorption ofketoconazole. Smoking may decrease the plasma levels of ranitidine. May cause an increase in the bioavailability of furosemide.

ADVERSE EFFECTS:

Headache, dizziness. Rarely hepatitis, thrombocytopaenia, leucopaenia, hypersensitivity, confusion, gynaecomastia, impotence, somnolence, vertigo, hallucinations.

Potentially Fatal: Anaphylaxis, hypersensitivity reactions

#### 137. RANIBIZUMAB INJ

SALINET ACTIONS:

It is a recombinat humanized lgGI kappa isotype monoclonal antibody fragment designed for intraocular use. Ranibizumab binds to and inhibits the biologic activity ofhuman vascular endothelial growth factorA (VEGF-

# A). It is antineovascularisation agent.

## INDICATIONS:

Wet age-related macular degeneration (wet AMD), macular edema following retinal vein occlusion (RVO), and diabetic macular edema (DME).

# DOSAGE REGIMENS:

Intraocular injection, 0.5mg.

# CONTRAINDICATIONS:

Hypersensitivity, Ocular infection, intraocular inflammation.

# SPECIAL PRECAUTIONS:

Paediatric: Not recommended.

Pregnancy: Wait at least 3 months after last dose before conceiving a child.

Lactation: Not recommended.

Elderly: safe.

## DRUG INTERACTIONS:

With verteporfin photodynamic therapy intraocular inflammation is seen.

## ADVERSE EFFECTS:

Endophthalmitis retinal detachments, and iatrogenic traumatic cataracts, hypertension/elevated blood pressure, nasopharyngitis, arthralgia, headache, bronchitis, cough, anemia, nausea, sinusitis, influenza.

# 138. RECOMBINANT HEPATITS -B VACCINE Inj 20 mg/ml, 10 ml vial SALIENT ACTIONS:

Hepatitis B vaccines are used for active immunisation against hepatitis B infection. Two types of vaccine have been available each containing hepatitis B surface antigen (HBsAg) adsorbed onto aluminium hydroxide or a similar adsorbent.

## INDICATIONS:

Active immunisation against hepatitis B

## DOSAGE REGIMENS:

Basic course consists of 3 doses: 2nd and 3rd doses given 1 and 6 mth after the 1st dose intramuscularly. Dose depends on the product used. Typical doses: 10 or 20 mcg. Given via SC administration in haemophiliaes.

# CONTRAINDICATIONS:

Previous confirmed anaphylactic reaction to a previous dose of a vaccine containing the same antigens. Hypersensitivity. Vaccines prepared in egg cultures are contraindicated in patients with hypersensitivity reactions to egg. Severe immunodeficiency. Malignant disease being treated with chemotherapy or radiotherapy and for at least 6 mth after stopping treatment. Patients with compromised immune system such as those on high-dose systemic corticosteroids, immunosuppressants or HIV positive.

# PRECAUTIONS:

If any alcohol or disinfectant is used for cleansing the skin it should be allowed to evaporate before vaccination otherwise inactivation of live vaccines may occur

## INTERACTIONS:

Reduced response to vaccination when used concurrently with immunosuppressants such as corticosteroids or antineoplastics

# ADVERSE EFFECTS:

Abdominal pain and GI disturbance, and musculoskeletal and joint pain and inflammation. Dizziness and sleep disturbance. CV effects include occasional hypotension and, rarely, tachycardia. Dysuria, visual disturbances and earache

# 139. ROCURONIUM BROMIDE INJ

# SALIENT ACTIONS:

Rocuronium competes for nicotinic cholinoreceptors at the motor end-plate, resulting to neuromuscular blockade

# INDICATIONS AND DOSAGE REGIMENS:

Intravenous

Muscle relaxant in general anaesthesia, Facilitate endotracheal intubation, Facilitate mechanical ventilation in intensive care

Adult: Initially, 600 mcg/kg by inj. Higher doses of 1 mg/kg may be used for intubation during rapid sequence induction of anaesth. Maintenance: 150 mcg/kg by inj (may reduce to 75-100 mcg/kg for prolonged inhalational anaesth) or by infusion at 300-600 mcg/kg/hr.

Child: Same as adult dose.

Elderly: Maintenance: 75-100 mcg/kg.

Renal impairment: Maintenance: 75-100 mcg/kg by inj or 300-400 mcg/kg/hr by infusion. Hepatic impairment: Maintenance: 75-100 mcg/kg by inj or 300-400 mcg/kg/hr by infusion.

Special Populations: Obese patients (≥130% of ideal body wt): Reduce dose, based on ideal body wt. Biliary

tract disease: Maintenance: 75-100 mcg/kg by inj or 300-400 mcg/kg/hr by infusion.

#### PRECAUTIONS:

Patient w/ biliary tract disease, neuromuscular disease, previous poliomyelitis, burn injury, severe electrolyte disturbances, Eaton-Lambert syndrome, myasthenia gravis, CV disease, resp disease, pulmonary HTN; obese patients. Renal and hepatic impairment. Elderly. Pregnancy and lactation. Monitoring Parameters Monitor heart rate, BP, twitch response, assisted ventilation status.

#### DRUG INTERACTION:

Increased effect w/ halogenated volatile anaesth (e.g. enflurane, isoflurane), antibiotics (e.g. aminoglycoside, lincosamide and polypeptide antibiotics, acylamino-penicillin antibiotics), diuretics, quinidine, quinine, Mg and lithium salts, Ca channel blockers, local anaesth, acute admin of phenytoin or β-blocking agents, corticosteroid (long-term use) and after intubation w/ suxamethonium. Decreased effect w/ Ca chloride and KCl, protease inhibitors (e.g. gabexate, ulinastatin), chronic admin of phenytoin or carbamazepine.

#### ADVERSE EFFECTS:

Changes in vital signs, prolonged neuromuscular block, myopathy; inj site pain/reaction.

Potentially Fatal: Anaphylaxis.

# 140. SODIUM BICARBONATE Inj 75 mg/ml, 10 ml ampoule

#### SALIENT ACTIONS:

Sodium bicarbonate raises blood and urinary pH by dissociation to provide bicarbonate ions, which neutralises the hydrogen ion concentration

#### INDICATIONS:

Severe metabolic acidosis, Dosage adjustments may be required —elderly, renal impairment, hepatic impairment **DOSAGE REGIMENS:** 

- 1. Severe metabolic acidosis: slow inj of a hypertonic solution of up to 8.4% (1000 mmol/L), or by continuous infusion of a weaker solution, usually 1.26% (150 mmol/L)
- 2. For correction of acidosis during advanced cardiac life support procedures: 50 ml of an 8.4% solution

#### CONTRAINDICATIONS:

Metabolic or respiratory alkalosis, hypernatraemia, severe pulmonary edema, hypocalcaemia, hypochlorhydria **PRECAUTIONS:** 

Pregnancy and lactation. Epilepsy, CHF, renal impairment, liver cirrhosis, hypertension, oedema, eclampsia, aldosteronism. Monitor serum electrolyte concentrations and acid-base status regularly during treatment of acidosis.

#### INTERACTIONS:

Increases toxicity of amphetamines, ephedrine, pseudoephedrine, flecainide, quinidine and quinine. Decreases effects of lithium, chlorpropamide and salicylates due to increased clearance. May affect the absorption of certain drugs due to raised intra-gastric pH.

#### ADVERSE EFFECTS:

Metabolic alkalosis, mood changes, tiredness, shortness of breath, muscle weakness, irregular heartbeat, muscle hypertonicity, twitching, tetany, hypernatraemia, hyperosmolality, hypocalcaemia, hypokalaemia; stomach cramps, flatulence. Tissue necrosis at injection site

### 141. SODIUM NITROPRUSSIDE 50MG INJ

#### SALIENT ACTIONS:

Sodium nitroprusside is a short-acting antihypertensive that acts directly on the venous and arteriolar smooth muscle causing peripheral vasodilation, thus decreasing peripheral resistance. It is also used to reduce preload and afterload in severe heart failure.

Metabolism: Rapidly metabolised to cyanide in red blood cells and smooth muscle, leading to release of nitric oxide.

Excretion: Cyanide is further metabolised hepatically to thiocyanate and excreted in the urine. Plasma half-life of thiocyanate is about 3 days.

# INDICATIONS & DOSAGE REGIMENS:

Adult: IV Hypertensive crisis For patients not receiving any antihypertensives: Initial: 0.3-1.5 mcg/kg/min, adjust gradually as needed. Usual: 0.5-6 mcg/kg/min. Max rate: 8 mcg/kg/min, discontinue if there is no response after 10 mins. May continue for a few hr if there is response. Introduce PO as soon as possible. Lower doses should be used in patients receiving antihypertensives. Induction of hypotension during anesth Recommended max: 1.5 mcg/kg/min. Heart failure Intial: 10-15 mcg/min, may increase if needed. Usual: 10-200 mcg/min. Max: 280 mcg/min.

#### INTERACTIONS:

Additive effect when used with other antihypertensives. May prolong the fibrinolytic activity of alteplase. Risk of severe hypotension if used with phosphodiesterase inhibitors. May reduce serum digoxin levels.

#### PRECAUTIONS:

Hypothyroidism, renal and hepatic impairment, ischaemic heart disease, impaired cerebral circulation, elderly. Monitor blood thiocyanate concentration if treatment is longer than 3 days and should not exceed 100 mcg/ml. Monitor acid-base balance, venous oxygen concentration and BP. Caution to avoid extravasation. To be diluted with sterile dextrose 5% solution before infusion. Avoid sudden withdrawal. Leber's optic atrophy, low plasma-cobalamin concentrations, impaired pulmonary function. Pregnancy and lactation.

#### CONTRAINDICATIONS:

Hypersensitivity, compensatory hypertension.

#### ADVERSE EFFECTS:

Nausea, retching, apprehension, headache, restlessness, muscle twitching, retrosternal discomfort; palpitation, dizziness, abdominal discomfort. Cyanosis and hypothyroidism (rare).

# 142. SODIUM PHOSPHATE IP 8G(enema)

#### SALIENT ACTIONS:

Belongs to the class of enemas.

#### INDICATIONS & DOSAGE REGIMENS:

Used in the treatment of constipation.

#### INTERACTIONS:

N/A

#### PRECAUTIONS:

N/A

#### CONTRAINDICATIONS:

diarrhea

#### ADVERSE EFFECTS:

Diarrhea

# 143. SODIUM TETRADECYL SULPHATE 30 MG INJ

#### SALIENT ACTIONS:

For Phlebitis & Varicose Preparations

#### INDICATIONS & DOSAGE REGIMENS:

For the treatment of varicose veins of the leg by injection sclerotherapy.

#### INTERACTIONS:

N/A

#### PRECAUTIONS:

N/A

#### CONTRAINDICATIONS:

N/A

#### ADVERSE EFFECTS:

N/A

# 144. SODIUM VALPROATE 100MG INJ

#### SALIENT ACTIONS:

Valproate is a generic term used to describe valproic acid, its salts and derivatives. It is available in various forms including the sodium salts (valproate semisodium and sodium valproate), the amide derivative (valpromide), or as valproic acid. Valproate is a carboxylic acid anticonvulsant. It has been suggested that its antiepileptic activity is related to increased brain levels of  $\gamma$ -aminobutyric acid (GABA).

#### INDICATIONS & DOSAGE REGIMENS:

Adult: PO Migraine prophylaxis Initial: 250 mg bid. Max: 1 g/day; extended-release 500 mg once daily for 7 days, increased to 1 g once daily. Usual dose: 500-1000 mg/day. Acute manic episodes of bipolar disorder As valproate semisodium: Initial: 750 mg/day in divided doses, increase as needed based on response. Max: 60 mg/kg/day. Complex partial seizures As valproic acid or valproate semisodium: ≥10 yrInitial: 10-15 mg/kg/day in 2-4 divided doses, increase if needed. Max: 60 mg/kg/day. As Na valproate: 600 mg/day in 2 divided doses, increase if needed. Usual: 1-2 g/day. Max: 2.5 g/day. Simple and complex absence seizures As monotherapy, conversion to monotherapy or adjunctive therapy. As valproic acid or valproate semisodium: ≥10 yr Initial: 15 mg/kg/day in 2-4 divided doses, increase if needed. Max: 60 mg/kg/day. Bipolar disorder As valpromide: 0.6-1.8 g/day in 2 divided doses. Usual: 1.2 g/day. May increase slowly to reach optimal dose w/ simultaneous and progressive dose reduction of concurrent psychotropic drugs. IV Complex partial seizures; Simple and complex absence seizures As monotherapy, conversion to monotherapy or adjunctive therapy. As Na valproate: Initial: 10-15 mg/kg/day, increase slowly until control is achieved. Usual: 20-30 mg/kg/day. Daily doses to be given in 2-4 divided doses. Max: 60 mg/kg/day.

#### INTERACTIONS:

Increased risk of toxicity w/ bupropion. Increased risk of convulsions w/ mefloquine. Increased risk of carnitine deficiency w/ pivmecillinam and pivampicillin. Increased risk of hepatotoxicity and carbamazepine toxicity w/ a decrease in valproic acid levels w/ concurrent carbamazepine. Decreased valproic acid and increased ethosuximide serum levels w/ ethosuximide. Decreased valproic acid levels w/ carbapenems, rifampicin, phenytoin, phenobarbital (or primidone) and antineoplastic drug regimens. Increased valproic acid levels w/ felbamate and aspirin. Increased risk of hepatotoxicity w/ olanzepine. Concurrent use increased phenobarbital, nimodipine, nifedipine, lamotrigine, zidovudine, amitriptyline, nortriptyline and benzodiazepines levels. Concurrent use decreased tigabine and clozapine levels. Increased risk of absence status w/ clonazepam. Increased risk of hyperammonaemia w/ topiramate. Increased free valproic acid concentrations w/ highly protein bound drugs.

Potentially Fatal: Concomitant carbapenem is not recommended as this may decrease valproate levels. Avoid concurrent salicylates in childn <3 yr due too risk of hepatotoxicity. Increased risk of hepatotoxicity w/ cosyntropin. Avoid ethanol as this may increase CNS depression.

#### PRECAUTIONS:

Increased risk of hepatotoxicity in childn <2 yr, congenital metabolic disorders, organic brain disease or severe seizure disorders. HIV or cytomegalovirus (CMV) infection; SLE. Decrease dose or discontinue in patients w/ excessive somnolence, decreased food or fluid intake. Gradual withdrawal or transition to and from another type of antiepileptic therapy. Suspect hyperammonemic encephalopathy and measure ammonia levels in patients who develop unexplained lethargy, vomiting or changes in mental status. Immobilised patients or those who have insufficient sun exposure or calcium intake should consider vitamin supplementation. Decrease GI side effects by taking w/ meals, starting w/ low dose or taking the enteric coated formulations. Lactation. Patient Counselling Seek medical advice during first signs of pancreatitis (e.g. abdominal pain, nausea, vomiting and anorexia), blood and liver toxicity. Monitoring Parameters Monitor LFT before and during the 1st 6 mth of therapy. Monitor blood cell count (including platelet count), bleeding time and coagulation tests before the start of therapy or before surgery, and in cases of spontaneous bruising or bleeding. Monitor for atypical behaviour (e.g. suicidal ideation and behaviour) during and after therapy.

# **CONTRAINDICATIONS:**

Preexisting or family history of hepatic dysfunction, active liver disease, porphyria; mitochondrial and urea cycle disorders. Hepatic impairment. Pregnancy.

#### ADVERSE EFFECTS:

Headache, nausea, vomiting, diarrhoea, anorexia, increased appetite, wt gain, nystagmus, somnolence, dizziness, fatigue, hyperammonaemic encephalopathy, hypothermia, hallucinations. Thrombocytopenia (dose related), tremors, LFT elevation. Chronic use may lead to carnitine deficiency.

Potentially Fatal: Fatal hepatotoxicity esp in childn <2 yr, multi-organ and dermatologic hypersensitivty reactions (e.g. Stevens-Johnson syndrome, erythema multiforme), pancreatitis, blood dyscrasias.

# 145. STREPTOKINASE Inj 1500000 IU/vial

#### SALIENT ACTIONS:

Streptokinase forms a complex with plasminogen which then converts plasminogen to plasmin. Plasmin breaks down clots as well as fibrinogen and other plasma proteins.

#### INDICATIONS:

Acute myocardial infarction, Pulmonary thromboembolism, Arteriovenous occlusions

#### DOSAGE REGIMENS:

1.Acute myocardial infarction- 1.5 million units as a single dose infused over 1 hr immediately after onset of symptoms

2.Pulmonary thromboembolism -Loading dose: 250,000 units infused over 30 min. Maintenance: 100,000 units/hr for 24-72 hr depending on the condition to be treated.

3. For cerebral retinal thrombosis - 12 hr may be sufficient. Monitor treatment by maintaining thrombin clotting time at 2-4 times normal values.

4.Arteriovenous occlusions- Loading dose: 250,000 units infused over 30 min. Maintenance: 100,000 units/hr for 24-72 hr depending on the condition to be treated.

#### CONTRAINDICATIONS:

Severe hypertension, recent stroke, cerebral neoplasm, recent history of peptic ulcer disease, ulcerative colitis, pancreatitis, subacute bacterial endocarditis, coagulation defects also due to liver or kidney disease, recent surgery, childbirth. Hypersensitivity, increased risk of cerebral bleeding, trauma. Pregnancy. Active internal bleeding, bleeding GI lesions.

#### PRECAUTIONS:

Mitral stenosis associated with AF, Streptokinase treatment within last 12 mth, Use after prolonged or traumatic CPR, diabetic retinopathy, Elderly.

#### INTERACTIONS:

Antagonistic effects with antifibrinolytic agents e.g. aminocaproic acid.

Potentially Fatal: Increase risk of haemorrhage with anticoagulants and antiplatelets

#### ADVERSE EFFECTS:

Fever, chills, back pain, abdominal pain, nausea, vomiting, arrhythmia, bruising, rash, pruritus, acute renal failure due to embolism and haemorrhage. Cerebral, peripheral and pulmonary embolism. Allergic reactions, liver enzyme abnormalities, hypotension.

Potentially Fatal: Haemorrhage; anaphylactic shock

#### 146. STREPTOMYCIN INJ

#### SALIENT ACTIONS:

Streptomycin inhibits bacterial protein synthesis by binding directly to the 30S ribosomal subunits causing faulty peptide sequence to form in the protein chain.

Absorption: Not absorbed from the GI tract. Rapidly absorbed (IM). Time to peak plasma concentration: 0.5-2 hr.

Distribution: Rapidly distributed into most body tissues and fluids except the brain. Crosses the placenta and enters breast milk. Plasma protein binding: Approx  $^{1}/_{3}$  of the drug in circulation.

Excretion: Via urine, approx 30-90% as unchanged drug. Half-life: Approx 2.5 hr.

#### INDICATIONS & DOSAGE REGIMENS:

Intramuscular

Tuberculosis

Adult: 15 mg/kg as a single dose daily. Max: 1 g daily. As part of intermittent regimen: 25-30 mg/kg 2-3 times wkly. Max: 1.5 g/dose.

Child: 20-40 mg/kg as a single dose daily. Max: 1 g daily. As part of intermittent regimen: 25-30 mg/kg 2-3 times wkly. Max: 1.5 g/dose.

Elderly: >40 yr Max: 500-750 mg daily.

Renal impairment: Dosage adjustment needed.

Reconstitution: Add 4.2 mL, 3.2 mL, or 1.8 mL of sterile water for inj to prepare a soln containing approx 200 mg, 250 mg, or 400 mg, respectively, of streptomycin per mL.

Intramuscular

Bacterial endocarditis

Adult: Streptococcal endocarditis: 1 g bid for 1 wk, then 500 mg bid for the 2nd wk. Enterococcal endocarditis: 1 g bid for 2 wk then 500 mg bid for 4 wk. Doses are given in combination w/ penicillin.

Child: Enterococcal endocarditis: 20-30 mg/kg daily in 2 divided doses, in combination w/ penicillin.

Elderly: Streptococcal endocarditis: >60 yr 500 mg bid for the entire 2 wk period.

Renal impairment: Dosage adjustment needed.

Reconstitution: Add 4.2 mL, 3.2 mL, or 1.8 mL of sterile water for inj to prepare a soln containing approx 200

mg, 250 mg, or 400 mg, respectively, of streptomycin per mL.

Intramuscular

Bacteraemia

Adult: For concomitant use w/ other agents and as 2nd line agent: 1-2 g daily in divided doses 6-12 hrly. Max: 2 daily.

Child: 20-40 mg/kg daily in divided doses 6-12 hrly.

Renal impairment: Dosage adjustment needed.

Reconstitution: Add 4.2 mL, 3.2 mL, or 1.8 mL of sterile water for inj to prepare a soln containing approx 200 mg, 250 mg, or 400 mg, respectively, of streptomycin per mL.

Intramuscular

Meningitis

Adult: For concomitant use w/ other agents and as 2nd line agent: 1-2 g daily in divided doses 6-12 hrly. Max: 2 daily.

Child: 20-40 mg/kg daily in divided doses 6-12 hrly.

Renal impairment: Dosage adjustment needed.

Reconstitution: Add 4.2 mL, 3.2 mL, or 1.8 mL of sterile water for inj to prepare a soln containing approx 200 mg, 250 mg, or 400 mg, respectively, of streptomycin per mL.

Intramuscular

Pneumonia

Adult: For concomitant use w/ other agents and as 2nd line agent: 1-2 g daily in divided doses 6-12 hrly. Max: 2 daily.

Child: 20-40 mg/kg daily in divided doses 6-12 hrly.

Renal impairment: Dosage adjustment needed.

Reconstitution: Add 4.2 mL, 3.2 mL, or 1.8 mL of sterile water for inj to prepare a soln containing approx 200 mg, 250 mg, or 400 mg, respectively, of streptomycin per mL.

Intramuscular

Brucellosis

Adult: For concomitant use w/ other agents and as 2nd line agent: 1-2 g daily in divided doses 6-12 hrly. Max: 2 daily.

Child: 20-40 mg/kg daily in divided doses 6-12 hrly.

Renal impairment: Dosage adjustment needed.

Reconstitution: Add 4.2 mL, 3.2 mL, or 1.8 mL of sterile water for inj to prepare a soln containing approx 200 mg, 250 mg, or 400 mg, respectively, of streptomycin per mL.

Intramuscular

Urinary tract infections

Adult: For concomitant use w/ other agents and as 2nd line agent: 1-2 g daily in divided doses 6-12 hrly. Max: 2 daily.

Child: 20-40 mg/kg daily in divided doses 6-12 hrly.

Renal impairment: Dosage adjustment needed.

Reconstitution: Add 4.2 mL, 3.2 mL, or 1.8 mL of sterile water for inj to prepare a soln containing approx 200 mg, 250 mg, or 400 mg, respectively, of streptomycin per mL.

Intramuscular

Plague

Adult: 2 g daily in 2 divided doses for a minimum of 10 days.

Child: 30 mg/kg daily in 2-3 divided doses. Max: 2 g daily.

Renal impairment: Dosage adjustment needed.

Reconstitution: Add 4.2 mL, 3.2 mL, or 1.8 mL of sterile water for inj to prepare a soln containing approx 200 mg, 250 mg, or 400 mg, respectively, of streptomycin per mL.

Intramuscular

Tularaemia

Adult: 1-2 g daily in divided doses for 7-14 days until the patient is afebrile for 5-7 days.

Child: 15 mg/kg bid for at least 10-14 days. Max: 2 g daily.

Renal impairment: Dosage adjustment needed.

Reconstitution: Add 4.2 mL, 3.2 mL, or 1.8 mL of sterile water for inj to prepare a soln containing approx 200 mg, 250 mg, or 400 mg, respectively, of streptomycin per mL.

INTERACTIONS:

Additive neurotoxic and nephrotoxic effect w/ neomycin, kanamycin, gentamicin, cefaloridine, paronomycin, viomycin, polymyxin B, colistin, tobramycin, and ciclosporin. Enhanced ototoxic and nephrotoxic effect w/ ethacrynic acid, mannitol, furosemide and possibly other diuretics. May enhance the resp depressant effect of neuromuscular blockers. Increased risk of nephrotoxicity w/ cephalosporins. Reduced excretion w/ NSAIDs.

#### PRECAUTIONS:

Patient w/ neuromuscular disorders (e.g. myasthenia gravis), pre-existing vertigo, or hearing loss. Renal impairment. Elderly, childn. Pregnancy and lactation. Monitoring Parameters Monitor renal and auditory function.

# CONTRAINDICATIONS:

Hypersensitivity to streptomycin and other aminoglycosides.

#### ADVERSE EFFECTS:

Neurotoxic reactions (e.g. vestibular and cochlear function disturbance, optic nerve dysfunction, peripheral neuritis, arachnoiditis, encephalopathy); paraesthesia of face, rash, fever, angioneurotic oedema, eosinophilia; exfoliative dermatitis, azotemia, leucopenia, thrombocytopenia, pancytopenia, haemolytic anaemia, muscular weakness, amblyopia.

Potentially Fatal: Resp paralysis from neuromuscular blockade, Clostridium difficile-associated diarrhoea, anaphylaxis; rarely, nephrotoxicity.

# 147. SUCCINYLCHOLINE CHLORIDE Inj 50 mg/ml, 10 ml vial

#### SALIENT ACTIONS:

Succinyl chloride is an ultrashort-acting depolarising type skeletal muscle relaxant. It blocks the neuromuscular junction by binding to the cholinergic receptors and depolarising it.

#### INDICATIONS:

Muscle relaxant in general anaesthesia

#### DOSAGE REGIMENS:

Adult: as chloride: single dose of 0.3-1.1 mg/kg injected; supplementary doses of 50-100% of the initial dose may be given at 5-10 min intervals. Max dose (repeated IV injection or continuous infusion): 500 mg/hr Child: as chloride: <1 yr: 2 mg/kg; 1-12 yr: 1 mg/kg.

#### CONTRAINDICATIONS:

Genetic disorders of plasma pseudocholinesterase, personal/family history of malignant hyperthermia, hypersensitivity from previous neuromuscular drug, severe burns, massive trauma, extensive denervation of skeletal muscle, patients with risk of hyperkalaemia, renal impairment, angle closure glaucoma

#### PRECAUTIONS:

Bone fracture, raised intraocular pressure, neuromuscular disease, infants, children, adolescents, pregnancy and lactation.

#### INTERACTIONS:

Concurrent use with anticholinesterases, cyclophosphamide, antiarrhythmics, aminoglycosides, lincosamides (clindamycin and lincomycin), anticonvulsants, phenelzine, magnesium, metoclopramide, inhalation anaesthetics, exposure to organophosphate insecticides may enhance neuromuscular block of suxamethonium. Increased risk of arrhythmias with cardiac glycosides.

#### ADVERSE EFFECTS:

Bradycardia, tachycardia, hypotension, hyperpertension, raised intraocular pressure, hyperkalaemia, excessive salivation. *Potentially Fatal:* Respiratory depression, dysrhythmias, rhabdomyolsis, malignant hyperthermia.

#### 148. TERLIPRESSIN INJ.1MG/10ML

#### SALIENT ACTIONS:

Terlipressin, a synthetic triglycyl-lysine derivative of vasopressin, is a inactive prodrug. It has pressor and antidiuretic effects. Following IV injection, lysine vasopressin are released following the enzymatic cleavage of 3 glycyl moieties.

Duration: 4-6 hr.

# INDICATIONS & DOSAGE REGIMENS:

Intravenous

Acute oesophageal variceal haemorrhage

Adult: Initially, 2 mg followed by 1 or 2 mg every 4-6 hr until bleeding is controlled, for up to 72 hr.

#### INTERACTIONS:

N/A

#### PRECAUTIONS:

Patients with hypertension, artherosclerosis, cardiac disorders, conditions which may be aggravated by water retention, eg. heart failure.

#### CONTRAINDICATIONS:

Hypersensitivity, vascular disease esp coronary artery disease, chronic nephritis (until normal blood-nitrogen conc attained). Pregnancy.

#### ADVERSE EFFECTS:

Abdominal cramps, cardiac arrhythmias, headache, transient blanching, increased arterial pressure. Potentially Fatal: MI, cardiac failure.

# 149. TETANUS TOXOID Inj 5ml (10 doses), 5 ml vial

#### **SALIENT ACTIONS:**

Tetanus toxoid and tetanus toxoid adsorbed induces active immunity to the tetanus antigen by stimulating the immune system to produce specific antitoxin

# INDICATIONS:

Active immunisation against tetanus

#### DOSAGE REGIMENS:

1.Primary immunisation (using tetanus toxoid adsorbed via deep IM Inj): 3 doses of 0.5 ml each; 2nd dose is given 4-8 wk after the 1st dose and the 3rd dose is given 6-12 mth after the 2nd dose. Booster dose (using tetanus toxoid via IM/SC or tetanus toxoid adsorbed via deep IM): 0.5 ml every 10 yr. Pregnant women who have not completed primary vaccination against tetanus: if insufficient time, 2 doses at least 4 wk apart (wait until second trimester to reduce risk to foetus), and 2<sup>nd</sup> dose at least 2 wk before delivery.

2.Postexposure prophylaxis of tetanus: Emergency booster dose of 0.5 ml tetanus toxoid (IM/SC) or tetanus toxoid adsorbed (Deep IM Inj) to be given: if previously received <3 doses of a tetanus

#### **CONTRAINDICATIONS:**

Guillian-Barre syndrome

# PRECAUTIONS:

Do not administer IV. Use subcutaneous route in bleeding disorders. Withhold vaccination in moderate or severe febrile illness. Pregnancy, lactation

#### INTERACTIONS:

Decreased immunologic response with concurrent immunosuppressants. Neutralisation of tetanus immune globulin and tetanus toxoid adsorbed if not given at different sites using different syringes

#### ADVERSE EFFECTS:

Mild injection site reactions eg transient swelling, rash, fever, malaise, tiredness, nausea, vomiting, arthralgias, pruritus, dizziness. *Potentially Fatal:* Anaphylactic reactions

# 150. TEICOPLANIN Inj 400 mg/ vial

#### SALIENT ACTIONS:

Glycopeptide antibiotic, more active in vitro against enterococci and some anaerobic organisms but some coagulase-negative Staphylococci are less sensitive to teicoplanin than to vancomycin.

#### INDICATIONS:

Severe Gram-positive infections, Prophylaxis of Gram-positive infection in high-risk patients undergoing surgery, Continuous ambulatory peritoneal dialysis (CAPD)-associated peritonitis

#### DOSAGE REGIMENS:

1.Severe Gram-positive infections: 6 mg/kg on first day, followed by 3 mg/kg/day. Severe infection: 6 mg/kg every 12 hr for the 1st 3 doses followed by 6 mg/kg/day.,given via IM inj, IV bolus or IV infusion over 30 minutes. *Child:* Loading dose: 10 mg/kg every 12 hr for 3 doses followed by 6-10 mg/kg/day depending on severity of the infection. Neonates: Loading dose: 16 mg/kg on the 1st day, followed by maintenance doses of 8 mg/kg/day by IV infusion.

2. Prophylaxis of Gram-positive infection in high-risk patients undergoing surgery- 400 mg as single dose at induction of anesthesia.

3. Continuous ambulatory peritoneal dialysis (CAPD)-associated peritonitis- patient is febrile, an initial loading dose of 400 mg may be given. Teicoplanin is added to the dialysis solution at a concentration of 20 mg/litre; dose is added into each bag of solution in the first wk, followed by alternate bags in the second wk and then in the overnight dwell bag in the third wk. Dose adjustment may be required in renal impairment

# CONTRAINDICATIONS:

Hypersensitivity.

# PRECAUTIONS:

Preexisting renal insufficiency, hypersensitivity to vancomycin. Perform periodic haematological studies, renal, LFT. Pregnancy, lactation

#### INTERACTIONS:

Other nephrotoxic and/or neurotoxic drugs.

# ADVERSE EFFECTS:

Fever, chills, allergic reactions, GI disturbances, headache, dizziness, "red-man" syndrome, disturbances in liver enzymes, renal impairment, ototoxicity, blood dyscrasias. Pain, erythema, thrombophloebitis, abscess at site of admin. Potentially Fatal: Stevens-Johnson syndrome, toxic epidermal necrolysis.

# 151. THIAMIN HCL INJ

# SALIENT ACTIONS:

Thiamine, a water soluble vitamin, combines with ATP to form thiamine pyrophosphate, an essential coenzyme in carbohydrate metabolism.

Absorption: Well-absorbed from the GI tract after oral admin and rapidly and completely absorbed following IM administration

Distribution: Widely distributed in most body tissues; enters breastmilk.

Excretion: Excess thiamine is excreted in the urine as metabolites and unchanged drug.

# INDICATIONS & DOSAGE REGIMENS:

Parenteral

Wernicke-Korsakoff syndrome

Adult: Initially, 100 mg by slow IV Inj over 10 min, then 50-100 mg/day IM or IV until the patient can take oral

Incompatibility: Alkaline or neutral solutions and with oxidizing and reducing agents.

# INTERACTIONS:

May enhance the effect of neuromuscular blocking agents.

# PRECAUTIONS:

Parenteral admin. Increased daily requirements in pregnancy and lactation.

# CONTRAINDICATIONS:

N/A

# ADVERSE EFFECTS:

IV: Warm sensation, tingling, pruritus, pain, urticaria, weakness, sweating, nausea, restlessness, tightness of the throat, angioedema, respiratory distress, cyanosis, pulmonary oedema, GI bleeding, transient vasodilation and hypotension, vascular collapse. IM: Tenderness and induration.

Potentially Fatal: Very rarely, fatal anaphylactic shock.

# 152. THIOCOLCHICOSIDE INJ

# SALIENT ACTIONS:

Thiocolchicoside is a muscle relaxant which has been claimed to possess GABA-mimetic and glycinergic

# INDICATIONS & DOSAGE REGIMENS:

Intramuscular

Muscle spasms

Adult: Up to 8 mg daily.

INTERACTIONS: N/A

PRECAUTIONS:N/A

CONTRAINDICATIONS: N/A

# ADVERSE EFFECTS:

Photosensitivity reactions.

# 153. THEOPHYLINE 25.3 mg AND ETOPHYLLINE 84.7 mg Inj, 2ml ampoule SALIENT ACTIONS:

The applied Preparation is a combination of the ophylline and etophylline in the ratio of 1:3. Etophylline is the hydroxy ethyl ester of theophylline (containing 80% of theopylline by weight). They belong to methyl xanthine group of drugs.

It inhibits phosphodiesterase, which degrades cyclic nucleotides, hence increased amount of intra cellular CAMP molecules causing smooth muscle relaxation. Blockade of adenosine receptors (which enhance release of histamine and other inflammatory mediator and bronchospasm). Overall effect of the drug is to produce. Bronchodilation by bronichial muscle relaxation. Suppression of response of airways to stimuli. Cardiac stimulation (increases heart rate and cardiac output). Respiratory stimulation it also induces diuresis.

#### INDICATIONS

1. Treatment of acute attacks or status asthmaticus in conjunction with other drugs.

Suppression of attacks in chronic asthma.

3. Relief of dyspnoea, bronchospasm in other respiratory disorders like COPD, emphysema.

4. Acute left ventricular failure and pulmonary edema.

#### DOSAGE REGIMEN:

1. In chronic suppressive therapy – dosage should be adjusted so that serum levels are 10 – 20 mg/ml. Adults – 400 – 1600 mg/day in 2 –3 divided doses. Children – 3 –4 mg/kg/dose. Dosage must be individualized to each patient depending on the clinical response. Increase the drug increments of 100 mg every 3 – 4 days.

2. In acute attacks - I.V. infusion of 0.6 mg./kg/hour (in hepatic failure reduce to 0.3 mg/kg/hour). Routes of

Administration Oral, I.V

#### **CONTRAINDICATIONS:**

Hypersensitivity, Uncontrolled arrhythmias, Hyperthyrodism, Active peptic ulcer, Uncontrolled seizure disorders, Prophyria.

# PRECAUTION:

Measurement of serum theophylline levels should be done. During initiation of therapy for guiding the maintenance dose. When on long-term therapy, if there are any signs of toxicity. When theophylline needs are altered as in never, stress and hepatitis. Dosage is to be reduced instates of decreased thephylline clearance like in hepatic dysfunction, elderly, children and neonates and presence of concurrent diseases, which reduce clearance of thephylline such as CCF, pulmonary edema, sepsis and shock (decreased hepatic blood flow). Fever, hypothyrodiam (altered binding to plasma proteins) Smokers have increased clearance of theophylline hence they need large doses. Nursing should be avoided because it is secreted in milk and may cause CNS stimulation in the infant. With caution in patients with CNS disorders, epilepsy (CNS stimulatory effects) and seizure disorders. With caution in patients with acid peptic disease (increased gastric acid secretion). Ask patients to report immediately if signs of toxicity like nausea, vomiting, insomnia, nervousness, tremor and palpitation occurs.

#### Administration instructions:

- Adverse them to stick to the schedule of dosage, it time of day and along with food. I.V. injections should be given slowly (not more than 25 mg/min) to prevent dangerous CNS and CVS effects resulting from direct stimulation of the respective systems. Should not be given I.M or S.C as severe tissue irritation may occur. Administer round the clock to prevent variation in serum levels and clinical effects.

#### DRUG INTERACTIONS:

Potentially fatal: Ciprofloxacin, erythromycin, clarithromycin, fluconazole, ketoconazole. Didulfiram, estogen contain oral contraceptive pills, pentoxphylline, ticlopidine, methotrexate, propofenone, diltiazem, and verapmil. Allopurinol, fluvoxamine.

Halothane sensitizes the myocardium to catecholamines which are released by thephylline (hence risk of arrhythmias). *Non Fatal*: carbamazepine, phenytoin, phenobarbitone, rifampicin and alcohol:increase in dose is required. The ophylline increase lithium excretion. The ophylline may antagonize non-polarizing relaxants. Propranolol antagonizes the effects of the phylline by beta-receptors blockade. Risk of hypokalemia if given with salbutamol, terbutaline.

#### ADVERSE EFFECTS:

They are dose dependent.GIT disturbances like nausea, vomiting, abdominal pain diarrhoea and GI bleeding.CNS effects – insomnia, headache, restlessness.Palpitation, diuresis,Tachycardia,Drug Toxicity,Nausea, persistent repetitive vomiting, sinus tachycardia, arrhythmias (supraventicular , ventricular tachyarhythmias, ectopic beats). Haemodynamic effects like shock, tremors, nervousness, delirium, agitation and seixures can occur. Metabolic effects like hypokalemia, hyperglycemia, and aside base disturbances etc can occur.

# 154. THIOPENTONE SODIUM Inj 500 mg/vial

#### SALIENT ACTIONS:

Thiopental sodium, a short-acting barbiturate anaesthetic, is a CNS depressant inducing hypnosis and anaesthesia but not analgesia.

#### INDICATIONS:

Induction of anaesthesia, Status epilepticus

#### DOSAGE REGIMENS:

1.Induction of anaesthesia -Adult: 100-150 mg of a 2.5 or 5% solution injected over 10-15 sec repeated every 30-60 sec according to response or as a continuous infusion of a 0.2 or 0.4% solution. Max: 500mg. Max in pregnancy: 250mg. Child: 2-7 mg/kg over 10-15 seconds; repeated after 1 minute if needed...

2.Status epilepticus -Adult: In conjunction with assisted ventilation: 75-125 mg as a 2.5% solution. Child: 5 mg/kg by slow IV inj followed by, neonates: continuous iv infusion of 2.5 mg/kg/hr; >1 month: 2-8 mg/kg/hr. Adjust infusion dose according to response.

# CONTRAINDICATIONS:

Porphyria; dyspnoea or respiratory obstruction

#### PRECAUTIONS:

Hypovolaemia; history of severe asthma, severe cardiac disease, severe anaemia, hyperkalaemia, toxaemia, myasthenia gravis, myxoedema; severe renal or hepatic disease; muscular dystrophies, adrenocortical insufficiency; increased intracranial pressure; elderly, pregnancy, lactation.

#### INTERACTIONS:

Increases action with other CNS depressants including sedatives, hypnotics, antisychotics, nitrous oxide or alcohol. Decreased dose with metoclopramide, sulfisoxazole, aspirin, meprobamate, probenecid and other highly protein bound drugs. Potentially Fatal: Increased resp depression with opioids.

#### ADVERSE EFFECTS:

Coughing, hiccupping, sneezing, muscle twitching, laryngospasm, bronchospasm. IV: tissue necrosis (if extravasation occurs). Intra-arterial: Severe arterial spasm with burning pain, blanching of forearm and hands and gangrene of digits thrombophloebitis

Potentially Fatal: Respiratory depression, arrhythmias, circulatory failure and anaphylactoid reactions.

# 155. TORSEMIDE 10MG INJ.

#### SALIENT ACTIONS:

Torasemide, a sulfonylurea loop diuretic, acts from within the lumen of the thick ascending portion of the loop of Henle, where it inhibits the Na<sup>+</sup>/K<sup>+</sup>/2CI-carrier system.

Onset: Diuresis: Oral: Within 1 hr; IV: Within 10 min.

Duration: Diuresis: Oral and IV: 8 hr.

Absorption: Absorbed rapidly and almost completely (oral). Peak serum levels after 1-2 hr. Food decreases rate but not extent of absorption.

Distribution: Protein-binding: >99%. Apparent distribution volume: 16 L.

Metabolism: Metabolised by the cytochrome P450 isoenzyme CYP2C9. Elimination half-life: 3.5 hr.

Excretion: Excreted by urine as unchanged drug (24%) and metabolites.

# INDICATIONS & DOSAGE REGIMENS:

Intravenous

Oedema

Adult: 10-20 mg daily as IV inj slowly over 2 min. Max: 200 mg daily.

#### INTERACTIONS:

Increased risk of severe hypokalaemia with amphotercin B, corticosteroids, carbenoxolone, hypokalaemiacausing medications. Increased risk of lithium toxicity. Increased potential for ototoxicity and nephrotoxicity with nephrotoxic or ototoxic medications e.g. aminoglycosides. High dose salicylates may increase the risk of salicylate toxicity. Increased risk of toxicity with digoxin. Reduced diuretic effect with NSAIDs. Increased risk Of hypotension with antihypertensives.

#### PRECAUTIONS:

Risk of hyperuricaemia, gout and DM. Correct electrolyte distubances and disorders of micturition before treatment. Monitor electrolyte balance, glucose, uric acid, creatinine and lipids regularly. May impair ability to drive or operate machinery.

#### CONTRAINDICATIONS:

Hypersensitivity to sulfonylureas, renal failure with anuria, hepatic coma and pre-coma, hypotension, cardiac arrhythmias. Pregnancy and lactation.

#### ADVERSE EFFECTS:

Electrolyte disturbances e.g. hypokalaemia, dehydration, dry mouth, headache, dizziness, hypotension, weakness, drowsiness, confusional states, loss of appetite, cramps, increased serum uric acid, glucose, lipids, urea and creatinine, increase in LFT, metabolic alkalosis, tinnitus and hearing loss.

#### 156. TRAMADOL Inj 50 mg/ml, 2 ml ampoule

#### SALIENT ACTIONS:

Tramadol inhibits reuptake of norepinephrine, serotonin and enhances serotonin release. It alters perception and response to pain by binding to mu-opiate receptors in the CNS.

#### INDICATIONS:

Moderate to severe pain, Postoperative pain

#### DOSAGE REGIMENS:

Moderate to severe pain: IM/IV inj over 2-3 min/IV infusion: 50-100 mg given every 4-6 hr.

Postoperative pain: IM/IV inj over 2-3 min/IV infusion: Initially, 100 mg followed by 50 mg every 10-20 min if necessary up to 250 mg for the 1st hr. Maintenance: 50-100 mg every 4-6 hr. Max: 600 mg daily.

Elderly: Lower initial dose. Max: 300 mg daily (>75 yr).

#### CONTRAINDICATIONS:

Suicidal patients, acute alcoholism; head injuries; raised intracranial pressure; severe renal impairment; lactation PRECAUTIONS:

Hypothyroidism; adrenocortical insufficiency; renal or hepatic impairment; history of epilepsy or increased risk of seizures; inflammatory or obstructive bowel disease; myasthaenia gravis; respiratory depression; prostatic hyperplasia. Pregnancy.

#### INTERACTIONS:

increase in anticoagulation with warfarin, risk of seizures with SSRI, TCA and risk of serotonin syndrome with mirtazapine, venlafaxine, SSRI and MAOI. Tramadol should not be given to patients receiving MAOIs or within 14 days of their discontinuation. Reduced analgesic efficacy of tramadol with carbamazepine, 5-HT<sub>3</sub>-receptor antagonist e.g. ondansetron. Increased respiratory and CNS depression with CNS depressants e.g. alcohol, opioids, anaesthetic agents, narcotics, phenothiazines, tranquilisers or sedative hypnotics

#### ADVERSE EFFECTS:

Sweating, dizziness, nausea, vomiting, dry mouth, fatigue, asthenia, somnolence, confusion, constipation, flushing, headache, vertigo, tachycardia, palpitations, miosis, insomnia, orthostatic hypotension, seizures, CNS stimulation e.g. hallucinations. *Potentially Fatal:* Respiratory depression.

# 157. TRANEXAMIC ACID Inj 500 mg, 5 ml ampoule

#### **SALIENT ACTIONS:**

Tranexamic acid is an antifibrinolytic agent that competitively inhibits breakdown of fibrin clots. It blocks binding of plasminogen and plasmin to fibrin, thereby preventing haemostatic plug dissolution.

#### INDICATIONS:

Short-term management of hemorrhage

#### DOSAGE REGIMENS:

Adult: 0.5-1 g or 10 mg/kg three times a day or 25-50 mg/kg daily by continuous infusion.

Child: 10 mg/kg 2-3 times a day.

Renal impairment: Adjust dose based on the serum-creatinine concentration: 120-250 micromol/l: 10 mg/kg bid daily; 250-500 micromoles/l: 10 mg/kg once daily; >500 micromol/l: 5 mg/kg once daily or 10 mg/kg once every 48 hr.

#### CONTRAINDICATIONS:

Severe renal failure, active intravascular clotting, thromboembolic disease, colour vision disorders, subarachnoid bleeding.

#### PRECAUTIONS:

Pregnancy and lactation. Mild to moderate renal impairment, irregular menstrual bleeding, previous history of thromboembolic disease, haematuria. Monitor closely in disseminated intravascular coagulation. Monitor LFT and eye examination regularly during long-term use. Discontinue if disturbance in colour vision occurs. Avoid IV inj rate >1 ml/minute due to risk of hypotension.

#### INTERACTIONS:

Increased risk of thrombus formation with estrogens, Factor IX complex concentrates or anti-inhibitor coagulant concentrates. Increased risk of fatal thrombotic complications with tretinoin in acute promyelocytic leukaemia **ADVERSE EFFECTS:** 

Diarrhoea, nausea, vomiting, disturbances in colour vision, giddiness, hypotension (after rapid IV inj), thromboembolic events.

# 158. TRIAMCINOLONE ACETONIDE INJ

#### SALIENT ACTIONS:

Triamcinolone has mainly glucocorticoid activity. It suppresses the migration of polymorphonuclear leukocytes and reduces capillary permeability thereby decreasing inflammation.

#### INDICATIONS & DOSAGE REGIMENS:

Intramuscular

Suppression of allergic and inflammatory disorders

Adult: As acetonide: 20-80 mg via deep IM into gluteal muscles. As diacetate: 40 mg inj.

Child: As acetonide: deep IM into gluteal muscle: initial 0.11 to 1.6 mg/kg/day in 3-4 divided doses. Do not use in premature infants and infants of low birth weight as it contains benzyl alcohol.

Intramuscular

Symptomatic control for hay fever

Adult: As acetonide: 40-100 mg via deep IM into gluteal muscles. As diacetate: 40 mg wkly.

Child: As acetonide: deep IM into gluteal muscle: initial 0.11 to 1.6 mg/kg/day in 3-4 divided doses. Do not use in premature infants and infants of low birth weight as it contains benzyl alcohol.

Intra-articular

Inflammatory joint diseases

Adult: As acetonide: Smaller joints: 2.5-5 mg (up to 10 mg), larger joints: 5-15 mg (up to 40 mg). Max: 20-80 mg/treatment. As hexacetonide: Initial: 2-20 mg/day.

#### INTERACTIONS:

Lowering of plasma salicylates levels. Increased risk of GI bleeding and ulceration with NSAIDs. Antagonised blood glucose-lowering effects of the antidiabetics. Increased risk of hyperkalaemia with amphotericin B,  $\beta$  agonists,  $\beta$ -blockers, potassium-depleting diuretics, theophylline. Increased clearance of the triamcinolone with ciclosporin, carbamazepine, phenytoin, barbiturate, rifampicin. Infections may develop if given with live vaccines.

#### PRECAUTIONS:

Diabetes; hypertension, renal and liver impairment; glaucoma; psychosis; delayed tissue healing; cirrhosis; heart failure; recent MI; hypothyroidism; osteoporosis; peptic ulceration; thromboembolic disorders. Monitor height in children on prolonged therapy. Avoid rapid drug withdrawal. Elderly, children, pregnancy, lactation.

#### CONTRAINDICATIONS:

Untreated systemic fungal, bacterial, viral or parasitic infection, hypersensitivity. Neonates (Parenteral)

#### ADVERSE EFFECTS:

HPA axis supression, intracranial hypertension, Cushing's syndrome, growth retardation in children; osteoporosis, fractures. Peptic ulceration; glaucoma; hyperglycaemia; GI upsets; increased appetite; increased fragility of skin; behavioural changes. Topical: Systemic absorption if applied to large areas, broken skin or under occlusive dressing.

Potentially Fatal: Acute adrenal insufficiency may be precipitated by infection or trauma in patients on long-term corticosteroid therapy or rapid withdrawal.

#### 159. UROFOLLITROPIN INJ

#### SALIENT ACTIONS:

Urofollitropin, a gonadotrophin obtained from postmenopausal women's urine, possesses follicle-stimulating hormone (FSH) activity but almost no luteinising activity. Admin for 7-12 days results in follicular growth and maturation in females. When sufficient follicular maturation has occurred, human chorionic gonadotrophin should be given to induce ovulation.

Absorption: Peak plasma concentration: 10 hr (after multiple dosing).

# INDICATIONS & DOSAGE REGIMENS:

Injection

Polycystic ovarian syndrome

Adult: Initially, 150 IU daily SC/IM for the first 5 days. Adjust subsequent dosing based on clinical monitoring (e.g. serum oestradiol levels and vaginal ultrasound). Dose adjustments should not be made more frequently than once every 2 days and be ≤75-150 units per adjustment. Max dose: 450 units daily and max course of treatment: 12 days. Stop treatment when adequate response obtained as determined by oestrogen monitoring or ultrasonic visualisation of follicles. A single dose of chorionic gonadotrophin 5000 to 10 000 units is given to induce ovulation after 1-2 days. Urofollitropin treatment may be tried again in future cycles.

Female infertility

Adult: Initially, 150 IU daily SC/IM for the first 5 days. Adjust subsequent dosing based on clinical monitoring (e.g. serum oestradiol levels and vaginal ultrasound). Dose adjustments should not be made more frequently than once every 2 days and be ≤75-150 units per adjustment. Max dose: 450 units daily and max course of treatment: 12 days. Stop treatment when adequate response obtained as determined by oestrogen monitoring or ultrasonic visualisation of follicles. A single dose of chorionic gonadotrophin 5000 to 10 000 units is given to induce ovulation after 1-2 days. Urofollitropin treatment may be tried again in future cycles.

Injection

In vitro fertilisation procedures or other assisted conception techniques

Adult: In conjunction with other agents: 150-225 units of FSH daily SC/IM from day 2 or 3 of menstrual cycle. Alternatively, begin therapy with clomifene citrate and continue with urofollitropin; or urofollitropin may be given after gonadorelin analogue is given to suppress gonadotrophin release. Continue treatment until an adequate response is obtained and admin 5000 to 10 000 units of chorionic gonadotrophin 1-2 days after final injection of urofollitropin. Oocyte retrieval is performed 34-35 hr later.

Injection

Male infertility

Adult: In conjunction with chorionic gonadotrophin, 150 units of FSH SC/IM 3 times a wk, continue for at least 4 mth.

#### INTERACTIONS:

Increased risk of ovarian hyperstimulation syndrome with drugs with luteinising hormone activity.

#### PRECAUTIONS:

May result in multiple pregnancies. Abnormal genital bleeding, hormone sensitive malignancies, ovarian cysts not caused by polycystic ovary syndrome. Exclude and treat other causes of infertility e.g. pituitary or hypothalamic lesions, adrenal or thyroid disorders and hyperprolactinaemia.

#### CONTRAINDICATIONS:

Pregnancy, ovarian cysts or enlargement not due to polycystic ovary syndrome, primary ovarian failure, organic intracranial lesion e.g. pituitary tumour, uncontrolled thyroid and adrenal dysfunction, presence of any cause of infertility other than anovulation, abnormal bleeding of undetermined origin.

#### ADVERSE EFFECTS:

Nausea, vomiting, joint pain, ovarian hyperstimulation syndrome, adnexal torsion, mild to moderate ovarian enlargement, abdominal pain, ovarian cysts, local reaction at inj site, headaches, haemoperitoneum, benign and malignant ovarian neoplasms, ascites, pleural effusion, hypovolaemia, thromboembolic disorders. Weight gain, acne and gynaecomastia in men.

Potentially Fatal: Ovarian cysts rupture, intraperitoneal haemorrhage.

# 160. UROKINASE 5LAKH INJ

#### SALIENT ACTIONS:

#### INDICATIONS & DOSAGE REGIMENS:

Intravenous

Deep vein thrombosis

Adult: Initially, 4400 units/kg dissolved in 15 ml of sodium chloride 0.9%, infused IV over 10 minutes followed by 4400 units/kg/hr for 12-24 hr.

Parenteral

Acute myocardial infarction

Adult: 6000 units/min infused into the coronary artery for 2 hr preceded by IV heparin. Alternatively, 2-3 million units IV is given over 45-90 min.

Intravenous

Peripheral arterial thromboembolism

Adult: As solution containing 2000 units/ml: Infuse into the clot via a catheter at a rate of 4000 units/minute for

2 hr. Monitor response using angiography. If clot is not removed, advance the catheter into the occluded vessel and continue infusion at the same rate for another 2 hr. May repeat procedure, if needed, up to 4 times. Once blood flow is re-established, partially withdraw the catheter and continue infusing at 1000 units/minute until the remaining clot has lysed.

Intravenous

Pulmonary embolism

Adult: Initially, 4400 units/kg dissolved in 15 ml sodium chloride 0.9%, infused over 10 min followed by 4400 units/kg/hr for 12 hr. Alternatively, 15000 units/kg as bolus Inj into the pulmonary artery; may repeat inj, adjust dose according to plasma fibrinogen concentrations up to 3 times in 24 hr. Injection

Clearance of occluded catheters and shunts

Adult: 5000 - 25000 units in 2 ml sodium chloride 0.9% instilled into affected IV catheter or shunt and clamped for up to 4 hr. Aspirate the lysate and repeat the procedure if needed. Alternatively, infuse a solution containing 5000 units of urokinase in 200 mL of sodium chloride 0.9% into the device over 30 minutes.

Break down of clots in hyphaema

Adult: To prepare the solution: Dissolve 5000 units in 2 ml of sterile distilled water. Irrigate the anterior chamber slowly with 0.3 ml of the solution; leave solution in situ for 3 minutes and then wash out with saline. Repeat procedure 5 times. If residual clot is still present at the end of the treatment, leave 0.3 ml of the solution in the anterior chamber for 24-48 hr.

#### INTERACTIONS:

Reduced thrombolytic effect when given again some time later due to development of high levels of antibodies. Potentially Fatal: Platelet inhibitors eg, aspirin and indometacin can potentiate the action of urokinase and cause haemorrhage. Heparin and oral anticoagulants may increase risk of bleeding.

#### PRECAUTIONS:

Any vascular punctures or invasive procedures should be avoided as far as possible during, and immediately before and after urokinase therapy and if unavoidable done with great care. External chest compression. Caution in conditions eg, possibility of left heart thrombus, subacute bacterial endocarditis, coagulation defects, cerebrovascular disease, diabetic retinopathy and any conditions in which bleeding could be dangerous. Monitor for reperfusion arrhythmias when used in MI.

#### CONTRAINDICATIONS:

Active internal bleeding; history of cerebrovascular accident; recent (within 2 mth) trauma of any kind including surgery; aneurysm; known bleeding diathesis; severe uncontrolled hypertension. Recent history of peptic ulcer disease, oesophageal varices, ulcerative colitis or other bleeding GI lesions; pancreatitis; subacute bacterial endocarditis; coagulation defects including those due to liver or kidney disease, or after recent surgery, childbirth or trauma. Increased risk of cerebral bleeding e.g. recent stroke or cerebral neoplasm. Pregnancy.

#### ADVERSE EFFECTS:

Bleeding, pyrexia, haematuria, thromboembolic episodes, hypersensitivity reactions. Potentially Fatal: Severe bleeding, anaphylaxis.

# 161. VALETHAMATE BROMIDE INJ

#### SALIENT ACTIONS:

A quaternary ammonium anticholinergic with peripheral actions close to those of atropine INDICATIONS & DOSAGE REGIMENS:

Parenteral

Dysmenorrhoea

Adult: 8-16 mg daily, via IM or IV inj.

Parenteral

Visceral spasms

Adult: 8-16 mg daily, via IM or IV ini.

Parenteral

Gastrointestinal tract spasm

Adult: 8-16 mg daily, via IM or IV inj.

Parenteral

Urinary tract and bile stone colic

Adult: 8-16 mg daily, via IM or IV inj.

#### INTERACTIONS:

Increased antimuscarinic side effects with drugs with antimuscarinic properties e.g. amantadine, antihistamines, phenothiazide antipsychotics, TCAs. Antagonise GI effects of domperidone, metoclopramide. Delayed gastric emptying reduces absorption of other drugs.

#### PRECAUTIONS:

May impair ability to drive or operate machinery at high doses.

#### CONTRAINDICATIONS:

Narrow angle glaucoma, benign prostatic hyperplasia, paralytic ileus, pyloric stenosis, ulcerative colitis, megacolon, tachyarrhythmia. Severe hepatic and renal impairment.

#### ADVERSE EFFECTS:

Dry mouth, blurring of vision, difficulty in swallowing and talking, constipation, urinary retention, mydriasis, arrhythmias.

#### 162. VANCOMYCIN Inj 500 mg/vial

#### SALIENT ACTIONS:

Glycopeptide antibiotic, is used in the treatment of severe staphylococcal or other gram positive infections where other drugs cannot be used due to resistance or intolerance.

#### INDICATIONS:

Severe staphylococcal or other Gram-positive infections, Osteomyelitis, Septicaemia, Soft tissue infections, Prophylaxis of endocarditis

#### DOSAGE REGIMENS:

Adult: 500 mg every 6 hr infused over at least 60 minutes or 1 g every 12 hr infused over 100 minutes. Child: Various dosing regimens available. By IV infusion over at least 60 minutes: Neonates: <29 wk postmenstrual age: 15 mg/kg every 24 hr; 29-35 wk postmenstrual age: 15 mg/kg every 12 hr; >35 wk postmenstrual age: 15 mg/kg every 8 hr. 1 mth-18 yr: 15 mg/kg every 8 hr (max: 2 g daily), adjusted according to plasma concentrations.

#### CONTRAINDICATIONS:

Hypersensitivity to the drug; history of impaired hearing; IM administration

#### PRECAUTIONS:

Renal impairment; neonates, elderly, pregnancy and lactation. Monitor renal function, blood counts and auditory functions regularly. Discontinue if tinnitus develops.

#### INTERACTIONS:

Increased nephrotoxicity with concomitant aminoglycosides, cisplatin, NSAIDs, amphotericin B, polymycin B, colistin or other nephrotoxic agents. Increased neuromuscular blockade with concomitant use of suxamethonium or vecuronium. Increased risk of ototoxicity with other aminoglycoside antibiotics, loop diuretics and ethacrynic acid. Increased risk of toxicity with methotrexate. Decreased vancomycin levels withdopamine, dobutamine. Increased risk of neutropenia with zidovudine.

#### ADVERSE EFFECTS:

Ototoxicity, nephrotoxicity, eosinophilia, "red-man" syndrome (e.g. flushing, hypotension, erythema), urticaria, thrombophloebitis, hypersensitivity reactions.

Potentially Fatal: Stevens-Johnson syndrome; toxic epidermal necrolysis, blood dyscrasias such as neutropenia or thrombocytopenia.

#### 163. VASOPRESSIN INJECTION IP 1ML

#### SALIENT ACTIONS:

Vasopressin is a posterior pituitary hormone which may be synthetically prepared or extracted from animals. It exerts direct antidiuretic action on the kidneys by increasing tubular reabsorption of water. Vasopressin also acts by constricting the peripheral blood vessels and causes the smooth muscle of the intestine, gall bladder and urinary bladder to contract. Vasopressin is given parenterally or intranasally in the form of argipressin or lypressin. Argipressin is a synthetic type of vasopressin derived from most mammals (including man but excluding pig) while lypressin is vasopressin from pig.

# INDICATIONS & DOSAGE REGIMENS:

Adult : IV Initial control of variceal bleeding As argipressin: 20 u. IM/SC Cranial diabetes insipidus As argipressin: 5-20 u 4 hrly.

# INTERACTIONS:

Carbamazepine, chlorpropamide, clofibrate, urea, fludrocortisone and tricyclic antidepressants may potentiate

the antidiuretic action of vasopressin. Demeclocycline, noradrenaline, lithium, heparin and alcohol may decrease antidiuretic action of vasopressin. Ganglionic blockers may increase sensitivity to the pressor effect of vasopressin. Increased risk of QT prolongation with dolasetron.

#### PRECAUTIONS:

Heart failure; migraine; epilepsy; asthma or other conditions which might be exacerbated by fluid retention; renal impairment; hypertension or other conditions that may worse with BP increase. Adjust fluid intake to avoid fluid overload. Lactation, pregnancy (especially 3rd trimester as it may have oxytocic effect).

# CONTRAINDICATIONS:

Hypersensitivity. Vascular disease especially coronary artery disease; chronic nephritis

#### ADVERSE EFFECTS:

Pallor, vomiting, nausea, belching, abdominal cramps, tremour, pounding headache, vertigo, fluid retention, hyponatraemia, hypersensitivity reaction, sweating, urticaria, gangrene, desire to defecate, arrhythmias, bradycardia, angina, MI and bronchoconstriction.

Potentially Fatal: Anaphylaxis; cardiac arrest or shock.

# 164.VECURONIUM BROMIDE Inj 4 mg/ ampoule SALIENT ACTIONS:

Vecuronium bromide inhibits depolarisation by blocking acetylcholine from binding to receptors on motor endplate.

# INDICATIONS:

Muscle relaxant in general anaesthesia, facilitate endotracheal intubation

# DOSAGE REGIMENS:

Initially, 80-100 mcg/kg given as inj (reduced doses at 30-50 mcg/kg have been suggested after use of suxamethonium; not to exceed 100 mcg/kg in caesarean and neonatal surgery). Maintenance in prolonged procedure: 20-30 mcg/kg, adjust according to response. Alternatively, as continuous infusion: 0.8-1.4 mcg/kg/minute after initial IV dose of 40-100 mcg/kg.

# CONTRAINDICATIONS:

Hypersensitivity to vecuronium or bromide

#### PRECAUTIONS:

Pregnancy, lactation, elderly. Renal and hepatic impairment. Decrease dose in obese patients, taking into account lean body-mass. Correct severe electrolyte disturbances, altered blood pH, dehydration where possible before vecuronium admin. Do not admin vecuronium unless facilities for intubation, artificial respiration, oxygen therapy and agents for neuromuscular reversal are immediately available. INTERACTIONS:

Increases neuromuscular blockade with volatile anaesthetic agents (halothane, ether, enflurane, isoflurane, methoxyflurane, propofol and cyclopropane), fentanyl, other non-depolarising muscle relaxants, prior admin of succinylcholine, tetracyclines, polymyxins, diuretics, thiamine, MAOIs, bacitracin, colistin, sodium colistimethate, acylaminopenicillins, aminoglycoside antibiotics, high dose metronidazole, protamine, βadrenergic blocking agents, calcium antagonists e.g. verapamil, and Mg. Decreased neuromuscular blockade with anticholinesterases, prior chronic admin of corticosteroids, phenytoin, carbamazepine, noradrenaline, azathioprine, theophylline, calcium chloride.

#### ADVERSE EFFECTS:

Muscle weakness, paralysis, muscle atrophy (after long term use), hypersensitivity reactions e.g urticaria and erythema. Potentially Fatal: Anaphylaxis, respiratory failure, apnoea.

# 165. VECURONIUM BROMIDE + MANNITOL q.s. Inj 10 mg/vial SALIENT ACTIONS:

Vecuronium bromide inhibits depolarisation by blocking acetylcholine from binding to receptors on motor endplate.

# INDICATIONS:

Muscle relaxant in general anaesthesia, facilitate endotracheal intubation

# **DOSAGE REGIMENS:**

Initially, 80-100 mcg/kg given as inj (reduced doses at 30-50 mcg/kg have been suggested after use of suxamethonium; not to exceed 100 mcg/kg in caesarean and neonatal surgery). Maintenance in prolonged procedure: 20-30 mcg/kg, adjust according to response. Alternatively, as continuous infusion: 0.8-1.4

mcg/kg/minute after initial IV dose of 40-100 mcg/kg.

#### CONTRAINDICATIONS:

Hypersensitivity to vecuronium or bromide

#### PRECAUTIONS:

Pregnancy, lactation, elderly. Renal and hepatic impairment. Decrease dose in obese patients, taking into account lean body-mass. Correct severe electrolyte disturbances, altered blood pH, dehydration where possible before vecuronium admin. Do not admin vecuronium unless facilities for intubation, artificial respiration, oxygen therapy and agents for neuromuscular reversal are immediately available.

#### INTERACTIONS:

Increases neuromuscular blockade with volatile anaesthetic agents (halothane, ether, enflurane, isoflurane, methoxyflurane, propofol and cyclopropane), fentanyl, other non-depolarising muscle relaxants, prior admin of succinylcholine, tetracyclines, polymyxins, diuretics, thiamine, MAOIs, bacitracin, colistin, sodium colistimethate, acylaminopenicillins, aminoglycoside antibiotics, high dose metronidazole, protamine,  $\beta$ -adrenergic blocking agents, calcium antagonists e.g. verapamil, and Mg. Decreased neuromuscular blockade with anticholinesterases, prior chronic admin of corticosteroids, phenytoin, carbamazepine, noradrenaline, azathioprine, theophylline, calcium chloride.

#### ADVERSE EFFECTS:

Muscle weakness, paralysis, muscle atrophy (after long term use), hypersensitivity reactions e.g urticaria and erythema. *Potentially Fatal:* Anaphylaxis, respiratory failure, apnoea

# 166.VINBLASTINE SULPHATE 1MG INJ INDICATIONS & DOSAGE REGIMENS:

Vinblastine Sulfate Injection is indicated in the palliative treatment of the following:

- I. Frequently Responsive Malignancies
- Generalized Hodgkin's disease (Stages III and IV, Ann Arbor modification of Rye staging system)
- Lymphocytic lymphoma (nodular and diffuse, poorly and well differentiated)
- Histiocytic lymphoma
- Mycosis fungoides (advanced stages)
- Advanced carcinoma of the testis
- Kaposi's sarcoma
- o Letterer-Siwe disease (histiocytosis X)
- II. Less Frequently Responsive Malignancies
- o Choriocarcinoma resistant to other chemotherapeutic agents
- Carcinoma of the breast, unresponsive to appropriate endocrine surgery and hormonal therapy

A simplified and conservative incremental approach to dosage at weekly intervals for adults may be outlined as follows:

First dose	3.7 mg/m2 bsa
Second dose	5.5 mg/m2 bsa
Third dose	7.4 mg/m2 bsa
Fourth dose	9.25 mg/m2 bsa
Fifth dose	11.1 mg/m2 bsa

#### INTERACTIONS:

N/A

# PRECAUTIONS:

General

Toxicity may be enhanced in the presence of hepatic insufficiency.

If leukopenia with less than 2,000 white blood cells/mm3 occurs following a dose of vinblastine sulfate, the patient should be watched carefully for evidence of infection until the white blood cell count has returned to a safe level

When cachexia or ulcerated areas of the skin surface are present, there may be a more profound leukopenic response to the drug; therefore, its use should be avoided in older persons suffering from either of these conditions.

In patients with malignant-cell infiltration of the bone marrow, the leukocyte and platelet counts have sometimes fallen precipitously after moderate doses of vinblastine sulfate. Further use of the drug in such patients is inadvisable.

#### CONTRAINDICATIONS:

Vinblastine sulfate is contraindicated in patients who have significant granulocytopenia unless this is a result of the disease being treated. It should not be used in the presence of bacterial infections. Such infections must be brought under control prior to the initiation of therapy with vinblastine sulfate.

#### ADVERSE EFFECTS:

Hematologic—Leukopenia (granulocytopenia), anemia, thrombocytopenia (myelosuppression).

Dermatologic—Alopecia is common. A single case of light sensitivity associated with this product has been reported.

Gastrointestinal—Constipation, anorexia, nausea, vomiting, abdominal pain, ileus, vesiculation of the mouth, pharyngitis, diarrhea, hemorrhagic enterocolitis, bleeding from an old peptic ulcer and rectal bleeding. Neurologic—Numbness of digits (paresthesias), loss of deep tendon reflexes, peripheral neuritis, mental depression, headache, convulsions.

Treatment with vinca alkaloids has resulted rarely in both vestibular and auditory damage to the eighth cranial nerve. Manifestations include partial or total deafness which may be temporary or permanent, and difficulties with balance including dizziness, nystagmus and vertigo. Particular caution is warranted when vinblastine sulfate is used in combination with other agents known to be ototoxic such as the platinum-containing oncolytics.

Cardiovascular—Hypertension—Cardiac effects such as myocardial infarction, angina pectoris and transient abnormalities of ECG related to coronary ischemia have been reported very rarely. Cases of unexpected myocardial infarction and cerebrovascular accidents have occurred in patients undergoing combination chemotherapy with vinblastine, bleomycin and cisplatin. Raynaud's phenomenon has also been reported with this combination.

#### 167. VITAMIN D3 INJ.7.5 MG

#### SALIENT ACTIONS:

Vit D may have anti-osteoporotic, immunomodulatory, anticarcinogenic, antipsoriatic, antioxidant & mood-modulatory activities. Along with parathyroid hormone & calcitonin, regulate serum calcium conc. Onset: Slow.

Duration: Relatively prolonged duration of action.

Absorption: Well absorbed from the GI tract. Presence of bile is essential for adequate intestinal absorption.

Hence absorption may be decreased in patients with decreased fat absorption.

Distribution: Bound to a specific α-globulin. Can be stored in adipose & muscle tissue for long periods of time. Slowly released from storage sites & skin where it is formed in the presence of sunlight or uv light. May

distribute into breast milk.

Metabolism: Hydroxylated in the liver by the enzyme vitamin D 25-hydroxylase to form 25-

hydroxycholecalciferol (calcifediol). Further hydroxylated in the kidneys by the enzyme vitamin D1-

hydroxylase to form the active metabolites 1,25-dihydroxycholecalciferol (calcitriol). Further metabolism also occurs in the kidneys, including the formation of the 1,24,25-trihydroxy derivatives.

Excretion: Mainly in the bile & faeces with only small amounts appearing in urine.

### INDICATIONS & DOSAGE REGIMENS:

Oral

Nutritional deficiency

Adult: 10 mcg (400 units) daily. May also be given via IM inj.

Orai

Deficiency due to malabsorption states or liver diseases

Adult: Up to 1 mg (40 000 units) daily. May also be given via IM inj.

Oral

Hypocalcaemia caused by hypoparathyroidism

Adult: Up to 5 mg (200 000 units) daily. May also be given via IM inj.

#### INTERACTIONS:

Increased risk of hypercalcaemia if given with thiazide diuretics, calcium or phosphate. Antiepileptics (e.g. carbamazepine, phenobarbitone, phenytoin & primidone) may increase vitamin D requirements. Rifampicin & isoniazid may reduce efficacy of vitamin D. Corticosteroids may counteract the effect of vitamin D. Digoxin or any cardiac glycoside. Reduced absorption when taken with cholestyramine, colestipol, mineral oil, orlistat. Ketoconazole.

#### PRECAUTIONS:

Excessive intake may lead to development of hyperphosphataemia or hypercalcaemia. Infants, renal impairment or calculi, heart disease. Monitor plasma phosphate & calcium level. Pregnancy, lactation.

#### CONTRAINDICATIONS:

Hypercalcaemia. Evidence of vitamin D toxicity

#### ADVERSE EFFECTS:

Hyperphosphataemia or hypercalcaemia (in excessive intake). Associated effects of hypercalcaemia include hypercalciuria, ectopic calcification, & renal & CV damage

#### 168. WATER FOR INJ 5 ml/10 ml ampoule

#### SALIENT ACTIONS:

Sterile Water for Injection, USP is used for fluid replacement only after suitable additives are introduced to approximate isotonicity and to serve as a vehicle for suitable medications.

#### INDICATIONS:

This parenteral preparation is indicated only for diluting or dissolving drugs for intravenous, intramuscular or subcutaneous injection, according to instructions of the manufacturer of the drug to be administered.

#### DOSAGE REGIMENS:

As per indication

#### **CONTRAINDICATIONS:**

Sterile Water for Injection, USP is a hemolytic agent due to its hypotonicity. Therefore, it is contraindicated for intravenous administration without additives.

#### PRECAUTIONS:

Do not use for intravenous injection unless adjusted to approximate isotonicity with a suitable solute. Do not administer unless solution is clear and seal is intact.

#### INTERACTIONS:

Some drugs for injection may be incompatible in a given vehicle, or when combined in the same vehicle or in a vehicle containing benzyl alcohol.

#### ADVERSE EFFECTS:

The administration of a suitable admixture of prescribed additives may be associated with adverse reactions because of the solution or the technique of administration including febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

# 169. ZOLEDRONIC ACID 4MG INJ

#### SALIENT ACTIONS:

Zoledronic acid inhibits osteoclast activity and skeletal Ca release induced by tumours. It decreases serum Ca and phosphorus, and increases their elimination. In osteoporosis, it inhibits osteoclast-mediated resorption, thus reducing bone turnover.

Distribution: Plasma protein binding: 28-56%.

Metabolism: Not metabolised.

Excretion: Via urine (approx 23-55% of the dose) as unchanged drug. Terminal elimination half-life: Approx 146 hr.

#### **INDICATIONS & DOSAGE REGIMENS:**

Adult: IV Hypercalcaemia of malignancy 4 mg as a single infusion, may repeat if necessary after at least 7 days. Bone metastases associated w/ solid tumours; Osteolytic lesions associated w/ multiple myeloma 4 mg by infusion 3-4 wkly. Paget's disease of bone 5 mg as a single infusion. Osteoporosis in postmenopausal women; Increase bone mass in men w/ osteoporosis; Corticosteroid-induced osteoporosis 5 mg as a single infusion once yrly. Prophylaxis of postmenopausal osteoporosis 5 mg as a single infusion once every 2 yr.

#### INTERACTIONS:

Increased exposure of concomitant drugs eliminated by renal excretion (e.g. digoxin). Increased risk of hypocalcaemia w/ loop diuretics. Lowered serum Ca concentrations for prolonged periods w/ aminoglycosides. Increased risk of renal dysfunction w/ nephrotoxic agents.

#### PRECAUTIONS:

Patient w/ aspirin-sensitive asthma. Mild to moderate renal impairment. Pregnancy. Patient CounsellingThis drug may cause dizziness, if affected, do not drive or operate machinery. Adequately hydrate patients prior to admin. Ensure adequate Ca and vit D intake. Monitoring Parameters Monitor serum Ca, Mg, phosphate and

electrolytes; haematocrit/Hb (oncology use); biochemical markers of bone turnover (non-oncology use). Prior to therapy, perform dental exam and preventive dentistry in patients at risk of osteonecrosis.

#### CONTRAINDICATIONS:

Hypocalcaemia, severe renal impairment (CrCl <35 mL/min) and those w/ evidence of acute renal impairment due to an increased risk of renal failure. Lactation.

#### ADVERSE EFFECTS:

Arthralgia, fever, flu-like symptoms, myalgia, headache, pain in extremity, nausea, vomiting, diarrhoea, eye inflammation; alopecia, hyperhidrosis, bone/joint/muscle pain, osteonecrosis of the jaw, femoral fracture, hypersensitivity reactions (e.g. urticaria, angioedema), Stevens-Johnson syndrome, toxic epidermal necrolysis, hypotension.

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Potentially Fatal: Severe hypocalcaemia, severe kidney problems.

# IV FLUIDS

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#### IV FLUIDS

#### 1. ABRADINE HCL IV

#### SALIENT ACTIONS:

Ivabradine selectively inhibits the pacemaker  $I_f$  current in a dose-dependent manner. Blocking this channel reduces cardiac pacemaker activity, selectively slowing the heart rate and allowing more time for blood to flow to the myocardium. This is in contrast to other commonly used rate-reducing medications, such as beta-blockers and calcium channel blockers, which not only reduce heart rate, but also the cardiac contractility.

#### INDICATIONS:

Treatment of CAD: Symptomatic treatment of chronic stable angina pectoris in CAD adults w/ normal sinus rhythm & heart rate  $\geq$ 70 beats/min. Indicated in adults unable to tolerate or w/ a CI to the use of β-blockers; or in combination w/ β-blockers in patients inadequately controlled w/ an optimal β-blocker dose. Treatment of chronic heart failure: Chronic heart failure NYHA class II-IV w/ systolic dysfunction in adults w/ sinus rhythm & whose heart rate is  $\geq$ 75 beats/min in combination w/ standard therapy including β-blocker therapy or when β-blocker is contraindicated or not tolerated.

#### DOSAGE REGIMENS:

5 mg bid. After 3-4 wk, increase to 7.5 mg bid. Elderly 2.5 mg morning & evening.

#### CONTRAINDICATIONS:

Resting heart rate <70 bpm prior to treatment, cardiogenic shock, heart rhythm disorder, acute MI, severe hypotension (<90/50 mmHg), unstable angina, heart failure which has recently become worse, severe hepatic insufficiency, pacemaker-dependent patient. Concomitant potent CYP3A4 inhibitors, verapamil or diltiazem. Women of childbearing potential not using appropriate contraceptive measures. Pregnancy & lactation. Childn <18 yr.

#### PRECAUTIONS:

Heart rhythm disorders, sustained atrial fibrillation, long QT syndrome, symptoms of bradycardia (eg tiredness, dizziness or shortness of breath), recent stroke, mild to moderate hypotension, uncontrolled BP, especially after change in antihypertensive treatment, severe heart failure or heart failure w/ ECG abnormality, chronic eye retinal disease, moderate hepatic insufficiency, severe renal insufficiency. May cause temporary luminous visual phenomena (phosphenes) which may impair ability to drive or operate machinery.

#### INTERACTIONS:

QT-prolonging drugs.CYP3A4 inhibitors (eg azole antifungals, macrolides, HIV-PIs, nefazodone, diltiazem & verapamil) & inducers (eg rifampicin, barbiturates, phenytoin, St. John's wort). Decreased blood K level w/ diuretics eg furosemide, hydrochlorothiazide, indapamide. Grapefruit juice.

#### ADVERSE EFFECTS:

Luminous visual phenomena (phosphenes, onset is generally w/in the 1st 2 mth of treatment or resolved during or after treatment), blurred vision, bradycardia (particularly w/in 1st 2-3 mth of initiation), 1st-degree AV block, ventricular extrasystoles, atrial fibrillation, uncontrolled BP, headache, dizziness.

# 2. AMINO ACIDS SOLUTION FOR I/V INFUSION

#### SALIENT ACTIONS:

It works by inhibiting viral replication; making chemical messengers that are involved in brain functioning; providing the body with a building block needed for biosynthesis; breaking down products of acetaminophen from damaging the liver; calming the sympathetic nervous system; Phenylalanine changed into tyrosine amino acid before being used by body; strengthening the immune system and helping in the metabolism of sugars; reducing the muscle breakdown; reducing the constant and unwanted muscle contractions in the brain; transmitting signals between nerve cells; contributing to the structure of proteins; involving in metabolic processes of the body; works as a non-essential amino acid for the proper functioning of joints and tendons; doing cell growth and development.

#### INDICATIONS:

For supply of amino acids as part of a parenteral nutrition regimen

#### DOSAGE REGIMEN:

Dosage depends on the severity of the catabolic state and on the amino acid requirement.

A maximum daily dosage of 2 g amino acids/kg body weight should not be exceeded in parenteral nutrition. Daily Dose: 10-20 mL/kg body weight (equivalent to 1-2 g amino acids/kg body weight) corresponding to 700-1 400 ML Aminoven 10% at 70 kg body weight.

Maximum Infusion Rate: 1 mL/kg body weight/hr (equivalent to 0.1 g amino acids/kg body weight/hr).

Maximum Daily Dose: 20 mL/kg body weight (equivalent to 2 g amino acids/kg body weight) corresponding to

1400 mL Aminoven 10% or 140 g amino acids at 70 kg body weight.

#### CONTRAINDICATIONS:

Disturbances of amino acid metabolism, metabolic acidosis, renal insufficiency w/o haemodialysis or haemofiltration treatment, advanced liver insufficiency, fluid overload, shock, hypoxia, decompensated heart failure. Neonates.

#### PRECAUTIONS:

Precaution should be taken in Alcohol consumption, allergic reactions, low blood pressure, asthma, pregnancy and breastfeeding.

#### INTERACTIONS:

NA

#### ADVERSE REACTIONS:

Nausea, Abdominal cramps, Diarrhea, Headache, Fatigue, Heartburn.

# 3. AMINO ACIDS WITH MULTI VITAMINS LIQ 100ML

#### SALIENT ACTIONS:

It works by inhibiting viral replication; making chemical messengers that are involved in brain functioning; providing the body with a building block needed for biosynthesis; breaking down products of acetaminophen from damaging the liver; calming the sympathetic nervous system; Phenylalanine changed into tyrosine amino acid before being used by body; strengthening the immune system and helping in the metabolism of sugars; reducing the muscle breakdown; reducing the constant and unwanted muscle contractions in the brain; transmitting signals between nerve cells; contributing to the structure of proteins; involving in metabolic processes of the body; works as a non-essential amino acid for the proper functioning of joints and tendons; doing cell growth and development.

#### INDICATIONS:

For supply of amino acids as part of a parenteral nutrition regimen.

#### DOSAGE REGIMEN:

1 tsf OD

#### CONTRAINDICATIONS:

Disturbances of amino acid metabolism, metabolic acidosis, renal insufficiency w/o haemodialysis or haemofiltration treatment, advanced liver insufficiency, fluid overload, shock, hypoxia, decompensated heart failure. Neonates.

#### PRECAUTIONS:

Precaution should be taken in Alcohol consumption, allergic reactions, low blood pressure, asthma, pregnancy and breastfeeding.

#### INTERACTIONS:

NA

#### ADVERSE REACTIONS:

Nausea, Abdominal cramps, Diarrhea, Headache, Fatigue, Heartburn.

#### 4. CIPROFLOXACIN Inj 0.2 gm / 100ml bottle

# SALIENT ACTIONS:

Ciprofloxacin promotes breakage of double-stranded DNA in susceptible organisms and inhibits DNA gyrase, which is essential in reproduction of bacterial DNA.

#### INDICATIONS:

Typhoid and paratyphoid fever, Septicemia, Peritonitis, Cat scratch disease, Q fever, spotted fever, Typhus, Urinary and biliary tract infection, Bone and joint infections, Chanroid, Infections in immunocompromised patients, Legionnaire's disease, Lower respiratory tract infections, Septicaemia, Skin infections, Brucellosis, Infected animal bites, Anthrax, Gastroenteritis, Pseudomonal lung infections in cystic fibrosis

# DOSAGE REGIMENS:

Susceptible infections-Adult: 100-400 mg bid infused over 30-60 minutes, Child: 4-8 mg/kg bid.

#### **CONTRAINDICATIONS:**

Hypersensitivity. Not to be used concurrently with tizanidine. Avoid exposure to strong sunlight or sun lamps during treatment

#### PRECAUTIONS:

Epilepsy, history of CNS disorders; severe renal or hepatic dysfunction; G6PD deficiency; maintain adequate hydration; myasthaenia gravis. Caution when used in patients with QT prolongation. Discontinue treatment if

patients experience tendon pain, inflammation or rupture. Pregnant and lactating women.

#### INTERACTIONS:

Increased methotrexate, caffeine, theophylline levels, Probenecid reduces renal clearance of ciprofloxacin. Potentiates oral anticoagulants and glibenclamide. Concurrent use with corticosteroids may increase tendon rupture. Concurrent use with ciclosporin may cause transient increases in serum creatinine. Potentially Fatal: Concurrent use with tizanidine can cause marked elevation in serum levels of tizanidine; avoid concurrent usage.

# ADVERSE EFFECTS:

GI disturbances; headache, tremor, confusion, convulsions; rashes; joint pain; phototoxicity. Transient increases in serum creatinine. Haematological, hepatic and renal disturbances. Vasculitis, pseudomembranous colitis and tachycardia. Phototoxicity. Potentially Fatal: Anaphylactoid reaction; cardiopulmonary arrest.

# 5. DEXTROSE Inj 5 gm (5% w/v) or 10 gm (10% w/v) / 100 ml, 500 ml bottle SALIENT ACTIONS:

Dextrose Injections have value as a source of water and calories. They are capable of inducing diuresis depending on the clinical condition of the patient.

#### INDICATIONS:

As a caloric component in a parenteral nutrition regimen. They are used with an appropriate protein (nitrogen) source in the prevention of nitrogen loss or in the treatment of negative nitrogen balance in patients where: (1) the alimentary tract cannot or should not be used, (2) gastrointestinal absorption of protein is impaired, or (3) metabolic requirements for protein are substantially increased, as with extensive burns.

#### DOSAGE REGIMENS:

As per indication and physician

# CONTRAINDICATIONS:

Intracranial or intraspinal hemorrhage, severely dehydrated, anuric patients, and hepatic coma. Patients with known allergy to corn or corn products.

#### PRECAUTIONS:

Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants..

#### INTERACTIONS:

None

#### ADVERSE EFFECTS:

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

# 6. DEXTROSE (ANHYDROUS) Inj 25 gm (25 % w/v), 25 ml and 100 ml bottle SALIENT ACTIONS:

Dextrose Injections have value as a source of water and calories. They are capable of inducing diuresis depending on the clinical condition of the patient.

#### INDICATIONS:

As a caloric component in a parenteral nutrition regimen. They are used with an appropriate protein (nitrogen) source in the prevention of nitrogen loss or in the treatment of negative nitrogen balance in patients where: (1) the alimentary tract cannot or should not be used, (2) gastrointestinal absorption of protein is impaired, or (3) metabolic requirements for protein are substantially increased, as with extensive burns

# DOSAGE REGIMENS:

As per indication and physician

# CONTRAINDICATIONS:

Intracranial or intraspinal hemorrhage, severely dehydrated, anuric patients, and hepatic coma. Patients with known allergy to corn or corn products.

#### PRECAUTIONS:

While giving solution via central venous catheter, nursing woman. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants. Because of hypertonicity, injections must be diluted prior to administration.

# INTERACTIONS:

None

#### ADVERSE EFFECTS:

Too rapid infusion result in diuresis, hyperglycemia, glycosuria, and hyperosmolar coma. Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

#### 7. FAT EMULSION IV FOR INFUSION

#### SALIENT ACTIONS:

This product is used to provide calories to patients who are getting their nutrition through an injection into the vein. This product is also used to provide a certain nutrient (essential fatty acids) to people who do not have enough of it. This product helps to prevent or reverse the signs of this deficiency (e.g., scaly skin, poor growth, poor wound healing).

#### INDICATIONS:

It is indicated as a source of calories and essential fatty acids for patients requiring parenteral nutrition for extended periods of time (usually for more than 5 days) and as a source of essential fatty acids for prevention of efad.

#### DOSAGE REGIMENS:

Adult Patients

The initial rate of infusion in adults should be 0.5 ml/minute for the first 15 to 30 minutes of infusion.

The dosage for premature infants starts at 0.5 g fat/kg body weight/24 hours

#### **Contraindications:**

patients with disturbances of normal fat metabolism such as pathologic hyperlipemia, lipoid nephrosis or acute pancreatitis if accompanied by hyperlipidemia.

#### Precautions:

the daily dosage should not exceed 2.5 g of fat/kg of body weight

during long term intravenous nutrition with intralipid® 20% (20% i.v. fat emulsion), liver function tests should be performed

#### Interactions:

n/a

#### Adverse effects:

Dyspnea, cyanosis, allergic reactions, hyperlipemia, hypercoagulability, nausea, vomiting, headache, flushing, increase in temperature, sweating, sleepiness, pain in the chest and back, slight pressure over the eyes, dizziness, and irritation at the site of infusion, and, rarely, thrombocytopenia in neonates;

# 8. FLUCONAZOLE Inj 200 mg, 100 ml bottle

#### SALIENT ACTIONS:

Fluconazole decreases ergosterol synthesis by interfering with cytochrome P450 activity, thus inhibiting cell membrane formation of susceptible fungi including B dermatitidis, Candida spp, C immitis, C neoformans, Epidermophyton spp, H capsulatum, Mycosporum spp, Trichophyton spp, thus leading to cell death. **INDICATIONS:** 

Systemic candidiasis, Cryptococcal infections, Prophylaxis of fungal infections in immunocompromised patients **DOSAGE REGIMENS**:

Adult: Initially, 400 mg followed by 200-400 mg daily. Max: 800 mg daily

Child: >4 wk: 6-12 mg/kg daily; same doses may given every 72 hr in neonates up to 2 wk and every 48 hr in neonates 2-4 wk. Max: 400 mg daily.

#### CONTRAINDICATIONS:

Hypersensitivity.

#### PRECAUTIONS:

Renal or hepatic impairment. May prolong QT interval. Pregnancy and lactation

#### INTERACTIONS:

Rifampicin reduces fluconazole levels. Reduces theophylline clearance. Affects efficacy of oral contraceptives. May increase serum levels ofalprazolam, triazolam, midazolam, diazepam. May raise serum concentrations and efficacy of oral sulphonylureas, phenytoin, ciclosporin, calcium channel blockers, tacrolimus, HMG-CoA reductase inhibitors (except pravastain and fluvastatin), warfarin and other anticoagulants. May reduce metabolism of caffeine. Avoid concurrent use with clopidogrel.

Potentially Fatal: Increased risk of cardiac arrhythmias with astemizole, cisapiride or terfenadine.

# ADVERSE EFFECTS:

Nausea, abdominal pain, vomiting, diarrhoea, flatulence; elevated liver function values; headache; rash, exfoliative dermatitis. Rarely, angioedema, anaphylactic reactions and thrombocytopenia. *Potentially Fatal:* Hepatotoxicity; rarely anaphylaxis; Stevens-Johnson syndrome

# 9.GLYCINE Inj 1.5 gm, 2000 ml bottle SALIENT ACTIONS:

Sterile solutions of glycine 1.5% in water are used for urogenital irrigation during certain surgical procedures, especially transurethral resection of the prostate.

#### INDICATIONS:

As an irrigant during transurethral prostatic or bladder surgery

#### DOSAGE REGIMENS:

As sterile solutions of glycine 1.5% in water

#### CONTRAINDICATIONS:

Anuric patients

#### PRECAUTIONS:

Hepatic impairment as any absorption and consequent metabolism may cause hyperammonaemia. Cardiopulmonary or renal dysfunction. Ensure that the solution is clear and used promptly once it is opened to minimise risk of particulate and/or bacterial contamination

#### INTERACTIONS:

No

#### ADVERSE EFFECTS:

Fluid and electrolyte disorders e.g. acidosis, electrolyte loss, marked diuresis, urinary retention, oedema and dehydration; CV/pulmonary disorders e.g. pulmonary congestion, hypotension, tachycardia, angina-like pain and thrombophlebitis. Visual disturbances, convulsions, nausea, vomiting, diarrhoea, vertigo and urticaria.

# 10. HUMAN ALBUMIN(25%) IV

## SALIENT ACTIONS:

More albumin in the blood helps to increase the volume of the blood in the blood vessels. It does this by helping to draw fluid from the body into the blood vessels. This is especially useful in treating shock (when blood can't carry enough oxygen to tissues in the body) due to various causes, including serious injury, bleeding, surgery, or severe burns. Albumin can also replace low blood protein. Albumin solutions are also used to treat acute liver failure because of its ability to bind excess bilirubin (a substance produced by the liver) and increase the volume of blood.

During certain surgeries, albumin solutions sometimes need to be given to replace albumin lost during the procedure. Albumin solutions may be used before blood transfusions in the treatment of newborn hemolytic disease (a disorder where red blood cells are destroyed) so that extra bilirubin can be bound, reducing the risk of a condition known as kernicterus (damage and staining of the brain tissue by bilirubin). In acute nephrosis(a type of kidney disease), albumin solutions are sometimes given to help reduce the edema(water retention) that occurs in this condition.

#### INDICATIONS:

- It is used to treat or prevent low blood volume.
- It is used to treat low blood pressure.
- It is used to replace albumin in people with low blood albumin levels.
- It is used to add back fluid after fluid loss.
- It is used to treat shock.

#### DOSAGE REGIMENS:

Initial dose: The patient may require 200 to 300 mL IV to reduce edema and to bring serum protein values to normal. Since such patients usually have approximately normal blood volume, doses of more than 100 mL of albumin 25% should not be given faster than 100 mL IV over 30 to 45 minutes to avoid circulatory overload. If slower administration is desired, 200 mL of albumin 25% may be mixed with 300 mL of 10% dextrose solution and administered by continuous drip at a rate of 100 mL an hour IV.

#### CONTRAINDICATIONS:

- allergic to albumin or any ingredients of the medication
- have a loss of kidney function
- · have heart failure, where the heart is not able to deliver enough blood to other organs in the body

- have pulmonary edema
- have severe anemia (low blood cell count, resulting in decreased oxygen delivery to tissue around the body)

#### PRECAUTIONS & INTERACTIONS:

Albumin infusions should not be mixed with other infusions of:

- packed red blood cells
- solutions containing alcohol
- · solutions containing amino acids
- solutions containing protein hydrolysates
- whole blood

#### ADVERSE EFFECTS:

if administered rapidly, may result in vascular overload with resultant pulmonary edema.

# 11. HYDROXYETHYL STARCH (sterile) Inj 6 gm / 100 ml, 500 ml bottle SALIENT ACTIONS:

Hydroxyethyl starch (HES) is an artificial colloid obtained from starch. It is composed almost exclusively of amylopectin, which is highly branched and more stable component of starch. Plasma volume expansion of about 100% of the infused volume takes place over 3-4 hrs .HES leads to an improvement of blood circulation and microcirculation.

#### INDICATIONS:

Prophylaxis and treatment of hypovolemia and shock due to surgery, trauma, burns and infections. Therapeutic hemodilution, cardiac priming, therapeutic plasma exchange. Preloading in spinalanesthesia, acute normovolemic hemodilution (autologous blood transfusion).

#### DOSAGE REGIMENS:

The dose and rate of infusion depend on the amount of fluid lost and degree of hemoconcentration: Usual doses are in the range of 500-2500 mL daily, depending on the preparation used and the infusion rate may be up to about 20 mL/kg body weight/hr if necessary.

#### CONTRAINDICATIONS:

Severe hemorrhagic defects; renal failure with oliguria and anuria; hyperhydration states; severe congestive cardiac failure; patients allergic to starch.

#### PRECAUTIONS:

Renal toxicity of amino sugar antibiotics eg, kanamycin, aminodeoxy kanamycin, gentamycin and paramomycin may be increased. Blood typing and cross matching should be performed, before the administration. Rapid infusion may cause circulatory disturbances and damage to tissues hence to be given slowly over 30 min. Do not mix with citrated blood or an oily suspension preparation for injection. Pregnancy

#### INTERACTIONS:

No

#### ADVERSE EFFECTS:

Hypersensitivity eg, rash or pruritis occurs, the administration should be discontinued or proper treatment should be given. Hematologic: If prolongation of bleeding tendency occurs, the administration should be discontinued or proper treatment should be given. GI: Nausea and vomiting occur rarely.

# 12. HYDROXYETHYL STARCH(low molecular weight 130/0.4) Inj 6% (multiple ingredient preparation), 500 ml bottle

# SALIENT ACTIONS:

Hydroxyethyl starch (HES) is an artificial colloid obtained from starch. It is composed almost exclusively of amylopectin, which is highly branched and more stable component of starch.

#### INDICATIONS:

Treatment of imminent or manifest hypovolemia and shock

#### **DOSAGE REGIMENS:**

Depend on the extent of blood loss and how much fluid is required

The initial 10-20 mL should be infused slowly and under careful monitoring of the patient so that any anaphylactoid reaction can be detected as soon as possible.

Maximum Daily Dose: Up to 50 mL/kg body weight (equivalent to 3 g HES/kg body weight)

#### CONTRAINDICATIONS:

Hyperhydration states including pulmonary edema; renal failure with oliguria and anuria; intracranial bleeding; hyperkalemia; severe hypernatremia or severe hyperchloremia; severely impaired hepatic function; congestive

cardiac failure; hypersensitivity to hydroxyethyl starch.

#### PRECAUTIONS:

Volume overload from overdosage should be avoided. Dosage should be carefully adjusted, especially in patients with cardiac insufficiency. Renal impairment. Pregnancy.

#### INTERACTIONS:

No interactions with other drugs or nutritional products are known to date. In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

#### ADVERSE EFFECTS:

Hemodilution, dilution of coagulation factors, hypersensitivity reactions, Reduced hematocrit and decreased plasma protein concentrations as a result of hemodilution, anaphylactic reactions of various intensities, pruritus .

### 13. IMMUNOGLOBULIN FOR IV USE

#### SALIENT ACTIONS:

IVIG is an immunomodulating agent that has multiple activities. These include modulation of complement activation; suppression of idiotypic antibodies; saturation of Fc receptors on macrophages; and suppression of various inflammatory mediators, including cytokines, chemokines, and metalloproteinases. <sup>[5]</sup> The Fc region of IgG facilitates interaction with and signaling through Fc receptors on phagocytes, B cells, and other cells and with Fc-binding plasma proteins (eg, components of the complement system)

#### INDICATIONS:

- Kawasaki disease,
- · Guillain-Barré syndrome,
- polymyositis/dermatomyositis.
- Allogeneic bone marrow transplantation
- Chronic lymphocytic leukemia
- Common variable immunodeficiency (CVID) A group of approximately 150 primary immunodeficiencies (PIDs) that have a common set of features (including hypogammaglobulinemia) but that have different underlying causes
- Chronic inflammatory demyelinating polyneuropathy (CIDP) Solely Gamunex
- Kidney transplantation with a high antibody recipient or with an ABO incompatible donor
- Primary immunodeficiency disorders associated with defects in humoral immunity.
- Immune-mediated thrombocytopenia
- Epilepsy and pediatric intractable Guillain-Barré syndrome
- Chronic inflammatory demyelinating polyneuropathy
- Myasthenia gravis: IVIG may improves the quality of life in patients; sometimes it is combined with plasmapheresis. [16] A 2014 report noted that IVIG may act as prophylaxis against acute exacerbations. [17]
- Lambert-Eaton myasthenic syndrome
- Multifocal motor neuropathy
- Multiple sclerosis

#### DOSAGE REGIMENS:

400 mg/kg, IV, every 3 to 4 weeks

#### CONTRAINDICATIONS:

#### PRECAUTIONS:

THROMBOSIS may occur with immune globulin products.

- -Thrombosis risk factors include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.
- -For patients at risk of thrombosis, administer this product at the minimum dose and infusion rate practicable.
- -Ensure adequate hydration in patients before administration.
- -Monitor for signs and symptoms of thrombosis and assess blood viscosity in at-risk patients.
- -RENAL DYSFUNCTION, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients.

#### INTERACTIONS:

Some products that may interact with this drug include: drugs that may harm the kidneys (e.g., aminoglycosides such as gentamicin), "water pills" (diuretics such as furosemide).

#### ADVERSE EFFECTS:

Flushing, headache, dizziness, chills, muscle cramps, back/joint pain, fever, nausea, or vomiting may occur.

#### 14. LEVOFLOXACIN INFUSION IP 500MG/100ML IV

#### SALIENT ACTIONS:

Levofloxacin exerts antibacterial action by inhibiting bacterial topoisomerase IV and DNA gyrase, the enzymes required for DNA replication, transcription repair and recombination. It has *in vitro* activity against a wide range of gram-negative and gram-positive microorganisms.

# INDICATIONS & DOSAGE REGIMENS:

Cystitis

Pyelonephriits

Nongonococcal Urethritis

Skin and structure Infection

Pneumonia

Bronchitis

Inhalation Anthrax

Plague

#### CONTRAINDICATIONS:

Allergy

Tendinitis or tendon rupture

Myasthenia gravis

# INTERACTIONS:

Increased concentration of ciclosporin or tacrolimus.Reduced absorption with didanosine, ferrous sulfate or dietary supplements containing zinc, calcium, magnesium or iron.Increase plasma levels of theophylline.

Increased risk of tendon rupture with corticosteroids. Reduced absorption with sucralfate and antacids containing magnesium and aluminium; administer at least 2 hr before or 2 hr after antacids. Increased half-life and decreased clearance of procainamide. Altered glucose levels with antidiabetic agents (e.g. insulin, glyburide).Potentially Fatal: Increased risks of ventricular arrhythmias with QT prolonging drugs e.g. class IA (quinidine, procainamide) or class III (amiodarone, sotalol) antiarrhythmics, fluoxetine, imipramine. Increased risk of CNS stimulation and seizures with NSAIDs. Increased prothrombin time with warfarin.

#### ADVERSE EFFECTS:

Nausea, diarrhoea, constipation, headache, insomnia. Potentially Fatal: Anaphylaxis.

# 15. LACTIC ACID SODIUM HYDROXIDE 0.32 gm + SODIUM CHLORIDE 0.6 gm + POTASSIUM CHLORIDE 0.04 gm + CALCIUM CHLORIDE 0.027 gm Inj , 500 ml bottle SALIENT ACTIONS:

Lactated Ringer's Injection provides electrolytes and is a source of water for hydration. It is capable of inducing diuresis depending on the clinical condition of the patient. This solution also contains lactate which produces a metabolic alkalinizing effect.

#### INDICATIONS:

Adults and pediatric patients as a source of electrolytes and water for hydration

#### DOSAGE REGIMENS:

Dosage is to be directed by a physician and is dependent upon age, weight, clinical condition of the patient and laboratory determinations. Frequent laboratory determinations and clinical evaluation are essential to monitor changes in blood glucose and electrolyte concentrations, and fluid and electrolyte balance during prolonged parenteral therapy. Fluid administration should be based on calculated maintenance or replacement fluid requirements for each patient.

#### CONTRAINDICATIONS:

This solution is contraindicated where the administration of sodium, potassium, calcium, lactate, or chloride could be clinically detrimental. Lactate administration is contraindicated in severe metabolic acidosis or alkalosis, and in severe liver disease or anoxic states which affect lactate metabolism.

#### PRECAUTIONS:

This solution should be used with care in patients with hypervolemia, renal insufficiency, urinary tract obstruction, or impending or frank cardiac decompensation. Caution should be exercised when Lactated Ringer's Injection USP is administered to a nursing woman

#### INTERACTIONS:

NO

#### ADVERSE EFFECTS:

Allergic reactions or anaphylactoid symptoms such as localized or generalized urticaria and pruritus; periorbital,

facial, and/or laryngeal edema; coughing, sneezing, and/or difficulty with breathing, reporting of signs/symptoms more in women during pregnancy.

# 16. LACTIC ACID IP 0.24 % + SODIUM CHLORIDE IP 0.6 % + POTASSIUM CHLORIDE IP 0.04 % + CALCIUM CHLORIDE IP 0.027 % Inj 500 ml glass bottle

#### SALIENT ACTIONS:

Lactated Ringer's Injection provides electrolytes and is a source of water for hydration. It is capable of inducing diuresis depending on the clinical condition of the patient. This solution also contains lactate which produces a metabolic alkalinizing effect.

#### INDICATIONS:

Adults and pediatric patients as a source of electrolytes and water for hydration

#### DOSAGE REGIMENS:

Dosage is to be directed by a physician and is dependent upon age, weight, clinical condition of the patient and laboratory determinations. Frequent laboratory determinations and clinical evaluation are essential to monitor changes in blood glucose and electrolyte concentrations, and fluid and electrolyte balance during prolonged parenteral therapy. Fluid administration should be based on calculated maintenance or replacement fluid requirements for each patient.

#### CONTRAINDICATIONS:

This solution is contraindicated where the administration of sodium, potassium, calcium, lactate, or chloride could be clinically detrimental. Lactate administration is contraindicated in severe metabolic acidosis or alkalosis, and in severe liver disease or anoxic states which affect lactate metabolism.

#### PRECAUTIONS:

This solution should be used with care in patients with hypervolemia, renal insufficiency, urinary tract obstruction, or impending or frank cardiac decompensation. Caution should be exercised when Lactated Ringer's Injection USP is administered to a nursing woman

#### INTERACTIONS:

NO

#### ADVERSE EFFECTS:

Allergic reactions or anaphylactoid symptoms such as localized or generalized urticaria and pruritus; periorbital, facial, and/or laryngeal edema; coughing, sneezing, and/or difficulty with breathing, reporting of signs/symptoms more in women during pregnancy.

#### 17. LINEZOLID Inj 200 mg

#### SALIENT ACTIONS:

Linezolid is an bacteriostatic oxazolidinone, inhibiting ribosomal protein synthesis. It is active against gram-positive bacteria including vancomycin-resistant enterococci and MRSA. It has limited in-vitro activity against gram-negative bacteria.

#### INDICATIONS:

Community-acquired pneumonia, Nosocomial pneumonia, Vancomycin-resistant enterococci infections, Methicillin-resistant *Staphylococcus aureus* infections

# DOSAGE REGIMENS:

Adult: 600 mg 12 hrly for 10-14 days, as an infusion over 30-120 minutes. Similar doses can also be given via oral route.

Child: Preterm neonates (<34 wk gestational age): 10 mg/kg every 12 hr; may increase to 10 mg/kg every 8 hr if response is suboptimal. By day 7 of life, all neonates should receive 10 mg/kg every 8 hr. Infant (excluding preterm neonates <1 wk) and children ≤11 yr: 10 mg/kg every 8 hr for 10-14 days.

#### CONTRAINDICATIONS:

Hypersensitivity.

#### PRECAUTIONS:

Myelosuppression, renal impairment, uncontrolled hypertension, phaeochromocytoma, carcinoid syndrome, untreated hyperthyroidism, chronic infection, history of seizures, bipolar depression, schizophrenia or acute confusional states. Pregnancy and lactation. Monitor complete blood counts weekly.

#### INTERACTIONS:

Use with caution with serotonergic, vasopressor or dopaminergic agents to reduce the incidence of serotonin syndrome. Adrenergic drugs may cause hypertension. Tramadol may increase risk of seizures. *Potentially Fatal:* MAOI; avoid concurrent use or use within 2 wk of stopping another MAOI to reduce risk of hypertensive

crisis.

# ADVERSE EFFECTS:

Diarrhoea, headache, nausea, vomiting, constipation, abnormal liver function tests, fever, vaginal and oral candidiasis, skin rash, pruritus, dizziness, insomnia, anaemia, tongue discoloration, taste disturbance, lactic acidosis, optic and peripheral neuropathy.

Potentially Fatal: Reversible myelosuppression including anaemia, leukopenia, pancytopenia and thrombocytopenia (particularly if using > 10-14 days), transient ischaemic attacks, renal failure, Stevens-Johnson syndrome.

# 18. MANNITOL Inj 20 gm, 100 ml bottle SALIENT ACTIONS:

Mannitol increases urinary output by inhibiting tubular reabsorption of water and electrolytes. It raises the osmotic pressure of the plasma allowing water to be drawn out of body tissues. Diuresis: 1-3 hr. Reduction in intracerebral pressure: around 15 min. Reduction in intracerebral pressure: 1.5-6 hr.

#### INDICATIONS:

Oliguric phase of renal failure, Cerebral oedema, Reduction of raised intracranial pressure, Reduction of raised intraocular pressure, Renal function testing.

#### DOSAGE REGIMENS:

- 1.Oliguric phase of renal failure- 50-100 g in a 24-hr period by IV infusion of a 5-25% solution. Adjust rate of administration to maintain a urine flow of at least 30-50 mL/hr. *Child*: 0.25-2 g/kg.
- 2.Cerebral oedema -0.25-2 g/kg by IV infusion of a 15-25% solution given over 30-60 minutes,
- 3.Reduction of raised intracranial pressure, Reduction of raised intraocular pressure -0.25-2 g/kg by IV infusion of a 15-25% solution given over 30-60 minutes.
- 4.Renal function testing 0.2 g/kg infused over 3-5 min.

# CONTRAINDICATIONS:

Pulmonary congestion or oedema; intracranial bleeding; CHF; metabolic oedema with abnormal capillary fragility; anuria due to severe renal disease; severe dehydration.

#### PRECAUTIONS:

Hypervolaemia; urinary tract obstruction; check for signs of fluid and electrolyte imbalance. Should not be administered with whole blood. pregnancy, lactation.

#### INTERACTIONS:

Increased nephrotoxicity with ciclosporin

#### ADVERSE EFFECTS:

Fluid and electrolyte imbalance; acidosis with high doses. Nausea, vomiting, thirst; headache, dizziness, convulsions, chills, fever; tachycardia, chest pain; blurred vision; urticaria and hypotension or hypertension; acute renal failure; skin necrosis; thrombophloebitis.

# 19. METRONIDAZOLE Inj 0.5 gm, 100ml bottle SALIENT ACTIONS:

It is effective against a wide range of organisms including E. histolytica, T. vaginalis, Giardia, anaerobes e.g. Bacterioides sp, Fusobacterium sp, Clostridium sp, Peptococcus sp and Peptostreptococcus sp, and moderately active against Gardnerella sp and Campylobacter sp.

#### INDICATIONS:

Anaerobic infections, prevention of postoperative anaerobic bacterial infections

#### DOSAGE REGIMENS:

*Adult:* 500 mg infused as 100 ml of a 5 mg/ml solution at 5 ml/min 8 hrly, alternatively, 15 mg/kg infusion followed by 7.5 mg/kg 6 hrly; infuse over 1 hr (max: 4 g in 24 hr). Substitute oral therapy as soon as possible. *Child:* 7.5 mg/kg 8 hrly.

Elderly: Use lower end of adult dose recommendations. Do not administer as a single dose.

# CONTRAINDICATIONS:

History of hypersensitivity to metronidazole or other nitroimidazole derivatives. Pregnancy (1st trimester) and lactation.

#### PRECAUTIONS:

Patients with CNS diseases, blood dyscrasias, severe hepatic impairment, oedema, Prolonged use may result in fungal or bacterial superinfection.

# INTERACTIONS:

Acute psychoses or confusion with disulfiram. Additive/synergistic effect with other antimicrobials. Effects reduced with phenobarbital or phenytoin.

Potentially Fatal: Disulfiram-like reaction with alcohol. Increased risk of adverse effects of coumarin ADVERSE EFFECTS:

GI disturbances: nausea, unpleasant metallic taste, vomiting, diarrhoea or constipation. Furred tongue, glossitis, and stomatitis due to overgrowth of Candida. Rarely, antibiotic-associated colitis. Weakness, dizziness, ataxia, headache, drowsiness, insomnia, changes in mood or mental state. Numbness or tingling in the extremities, epileptiform seizures (high doses or prolonged treatment). Transient leucopenia and thrombocytopenia. Hypersensitivity reactions. Urethral discomfort and darkening of urine. Raised liver enzyme values, cholestatic hepatitis, jaundice. Thrombophlebitis (IV).

Potentially Fatal: Anaphylaxis.

# 20. MULTIPLE ELECTROLYTES P & DEXTROSE Inj (Dextrose anhydrous IP 5gm + Potassium chloride IP 0.130 mg + Di-potassium hydrogen phosphate USP 0.026gm + Sodium acetate IP 0.320 gm + Magnesium chloride IP 0.031gm), 500 ml bottle SALIENT ACTIONS:

Provides electrolytes and calories, and is a source of water for hydration. It is capable of inducing diuresis depending on the clinical condition of the patient. Sodium, the major cation of the extracellular fluid, functions primarily in the control of water distribution, fluid balance, and osmotic pressure of body fluids. Sodium is also associated with chloride and bicarbonate in the regulation of the acid-base equilibrium of body fluid.

#### INDICATIONS:

Source of electrolytes, calories and water for hydration, and as an alkalinizing agent.

# DOSAGE REGIMENS:

Fluid administration should be based on calculated maintenance or replacement fluid requirements for each patient based on age, sex, weight.

# CONTRAINDICATIONS:

Solutions containing dextrose may be contraindicated in patients with hypersensitivity to corn products.

#### PRECAUTIONS:

This solution should be used with care in patients with hypervolemia, renal insufficiency, urinary tract obstruction, impending or frank cardiac decompensation. be slowly infused through a small bore needle, placed well within the lumen of a large vein to minimize venous irritation.

# INTERACTIONS:

Sodium-containing solutions should be administered with caution to patients receiving corticosteroids or corticotropin, or to other salt-retaining patients. Administration of barbiturates, narcotics, hypnotics, or systemic anesthetics should be adjusted with caution in patients also receiving magnesium-containing solutions because of an additive central depressive effect. Parenteral magnesium should be administered with extreme caution to patients receiving digitalis preparations.

#### ADVERSE EFFECTS:

Febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia. Too rapid infusion of hypertonic solutions may cause local pain and venous irritation.

# 21. MECOBALAMINE INJECTION

#### SALIENT ACTIONS:

Mecobalamin is the neurologically active form of vitamin B12. Gabapentin is structurally related to the neurotransmitter GABA but is neither a GABA agonist nor antagonist.

# INDICATIONS& DOSAGE REGIMENS:

Adult: Peripheral neuropathies500 mcg/day 3 times/wk. Megaloblastic anaemia caused by vit B12 deficiency 500 mcg/day 3 times/wk for about 2 mth. Maintenance: 500 mcg 1-3 mthly. diabetic neuropathy, and as a preliminary treatment for amyotrophic lateral sclerosis

# INTERACTIONS:

Decreased GI tract absorption with neomycin, aminosalicylic acid, H2-blockers and colchicine. Reduced serum concentrations with oral contraceptives. Reduced effects in anaemia with parenteral chloramphenicol.

#### ADVERSE EFFECTS:

Oral: Anorexia, nausea, vomiting and diarrhoea. Parenteral: Rash, headache, hot sensation, diaphoresis and

pain/induration at IM inj site.

Potentially Fatal: Anaphylactoid reactions (parenteral).

# 22. DEXTROSE (ANHYDROUS) 5 gm + SODIUM CHLORIDE 0.09 gm Inj 500 ml bottle SALIENT ACTIONS:

Has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

#### INDICATIONS:

Dextrose and Sodium Chloride Injection indicated as a source of water, electrolytes, and calories.

#### DOSAGE REGIMENS:

As directed by a physician. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations

#### CONTRAINDICATIONS:

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

#### PRECAUTIONS:

Nursing mother, very low birth weight infants. Excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

#### INTERACTIONS:

Caution must be exercised in the administration of Dextrose and Sodium Chloride Injection to patients receiving corticosteroids or corticotropin. Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Dextrose and Sodium Chloride Injection.

#### ADVERSE EFFECTS:

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

# 23. SODIUM CHLORIDE 0.9 gm Inj 10ml ampoule, 100ml/ 500ml/ 2000ml bottle SALIENT ACTIONS:

Has value as a source of water and electrolytes. Sodium, the major cation of the extracellular fluid, functions primarily in the control of water distribution, fluid balance, and osmotic pressure of body fluids. Sodium is also associated with chloride and bicarbonate in the regulation of the acid-base equilibrium of body fluid.

# INDICATIONS:

As a source of water and electrolytes.

#### DOSAGE REGIMENS:

As directed by a physician. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations

#### **CONTRAINDICATIONS:**

No

#### PRECAUTIONS:

Solutions containing sodium ions should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there is sodium retention with edema.

#### INTERACTIONS:

None

#### ADVERSE EFFECTS:

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

#### 24. RINGER LACTATE SOLUTION IV

#### SALIENT ACTIONS:

Lactated Ringer's solution contains isotonic concentrations of electrolytes in water for inj. It is used for parenteral replacement of extracellular losses of fluid and electrolytes. Each 100 ml of solution contains sodium chloride 600 mg, anhydrous sodium lactate 310 mg, potassium chloride 30 mg and calcium chloride dihydrate 20 mg.

### INDICATIONS AND DOSAGE REGIMENS:

Intravenous

As an alkaliniser agent, Replacement of fluid and electrolytes

Adult: Dose depends on age, wt and clinical state of the patient. Dose to be given by IV infusion.

#### PRECAUTIONS:

Patients with congestive heart failure, hyperkalaemia, severe renal insufficiency and clinical conditions whereby there is oedema with sodium or potassium retention. Caution in metabolic or respiratory alkalosis. Excessive use may result in metabolic alkalosis. Not to be administered concurrently with blood through the same administration set due to risk of coagulation. IV admin may cause fluid and/or solute overloading. Not to be used in the treatment of lactic acidosis. Monitor fluid balance, electrolytes and acid-base balance during prolonged treatment. Pregnancy.

#### ADVERSE EFFECT:

Allergic reactions e.g. localised or generalised urticaria and pruritus. Periorbital, facial, and/or laryngeal oedema. Coughing, sneezing, and/or breathing difficulty.

#### 25. TPN INFUSION

#### SALIENT ACTIONS:

Belongs to the class of electrolyte solutions used in I.V. solutions.

#### INDICATIONS & DOSAGE REGIMENS:

Supplement to IV nutrition of adult to meet the requirements of trace elements.

10 mL daily for addition to infusion fluids.

#### INTERACTIONS:

N/A

#### PRECAUTIONS:

Biliary &/or renal impairment. Patients w/ liver dysfunction especially cholestasis. Monitor manganese levels if >4 wk of treatment. Must not be given undiluted.

#### CONTRAINDICATIONS:

Total biliary obstruction.

#### ADVERSE EFFECTS:

Septicemia, thrombophlebitis, bacteremia & endotoxemia

# **ORALS**

# **TABLETS**

#### **TABLETS**

## 1. ACAMPROSATE CALSIUM TABLETS

SALIENT ACTIONS: : Acamprosate is a putative anti-craving drug used to maintain abstinence in alcoholdependent patients. Its mechanism of action is uncertain, but the drug is thought to interact with neuronal NMDA receptors and calcium channels, and these proteins are implicated in the induction of alcohol dependence.

#### INDICATIONS:

Maintenance of abstinence from alcohol in patients with alcohol dependence who are abstinent at treatment initiation.

## DOSAGE REGIMEN:

The recommended dose is two 333 mg tablets (each dose should total 666 mg) taken three times daily.

#### CONTRAINDICATIONS:

It is contraindicated in patients who previously have exhibited hypersensitivity to acamprosate calcium or any of its components, severe renal impairment.

#### PRECAUTIONS:

Mild to moderate renal impairment -requires a dose reduction

Suicidality And Depression

#### INTERACTIONS:

Co-administration of it with naltrexone led to a 33% increase in the Cmax and a 25% increase in the AUC of acamprosate.

## ADVERSE REACTIONS:

diarrhea, nausea, vomiting, stomach pain, loss of appetite, headache, drowsiness, dizziness, vision problems, problems with memory or thinking, constipation, fatigue, weight gain/loss, back pain, muscle or joint pain, weakness, cold or flu-like symptoms, dry mouth, decreased or distorted sense of taste, sleep problems (insomnia), sweating, skin rash, numbness or tingly feeling, impotence, change in or loss of sexual desire, or decreased sexual ability, Suicidal thoughts.

## 2. ACEBROPHYLLINE TAB:

## SALIENT ACTIONS:

Acebrophylline is an air way mucus regulator with anti-inflammatory action.

It inhibits phospholipase A, and phosphatidylcholine leading to lesser production of the powerful proinflammatory substances like leukotrienes and tumour necrosis factor. By inhibiting the synthesis and release of these inflammatory mediators, it reduces inflammation, a key factor in airway obstruction, specially in chronic forms.

#### INDICATIONS:

COPD and bronchial asthma.

## DOSAGE REGIMEN:

The recommended dosage for adults in treating COPD and bronchial asthma is 100 mg twice daily.

CONTRAINDICATIONS: Hypersensitivity to xanthine derivative, Patient suffering from acute myocardial infarction, hypotension, hemodynamic instability and arrhythmias, renal disease or liver disorder.

## INTERACTIONS:

The plasma concentration of acebrophylline may be affected on concurrent administration of erythromycin, cephalexin, oxytetracyclline, oligomycin, lincomycin, cimetidine, clindamycin, allopurinol, quinolones, anticoagulants, etc. If concurrent use is essential, the dose of acebrophylline should be reduced. The concomitant use of acebrophylline and frusemide can potentiate dieresis, while concomitant use of acebrophylline with reserpine can cause tachycardia. Acebrophylline plasma concentration may be decreased in patients by co administration with drugs like phenytoin and barbiturates and in patients with smoking habit. ADVERSE REACTIONS:

Abdominal, discomfort, stomach/ abdominal distension, vomiting, diarrhea, constipation, heart burn, loss of appetite, esophageal bleeding, rashes, urticaria, itching, drowsiness, difficulty in breathing, leukocytosis nasal inflammation, tachycardia, fatigue, albuminuria, glycosuria, occasionally hyperglycemia.

# 3. ACECLOFENAC Tab 100 mg

## SALIENT ACTIONS:

Aceclofenac, a phenylacetic acid derivative, has antiinflammatory and analgesic properties. It is a potent i nhibitor of cyclo-oxygenase which is involved in the production of prostaglandins.

#### INDICATION & DOSAGE REGIMEN:

Ankylosing spondylitis, Rheumatoid arthritis, Osteoarthritis

Adult: 100 mg bid.

Hepatic impairment: Reduce initial dose to 100 mg daily.

#### CONTRAINDICATIONS:

Hypersensitivity to aspirin or NSAIDs; moderate to severe renal impairment; pregnancy (3rd trimester); history of peptic ulceration or GI bleed; patients with infections.

#### PRECAUTIONS:

Cautiously administer to patients with GI disease, ulcerative colitis, Crohn's disease, haematological abnormalities, hepatic porphyria; history of bronchial asthma; history of heart failure or hypertension; mild renal, hepatic or cardiac impairment. May impair ability to drive or operate machinery. Elderly.

#### INTERACTIONS:

May increase plasma concentrations of lithium and digoxin. Increased nephrotoxicity when used with diuretics or ciclosporin. Monitor serum potassium when used with potassium-sparing diuretics and ACE inhibitors. May enhance activity of anticoagulants. May increase risk of methotrexate toxicity when administered within 24 hr of methotrexate admin. Increased risk of GI bleed with other NSAIDs. Increased risk of convulsion with quinolones.

#### ADVERSE DRUG REACTIONS:

Diarrhoea, nausea, dyspepsia, abdominal pain, dizziness, rashes; increased LFTs, Severe GI bleeding; nephrotoxicity; blood dyscrasias.

## 4. ACETAZOLAMIDE Tab 0.25 mg

#### SALIENT ACTIONS:

Acetazolamide specifically inhibits the enzyme carbonic anhydrase which catalyses the reversible reaction involving the hydration of  $CO_2$  and dehydration of carbonic acid. It increases the excretion of  $HCO_3$  ions and as well as Na and K leading to alkaline diuresis. Carbonic anhydrase is also inhibited in the CNS to retard abnormal and excessive discharge from neurons.

#### INDICATIONS & DOSAGE REGIMENS:

- 1. Diuresis: Adult: 250-375 mg once daily or on alternate days.
- 2. Preoperative management of angle-closure glaucoma 3. Adjunct in open-angle glaucoma *Adult:* 250-1000 mg daily in divided doses. *Child:* 1 mth-12 yr: 10-20 mg/kg daily. Max: 750 mg daily, in 2-4 divided doses.
- 4. Epilepsy: *Adult:* Either alone or with other antiepileptics: 250-1000 mg daily in divided doses. *Child:* Neonates and up to 12 yr: Initially, 2.5 mg/kg bid-tid; maintenance: 5-7 mg/kg bid-tid.
- 5. Prophylaxis of high-altitude disorders: Adult: 500-1000 mg daily in divided doses. Prompt descent is still advised if severe symptoms such as cerebral or pulmonary oedema occur.

## CONTRAINDICATIONS:

Hypersensitivity to sulphonamides; sodium or potassium depletion, hepatic insufficiency; hepatic cirrhosis; hyperchloraemic acidosis; severe renal impairment; severe pulmonary obstruction; chronic noncongestive angle-closure glaucoma; adrenocortical insufficiency. Pregnancy.

## PRECAUTIONS:

Potassium supplements may be required. Impaired hepatic or renal function; diabetes. Monitor plasma electrolytes and blood count regularly. IM route is not recommended. Caution when driving or operating machinery. Elderly.

#### INTERACTIONS:

Aids penetration of weakly acidic substances like sulphonamides across blood and CSF barrier. May inhibit renal excretion of basic drugs (e.g. quinidine, ephedrine, amphetamines) and promotes excretion of acidic drugs.

#### ADVERSE DRUG REACTIONS:

Drowsiness, paraesthesia, ataxia, dizziness, thirst, anorexia, headache; confusion, malaise, depression; GI distress, metabolic acidosis, polyuria, hyperuricaemia, renal calculi, nephrotoxicity, hepatic dysfunction, Rarely, skin reactions or blood dyscrasias.

# 5. ACETYLSALICYLIC ACID Tab 75 mg (aspirin delayed release tablet) SALIENT ACTIONS:

Aspirin is an analgesic, anti-inflammatory and antipyretic. It inhibits cyclooxygenase, which is responsible for the synthesis of prostaglandin and thromboxane. It also inhibits platelet aggregation.

#### INDICATION & DOSAGE REGIMENS:

- 1. Prophylaxis of myocardial infarction: Adult: 75-325 mg once daily.
- 2. Stent implantation: Adult: 325 mg 2 hr before procedure followed by 160-325 mg/day thereafter.
- 3. Juvenile rheumatoid arthritis: Child: 80-100 mg/kg daily in 5 or 6 divided doses. Up to 130 mg/kg daily in acute exacerbations if necessary.
- **4.** Mild to moderate pain and fever: Adult: 325-650 mg repeated every 4-6 hr according to response. Max: 4 g/day.
- 5. Pain and inflammation associated with musculoskeletal and joint disorders: *Adult:* Initial: 2.4-3.6 g/day in divided doses. Usual maintenance: 3.6-5.4 g/day. Monitor serum concentrations. Administration Should be taken with food.

#### CONTRAINDICATIONS:

Hypersensitivity (attacks of asthma, angioedema, urticaria or rhinitis), active peptic ulceration; pregnancy (3<sup>rd</sup> trimester), children <12 yr, patients with haemophilia or haemorrhagic disorders, gout, severe renal or hepatic impairment, lactation.

#### PRECAUTIONS:

History of peptic ulcer or those prone to dyspepsia and those with gastric mucosal lesion, asthma or allergic disorders, dehydrated patients, uncontrolled hypertension, impaired renal or hepatic function, elderly.

#### INTERACTIONS:

Alcohol, corticosteroids, analgin, phenylbutazone and oxyphenbutazone may increase risk of GI ulceration. Aspirin increases phenytoin levels. May antagonize actions of uricosurics and spironolactone, May potentiate effects of anticoagulants, methotrexate and oral hypoglycaemics.

#### ADVERSE DRUG REACTIONS:

GI disturbances; prolonged bleeding time, rhinitis, urticaria and epigastric discomfort; angioedema, salicylism, tinnitus; bronchospasm, Gastric erosion, ulceration and bleeding; severe, occasionally fatal exacerbation of airway obstruction in asthma; Reye's syndrome (children <12 yr). Hepatotoxicity; CNS depression which may lead to coma; CV collapse and resp failure.

# 6. ACETYLSALICYLIC ACID 150 mg Tab (aspirin delayed release tablet) SALIENT ACTIONS:

Aspirin is an analgesic, anti-inflammatory and antipyretic. It inhibits cyclooxygenase, which is responsible for the synthesis of prostaglandin and thromboxane. It also inhibits platelet aggregation.

## INDICATION & DOSAGE REGIMENS:

- 1. Prophylaxis of myocardial infarction: Adult: 75-325 mg once daily.
- 2. Stent implantation: Adult: 325 mg 2 hr before procedure followed by 160-325 mg/day thereafter.
- 3. Juvenile rheumatoid arthritis: Child: 80-100 mg/kg daily in 5 or 6 divided doses. Up to 130 mg/kg daily in acute exacerbations if necessary.
- **4. Mild to moderate pain and fever:** *Adult:* 325-650 mg repeated every 4-6 hr according to response. Max: 4 g/day.
- 5. Pain and inflammation associated with musculoskeletal and joint disorders: *Adult*: Initial: 2.4-3.6 g/day in divided doses. Usual maintenance: 3.6-5.4 g/day. Monitor serum concentrations. Administration Should be taken with food.

#### CONTRAINDICATIONS:

Hypersensitivity (attacks of asthma, angioedema, urticaria or rhinitis), active peptic ulceration; pregnancy (3<sup>rd</sup> trimester), children <12 yr, patients with haemophilia or haemorrhagic disorders, gout, severe renal or hepatic impairment, lactation.

#### PRECAUTIONS:

History of peptic ulcer or those prone to dyspepsia and those with gastric mucosal lesion, asthma or allergic disorders, dehydrated patients, uncontrolled hypertension, impaired renal or hepatic function, elderly.

## INTERACTIONS:

Alcohol, corticosteroids, analgin, phenylbutazone and oxyphenbutazone may increase risk of GI ulceration. Aspirin increases phenytoin levels. May antagonize actions of uricosuries and spironolactone, May potentiate effects of anticoagulants, methotrexate and oral hypoglycaemics.

## ADVERSE DRUG REACTIONS:

GI disturbances; prolonged bleeding time, rhinitis, urticaria and epigastric discomfort; angioedema, salicylism, tinnitus; bronchospasm, Gastric erosion, ulceration and bleeding; severe, occasionally fatal exacerbation of

airway obstruction in asthma; Reye's syndrome (children <12 yr). Hepatotoxicity; CNS depression which may lead to coma; CV collapse and resp failure.

# 7. ACETYLSALICYLIC ACID 350 mg + CA CARBONATE 105 mg + ANHYDROUS CITRIC ACID 35 mg Tablet

#### SALIENT ACTIONS:

Aspirin is an analgesic, anti-inflammatory and antipyretic. It inhibits cyclooxygenase, which is responsible for the synthesis of prostaglandin and thromboxane. It also inhibits platelet aggregation.

#### INDICATION & DOSAGE REGIMENS:

- 1. Prophylaxis of myocardial infarction: Adult: 75-325 mg once daily.
- 2. Stent implantation: Adult: 325 mg 2 hr before procedure followed by 160-325 mg/day thereafter.
- 3. Mild to moderate pain and fever: Adult: 325-650 mg repeated every 4-6 hr according to response. Max: 4 g/day.
- **5. Pain and inflammation associated with musculoskeletal and joint disorders:** *Adult:* Initial: 2.4-3.6 g/day in divided doses. Usual maintenance: 3.6-5.4 g/day. Monitor serum concentrations. Administration Should be taken with food.

#### CONTRAINDICATIONS:

Hypersensitivity (attacks of asthma, angioedema, urticaria or rhinitis), active peptic ulceration; pregnancy (3<sup>rd</sup> trimester), children <12 yr, patients with haemophilia or haemorrhagic disorders, gout, severe renal or hepatic impairment, lactation.

#### PRECAUTIONS:

History of peptic ulcer or those prone to dyspepsia and those with gastric mucosal lesion, asthma or allergic disorders, dehydrated patients, uncontrolled hypertension, impaired renal or hepatic function, elderly.

#### INTERACTIONS:

Alcohol, corticosteroids, analgin, phenylbutazone and oxyphenbutazone may increase risk of GI ulceration. Aspirin increases phenytoin levels. May antagonize actions of uricosuries and spironolactone, May potentiate effects of anticoagulants, methotrexate and oral hypoglycaemics.

#### ADVERSE DRUG REACTIONS:

GI disturbances; prolonged bleeding time, rhinitis, urticaria and epigastric discomfort; angioedema, salicylism, tinnitus; bronchospasm, Gastric erosion, ulceration and bleeding; severe, occasionally fatal exacerbation of airway obstruction in asthma; Reye's syndrome (children <12 yr). Hepatotoxicity; CNS depression which may lead to coma; CV collapse and resp failure.

## 8. ACICLOVIR 200 mg Tab

## SALIENT ACTIONS:

Activity against HSV types I and II and varicella-zoster virus is due to intracellular conversion of aciclovir to the monophosphate by viral thymidine kinase with subsequent conversion to the diphosphate and active triphosphate by cellular enzymes. This active form inhibits viral DNA synthesis and replication by interfering with viral DNA polymerase enzyme and being incorporated into viral DNA.

#### INDICATION & DOSAGE REGIMENS:

1. Primary herpes simplex infections

Adult: 200 mg 5 times daily every 4 hr for 5-10 days; for severely immunocompromised patients and those with impaired absorption: 400 mg 5 times daily for 5 days.

2. Suppression of recurrent herpes simplex

*Adult:* 800 mg daily in 2-4 divided doses. May reduce to 400-600 mg daily if necessary. Reassess the condition every 6-12 mth. For mild or infrequent recurrences: Episodic treatment may be used: 200 mg 5 times daily for 5 days, preferably begun during the prodromal period.

3. Prophylaxis of herpes simplex in immunocompromised patients

Adult: 200-400 mg 4 times daily. Child: ≥2 yr: 200-400 mg 4 times daily; <2 yr: 100-200 mg 4 times daily.

4. Varicella zoster

Adult: >40 kg: 800 mg 4 times daily for 5 days. Child:  $\geq$ 2 yr and  $\leq$ 40 kg: 20 mg/kg (up to 800 mg) 4 times daily for 5 days.

5. Herpes zoster (shingles)

Adult: 800 mg 5 times daily for 7-10 days. Child:  $\geq$ 6 yr: 800 mg 4 times daily; 2-5 yr: 400 mg 4 times daily;  $\leq$ 2 yr: 200 mg 4 times daily.

## CONTRAINDICATIONS:

Hypersensitivity.

## PRECAUTIONS:

Renal impairment. Pregnancy, lactation. Neurological abnormalities with significant hypoxia, serious hepatic or electrolyte abnormalities. Maintain adequate hydration.

#### INTERACTIONS:

Probenecid decreases urinary excretion and increases half-life. Risk of renal impairment increased by other nephrotoxic drugs.

## ADVERSE DRUG REACTIONS:

Nausea, vomiting, headache, diarrhoea, rash, haematological changes (occasional), increase in liver enzymes, burning, itching or erythema (topical use). Eye application may produce stinging, superficial punctate keratopathy, blepharitis or conjunctivitis

# 9. ACOTIAMIDE HYDROCHLORIDE

100 mg Tablet

## SALIENT ACTIONS:

Acotiamide hydrochloride is a novel selective acetylcholinesterase (AChE) inhibitor. Acetylcholine is an important neurotransmitter to regulate gastrointestinal motility, and through the inhibition of degradation of acetylcholine, acotiamide produces the improvement of impaired gastric motility and delayed gastric emptying, and consequently the symptoms of functional dyspepsia.

# INDICATIONS & DOSAGES REGIMENS:

For the treatment of bloating after meals, epigastric bloating and early satiety in functional dyspepsia 100 mg TDS x 4 weeks

## CONTRAINDICATIONS:

Data not available

#### PRECAUTIONS:

Data not available

## INTERACTIONS:

Data not available

## ADVERSE EFFECTS

Headache, Diarrohea

## 10. ALBENDAZOLE 400 mg Tab, Syrup 200 mg / 5 ml, 10 ml bottle SALIENT ACTIONS:

Albendazole is an anthelmintic drug having strong activity against echinococcus granulosus, enterobius vermicularis, ascaris lumbricoidis, and hookworm infestation.

# INDICATION & DOSAGE REGIMENS:

1. Echinococcosis. 2. Neurocysticercosis

Adult: 400 mg twice a day for 28 days, maximum dose 800 mg daily.

3. Enterobiasis, ascariasis, hookworm infections.

Adult: 400 mg single dose

4. Strongyloidiasis.

Adult: 400 mg once a daily or twice a day for 3 consecutive days, repeated after 3 weeks if necessary.

## CONTRAINDICATIONS:

Hypersensitivity, pregnancy, lactation, neonates, liver impairment.

## PRECAUTIONS:

Monitor blood counts & liver function. Administer within 7 days of start of menstrual cycle.

## INTERACTIONS:

Cimetidine increases albendazole metabolism, serum levels are increased if taken with dexamethasone & praziquantel.

# ADVERSE DRUG REACTIONS:

GI discomfort, headache, nausea, dizziness, allergic reactions, pruritis, raised liver enzymes, alopecia, dry mouth.

## 11. ALENDRONATE SODIUM USP 35MG TAB

#### SALIENT ACTIONS:

Alendronic acid inhibits bone resorption by binding to bone hydroxyapatite and specifically inhibiting the activity of osteoclasts, the bone-resorbing cells.

## INDICATIONS:

Treatment or prevention of postmenopausal & corticosteroid-induced osteoporosis; Paget's bone disease, bone metastases & hypercalcemia malignancy.

#### DOSAGE REGIMEN:

2 tabs once weekly.

## CONTRAINDICATIONS:

Hypersensitivity. Abnormalities of the oesophagus, stricture or achalasia. Inability to stand or sit upright for at least 30 min; hypocalcaemia. Pregnancy & lactation.

#### PRECAUTIONS:

Patient w/ active upper GI abnormalities; history of major GI disease (e.g. peptic ulcer, GI bleeding), or surgery of the upper GI tract other than pyloroplasty. Renal impairment. Pregnancy and lactation. Patient Counselling: Maintain good oral hygiene.

Monitoring Parameters: Monitor alkaline phosphatase, serum Ca and 25(OH)D levels. Re-evaluate bone density every 2 year; height/wt measurement (annual).

#### INTERACTIONS:

Reduced absorption w/ antacids, Ca supplements or oral medications containing multivalent cations. Increased risk of GI irritation w/ aspirin, NSAIDs.

#### ADVERSE REACTIONS:

GI symptoms (e.g. abdominal pain, dyspepsia, diarrhoea, constipation), severe oesophageal reactions (e.g. oesophagitis, erosions, ulceration, stricture), peptic ulceration, osteonecrosis of the jaw, bone/joint/muscle pain, femoral fracture, hypocalcaemia, nausea. Rarely, Stevens Johnson syndrome, toxic epidermal necrolysis.

## 12. ALLOPURINOL TAB IP 100 MG

#### **SALIENT ACTIONS:**

Allopurinol inhibits xanthine oxidase, the enzyme that catalyses the conversion of hypoxanthine to xanthine then uric acid. Oxipurinol, the major active metabolite of allopurinol is also an inhibitor of xanthine oxidase. Allopurinol acts on purine catabolism, reducing the production of uric acid w/o disrupting the biosynthesis of vital purines.

## INDICATIONS:

Hyperuricaemia, gout, Cancer therapy-induced hyperuricaemia, Recurrent calcium oxalate stones.

## DOSAGE REGIMEN:

Hyperuricaemia, gout

Adult: Initially, 100 mg daily, then adjusted according to serum urate concentration. Maintenance: Mild: 100-300 mg daily; moderately severe: Up to 600 mg daily. Max: 900 mg/day. Doses over 300 mg daily should be taken in divided doses.

Cancer therapy-induced hyperuricaemia

Adult: 600-800 mg daily in divided doses, 2-3 days before cancer treatment.

Child: <15 yr 10-20 mg/kg daily. Max: 400 mg/day.

Recurrent calcium oxalate stones

Adult: 200-300 mg daily in single or divided doses.

#### **CONTRAINDICATIONS:**

Hypersensitivity to allopurinol.

#### PRECAUTIONS:

Not intended for the treatment of an acute gout attack. Renal and hepatic impairment. Pregnancy and lactation.

Patient Counselling: This drug may cause somnolence, vertigo or ataxia, if affected, do not drive or operate machinery. Maintain adequate fluid intake to prevent renal xanthine deposition.

Monitoring Parameters: CBC, serum uric acid, fluid input and output, hepatic and renal function, signs and symptoms of hypersensitivity.

## INTERACTIONS:

May inhibit the metabolism of mercaptopurine and azathioprine; reduce dose of mercaptopurine and azathioprine when given w/ allopurinol. May increase effect of warfarin and other coumarin anticoagulants. Increased excretion of the oxipurinol (metabolite) w/ salicylates or uricosuric agents. Increased toxicity w/

thiazide diuretics, some antibacterials, other antineoplastics, ciclosporin, some sulfonylurea antidiabetics, theophylline and vidarabine.

#### ADVERSE REACTIONS:

Maculopapular, pruritus or purpuric rashes, fever and chills, lymphadenopathy, leucopenia or leucocytosis, eosinophilia, arthralgia, vasculitis leading to renal and hepatic damage and, very rarely, seizures. Rarely, paraesthesia, peripheral neuropathy, alopecia, gynaecomastia, HTN, taste disturbances, nausea, vomiting, abdominal pain, diarrhoea, headache, malaise, drowsiness, vertigo and visual disturbances. Potentially Fatal: Hypersensitivity reactions (e.g. exfoliative rashes, Stevens-Johnson syndrome, toxic epidermal necrolysis), hepatotoxicity, bone marrow suppression and granulocytopenia.

# 13. ALPRAZOLAM 0.25 mg Tab

#### SALIENT ACTIONS:

Alprazolam has anxiolytic, muscle-relaxant, anticonvulsant, antidepressant and sleep-modifying effects. It binds to the  $\gamma$  aminobutyric acid (GABA)-specific sites throughout the CNS, leading to an increase in the inhibitory effect of GABA on neuronal excitability. Increased neuronal permeability to chloride ions thus results in hyperpolarisation and stabilisation.

## INDICATIONS & DOSAGE REGIMENS:

1. Short-term management of anxiety

Adult: 0.25-0.5 mg tid, increased to 3-4 mg daily if necessary. Elderly: Initially, 0.25 mg bid/tid.

2. Panic attacks

Adult: Up to 10 mg daily.

## CONTRAINDICATIONS:

Acute narrow-angle glaucoma, preexisting CNS depression or coma, resp depression, acute pulmonary insufficiency or sleep apnoea; severe hepatic impairment; pregnancy, lactation.

#### PRECAUTIONS:

Dosage reduction or gradual withdrawal. Dependence. Geriatric or debilitated patients. Muscle weakness, impaired hepatic or renal function; arteriosclerosis; obesity; depression particularly suicidal tendency; chronic pulmonary insufficiency. May impair ability to drive or operate machinery. Children <18 yr.

#### INTERACTIONS:

Potentiates action of alcohol and CNS depressants. Reduced conc with cigarette smoking by 50%, Cimetidine and fluoxetine reduce the clearance of alprazolam. Alprazolam enhances activity of imipramine and desipramine.

## ADVERSE DRUG REACTIONS:

Psychological and physical dependence, withdrawal syndrome; drowsiness, sedation, vertigo, headache, visual disturbances, GI disturbances, jaundice; fatigue, muscle weakness, ataxia, dizziness, confusion and depression. Potentially Fatal: Blood dyscrasias.

# 14. AMBROXOL HYDROCHLORIDE IP 30MG TAB

#### SALIENT ACTIONS:

Ambroxol is the active metabolite of bromhexine. Ambroxol causes an increase in secretion in the respiratory tract. It promotes surfactant production and stimulates ciliary activity. These effects assist the flow of mucus and its removal (mucociliary clearance). An improvement in mucociliary clearance was demonstrated in clinical pharmacological studies. The increase in secretion and mucociliary clearance facilitate expectoration and reduce the cough.

### INDICATIONS:

All forms of tracheobronchitis, emphysema with bronchitis pneumoconiosis, chronic inflammatory pulmonary conditions, bronchiectasis, bronchitis with bronchospasm asthma. During acute exacerbations of bronchitis it should be given with the appropriate antibiotic.

## DOSAGE REGIMEN:

As a mucolytic

Adult: 60-120 mg daily, in 2-3 divided doses.

#### CONTRAINDICATIONS:

Hypersensitivity to ambroxol.

## PRECAUTIONS:

Avoid use during the first trimester of pregnancy.

#### INTERACTIONS:

Antitussives: Concomitant administration of antitussives may impair the expectoration of liquefied bronchial mucus due to inhibition of cough reflex and cause congestion of secretions (see precautions). Antibiotics: After using ambroxol, the concentrations of the antibiotics amoxicillin, cefuroxime and erythromycin in bronchial secretions and sputum are increased.

## ADVERSE REACTION:

Mild GI effects and allergic reactions.

#### 15. AMIODARONE 100MG TAB

#### **SALIENT ACTIONS:**

Amiodarone is a class III antiarrhythmic agent but exhibits characteristics of all Vaughn-Williams classes. Its main effect is to delay repolarisation by prolonging the action potential duration (APD) and effective refractory period (ERP) in myocardial tissues. Additionally, it inhibits transmembrane influx of Na via fast channels, decreasing the maximal rate of depolarisation similar to class I. It is a non-competitive inhibitor of  $\alpha$ - and  $\beta$ -adrenergic actions as that of class II. Lastly, it produces negative chronotropic effect in nodal tissues.

#### INDICATIONS:

Supraventricular and ventricular arrhythmias.

Dosage:

Adult: Initially, 200 mg tid for 1 wk, then reduced to 200 mg bid for a further wk. Maintenance: ≤200 mg daily. Elderly: Initiate at lower end of dosing range.

Hepatic impairment: Reduce dose if necessary.

#### CONTRAINDICATIONS:

Evidence or history of thyroid dysfunction, iodine sensitivity, severe resp failure, circulatory collapse, severe hypotension, cardiogenic shock, sinus bradycardia, SA heart block; 2nd or 3rd degree AV block, severe conduction disturbances (e.g. high grade AV block, bifascicular/trifascicular block), sinus node disease (except in patient w/ pacemaker). Lactation. Concomitant use w/ drugs that prolong QT interval.

#### PRECAUTIONS:

Patient w/ hypotension, decompensated cardiomyopathy, severe heart failure, acute porphyria, conduction disturbances, hypokalaemia. Patient who underwent surgery. Elderly. Hepatic impairment. Pregnancy. Patient Counselling Avoid exposure to sunlight. This drug may cause eye disorders, if affected, do not drive or operate machinery.

Monitoring Parameters: Monitor BP, heart rate and rhythm, serum electrolyes

(esp K and Mg) throughout therapy; and LFT prior to treatment then semi-annually. Assess thyroid function before initiation and then every 3-6 mth. Perform chest X-ray before treatment and regular ophthalmic exams. Monitor pacing/defibrillation thresholds in patient w/ implantable cardiac device.

## INTERACTIONS:

Increased concentration w/ inhibitors of CYP3A4 (e.g. HIV-protease inhibitors, cimetidine). Reduced concentration w/ inducers of CYP3A4 (e.g. rifampicin, phenytoin). May induce bradycardia w/ β-blockers, Ca channel blockers, and other antiarrhythmic drugs. May increase risk of arrhythmia w/ drugs that cause hypomagnesaemia and hypokalaemia (e.g. diuretics, systemic corticosteroids). May increase concentration of ciclosporin, clonazepam, digoxin, flecainide, phenytoin, procainamide, quinidine, simvastatin, and warfarin. May affect drugs that are P-glycoprotein substrates. Potentially Fatal: May cause prolongation of QT interval w/ fluoroquinolones (e.g. moxifloxacin), antipsychotics (e.g. chlorpromazine, thioridazine, fluphenazine), lithium, TCAs (e.g. doxepin, maprotiline, amitriptyline), halofantrine, and terfenadine.

# ADVERSE REACTIONS:

Significant: Bradycardia, hypotension, peripheral neuropathy. Nervous: Benign intracranial pressure, paraesthesia, tremor, nightmares, sleeplessness, headache, ataxia. CV: Thrombophlebitis. GI: Nausea, vomiting, metallic taste. Genitourinary: Epididymitis. Endocrine: Phospholipidosis. Haematologic: Haemolytic/aplastic anaemia. Musculoskeletal: Myopathy. Ophthalmologic: Benign yellowish-brown corneal micro-deposits, optic neuropathy/neuritis, blindness. Dermatologic: Hot flushes, sweating, bluegrey skin discolouration. Others: Fatigue. Potentially Fatal: Cirrhosis, hepatitis, hepatic failure, cholestasis; ventricular tachyarrhythmia, worsening of arrhythmia, cardiac arrest; pulmonary fibrosis, interstitial pneumonitis, thyrotoxicosis, Stevens-Johnson syndrome, toxic epidermal necrolysis. Rarely, torsade de pointes.

#### 16. AMISULPRIDE TABLETS

#### SALIENT ACTIONS:

Amisulpride is a substituted benzamide atypical antipsychotic which binds selectively w/ a high affinity to human dopaminergic D2 and D3 receptor subtypes.

#### INDICATIONS:

Acute psychosis.

#### DOSAGE REGIMEN:

Adult: 400-800 mg bid. Max: 1.2 g daily. Patients w/ predominantly negative symptoms: 50-300 mg daily.

#### CONTRAINDICATION:

Phaeochromocytoma, concomitant prolactin-dependent tumours (e.g. pituitary gland prolactinomas or breast cancer). Pre-pubertal childn. Combination w/ levodopa.

#### PRECAUTION:

Patient w/ history of epilepsy; Parkinson's disease, CV disease. Avoid abrupt withdrawal. Renal impairment. Elderly. Pregnancy and lactation.

#### INTERACTIONS:

Increased risk of arrhythmias w/ cisapride, thioridazine, halofantrine, erythromycin, some antiarrhythmics, pimozide, haloperidol, TCAs,  $\beta$ -blockers, some Ca channel blockers, clonidine, guanfacine, digoxin, Kdepleting diuretics, lithium, antimalarials. May enhance effects of antihypertensives and CNS depressants (e.g. sedative H1-antihistamines, narcotics, anaesth, analgesics, barbiturates, benzodiazepines, other anxiolytics, clonidine and derivatives).

Potentially Fatal: Reciprocal antagonism between levodopa and neuroleptics.

### ADVERSE REACTIONS:

Insomnia, anxiety, agitation, drowsiness, wt gain, acute dystonia, parkinsonism, akathisia, tardive dyskinesia, QT prolongation, hypotension, bradycardia, GI disorders (e.g. constipation, nausea, vomiting, dry mouth), hyperglycaemia; breast pain, erectile dysfunction, amenorrhoea, gynaecomastia, galactorrhoea. Rarely, allergic reactions, abnormal LFTs, seizures.

Potentially Fatal: Neuroleptic malignant syndrome.

## 17. AMITRYPTILINE HCL 10 mg Tab

#### **SALIENT ACTIONS:**

Amitriptyline is a TCA that exerts its action by blocking neuronal re-uptake of noradrenaline and serotonin thus increasing synaptic concentration of serotonin and/or norepinephrine in the CNS.

## **INDICATIONS & DOSAGE REGIMENS:**

## 1. Depression

Adult: Initially, 50-75 mg daily in divided doses or as a single dose at night. May increase dose gradually to 150 mg daily, if needed. Up to 300 mg daily may be used in severe cases. Child: Adolescents(>16yr): 30-75 mg daily or in divided doses, preferably at bedtime. Elderly: 30-75 mg daily or in divided doses, preferably at bedtime.

#### 2. Nocturnal enuresis

Child: >11 yr: 25-50 mg at bedtime; 6-10 yr: 10-20 mg at bedtime. Treatment should not continue >3 mth.

#### 3. Neuropathic pain

Adult: Initially, 10-25 mg daily at night, may increase to 75 mg daily if needed. Higher doses require specialist attention.

## 4. Prophylaxis of migraine

Adult: Initially, 10 mg at night. Maintenance: 50-75 mg at night.

#### CONTRAINDICATIONS:

Hypersensitivity, use of MAO inhibitors within the last 14 days; acute recovery phase post-MI. Concurrent usage with cisapride.

#### PRECAUTIONS:

Bipolar illness, pregnancy, lactation elderly, CVS disease, renal or liver impairment, epilepsy, thyroid dysfunction, DM. Avoid abrupt withdrawal; urinary retention, prostatic hyperplasia; chronic constipation; angle-closure glaucoma; phaeochromocytoma.

## INTERACTIONS:

Concurrent use with altretamine may cause orthostatic hypotension. May increase adverse CV effects when used with amphetamines. May increase serum levels of carbamazepine. Increased risk of cardiac arrhythmias when used with β-agonists. Additive sedative effects when used with CNS depressants. Concurrent use with CYP2D6

inhibtors (e.g. chlorpromazine, delavirdine, fluoxetine, miconazole, paroxetine) may increase serum levels of amitriptyline.

#### ADVERSE DRUG REACTIONS:

Postural hypotension, tachycardia, conduction disturbances. Dry mouth, wt gain, sour or metallic taste, stomatitis, constipation; blurring of vision, urinary retention, fatigue, dizziness, weakness, tremors, headache, confusion and delirium in elderly, sexual disturbances; peripheral neuropathy; urticaria, angioedema, sweating, Cardiac arrhythmias.

## 18. AMLODEPINE BESILATE 5 mg Tab SALIENT ACTIONS:

Amlodipine relaxes peripheral and coronary vascular smooth muscle. It produces coronary vasodilation by inhibiting the entry of Ca ions into the voltage-sensitive channels of the vascular smooth muscle and myocardium during depolarisation. It also increases myocardial O2 delivery in patients with vasospastic angina.

#### INDICATIONS & DOSAGE REGIMENS

1. Hypertension, Prinzmetal's angina, Stable angina

Adult: Initially, 5 mg once daily increased to 10 mg once daily if necessary.

Elderly: Initial dose: 2.5 mg once daily.

## CONTRAINDICATIONS:

Known hypersensitivity to dihydropyridines.

#### PRECAUTIONS:

Impaired liver or renal function, CHF, sick-sinus syndrome, severe ventricular dysfunction, hypertrophic cardiomyopathy, severe aortic stenosis. Caution when used in patients with idiopathic hypertrophic subaortic stenosis. Elderly, children. Pregnancy, lactation.

#### INTERACTIONS:

Increased metabolism with rifampin. Reduced hypotensive effect with calcium. Potentiates effects of thiazide diuretics and ACE inhibitors. Avoid combination with β-blockers in patients with markedly impaired left ventricular function. May increase serum levels of CYP1A2 substrates e.g. aminophylline, fluvoxamine, ropinirole. CYP3A4 inhibitors (e.g. clarithromycin, doxycycline, isoniazid, nicardipine) may increase the effects of amlodipine. Additive BP-lowering effects when used with sildenafil, tadalafil or vardenafil.

### ADVERSE DRUG REACTIONS:

Headache, peripheral oedema, fatigue, somnolence, nausea, abdominal pain, flushing, dyspepsia, palpitations, dizziness. Rarely pruritus, rash, dyspnoea, asthenia, muscle cramps, Hypotension, bradycardia, conductive system delay and CCF.

## 19. AMOLDEPINE 5 mg + ATENOLOL 50 mg Tab SALIENT ACTIONS:

Atenolol is a cardioselective beta blocker. Amlodipine is a dihydropyridine calcium-channel blocker that blocks the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. Combination of the two drugs results in additive antihypertensive action.

#### INDICATIONS & DOSAGE REGIMENS:

1. Chronic stable angina, Hypertension

Adult: Per tablet contains atenolol 50 mg and amlodipine (as besylate) 5 mg: 1 tab once daily, may increase to 2 tablets daily if needed. Elderly: Per tablet contains atenolol 25 mg and amlodipine (besylate) 5 mg: Initiate with 1 tablet daily.

## **CONTRAINDICATIONS:**

Hypotension, sinus bradycardia, 2nd & 3rd degrees of heart block, cardiogenic shock, overt congestive failure, poor LV function, hypersensitivity to either component, pregnancy.

#### PRECAUTIONS:

Excessive fall of BP may occur in elderly patients. Caution in patients with COPD, thyrotoxicosis, congestive failure, vasospastic angina, hepatic & renal impairment. Caution in diabetic patients as beta-blockers may mask tachycardia occurring with hypoglycaemia. Withdrawal should be gradual. Lactation. Safety and efficacy have not been established in children. Not to be used in untreated phaeochromocytoma.

#### INTERACTIONS:

Additive effect when used with catecholamine depleting drugs; monitor for hypotension and/or marked bradycardia. If used with clonidine, clonidine withdrawal should occur a few days after withdrawal of the betablocker to prevent rebound hypertension; if replacing clonidine by beta-blocker, beta-blocker should be

introduced only after clonidine administration has stopped for several days. Concurrent use with prostaglandin synthase inhibiting drugs (e.g. indomethacin) may reduce the hypotensive effects of beta-blockers.

#### ADVERSE DRUG REACTIONS:

Headache, hypotension, dizziness, breathlessness, fatigue, muscle cramps, bradycardia, palpitations, flushing, oedema, dyspnoea, dyspepsia, cold extremities. Drowsiness, chestpain & impotence rarely. Hypersensitivity reactions.

# 20. AMOXYCILLIN TRIHYDRATE 250 mg / 500 mg Tab, Syrup 125mg/ml & 250 mg/ ml SALIENT ACTIONS:

Amoxicillin inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell wall by binding to one or more of the penicillin-binding proteins (PBPs), thus inhibiting cell wall biosynthesis resulting in bacterial lysis.

## INDICATIONS & DOSAGE REGIMENS:

- 1. Biliary tract infections 2. Endocarditis 3. Gonorrhoea 4. Otitis media 5. Pneumonia
- 6. Bronchitis 7. Typhoid and paratyphoid fever 8. Gastroenteritis 9. Urinary tract infections

Adult: 250-500 mg every 8 hr or 500-875 mg every 12 hr. Child:  $\leq$ 10 yr: 125-250 mg every 8 hr; <40 kg: 20-40 mg/kg daily in divided doses every 8 hr.

10.Uncomplicated gonorrhea: Adult: 3 g as a single dose with probenecid 1 g.

- 11.Dental abscesses: Adult: Initially, 3 g, repeat once after 8 hr.
- 12. Prophylaxis of endocarditis

Adult: 2 or 3 g as a single dose, 1 hr before dental procedure. Child: Single dose of 50 mg/kg. To be taken 1 hr prior to dental procedure. Max: 2 g/dose.

- 13. Otitis media: Child: 3-10 yr: 750 mg bid for 2 days.
- 14. *H.pylori* infection: *Adult:* 0.75 or 1 g bid or 500 mg tid in combination with either metronidazole or clarithromycin.

## CONTRAINDICATIONS:

Hypersensitivity.

### PRECAUTIONS:

Renal and hepatic disease; pregnancy, lactation; infectious mononucleosis.

## INTERACTIONS:

Increased levels with disulfiram and probenecid. Decreased effects with tetracyclines and chloramphenicol.

## ADVERSE DRUG REACTIONS:

Hyperactivity, agitation, insomnia, dizziness; maculopapular rash, exfoliative dermatitis, urticaria, hypersensitivity vasculitis; diarrhoea, nausea, vomiting; anaemia, thrombocytopenia, leucopenia, agranulocytosis, Neuromuscular hypersensitivity; pseudomembranous colitis.

# 21. ANTACID Tab : ALUMINIUM HYDROXIDE 300mg + MAG. ALUM. SILICATE HYDRATE 50 mg + MAG. HYDROXIDE 25mg + SIMETHICONE 25 mg Tab

#### SALIENT ACTIONS:

Aluminium hydroxide acts as antacids.

## INDICATIONS & DOSAGE REGIMENS:

- 1. Antacid: Upto 1 g daily.
- 2. Hyperphosphatemia in patients with chronic renal failure: upto 10g per day in divided doses.
- 3. Prophylaxis of migraine: 50-100 mg daily.

## CONTRAINDICATIONS:

Hypersensitivity to aluminium salts.

## PRECAUTIONS:

Chronic renal failure, chronic heart failure, oedema, cirrhosis, recent gastrointestinal haemorrhage.

#### INTERACTIONS:

Increased absorption with citrate or ascorbic acid, decrease absorption of allopurinol, tetracyclines, quinolones, cephalosporin.

#### ADVERSE DRUG REACTIONS:

Constipation, intestinal obstruction, hypophosphataemia.

#### 22. ANTIOXIDANT CAP

#### SALIENT ACTIONS:

Antioxidant improves the patient's condition by Inhibiting the herpes simplex virus growth, Neutralizing the free radicals and also participates in vital redox reactions of the body, Facilitating the synthesis of proteins and DNA in the cartilage, Works as an antioxidant to protect cells from damage, Contributing to the formation of blood cells and transferrin.

#### INDICATIONS:

Vit A & E deficiencies, antioxidant.

## DOSAGE REGIMEN:

1 cap tid for 1st 2 mths & then 1 cap od.

#### CONTRAINDICATIONS:

Hypersensitivity to antioxidant.

#### PRECAUTIONS:

Overdose toxic effects.

#### INTERACTIONS:

Antoxid Capsule may interact with the Alendronate, Ascorbic acid, Cholecalciferol, Cinoxacin, Ciprofloxacin, Dimercaprol

#### ADVERSE REACTION:

GI upset, heartburn, fever, chills.

#### 23. ARIPIPRAZOLE tablet

#### SALIENT ACTIONS:

Aripiprazole is a quinolinone derivative antipsychotic agent which acts as a partial agonist at D2 and 5-HT1A receptors and as an antagonist at 5-HT2A receptors.

#### INDICATIONS:

Schizophrenia

Acute manic episodes of bipolar disorder.

Dosage:

Schizophrenia

Adult: Initially, 10 mg or 15 mg once daily. Maintenance: 15 mg once daily. Adjust dose at intervals of at least 2 wk. Max: 30 mg once daily.

Child: ≥15 yr Initially, 2 mg for 2 days, titrated to 5 mg for 2 additional days to achieve the recommended dose, 10 mg daily. Subsequent increases should be administered in 5 mg increments. Max: 30 mg daily.

Acute manic episodes of bipolar disorder

Adult: Initially, 15 mg once daily, increased to 30 mg once daily according to response.

#### CONTRAINDICATIONS:

Hypersensitivity to aripiprazole.

#### PRECAUTIONS:

Patient w/ CV disease (e.g. prior MI, ischaemic heart disease, heart failure, conduction abnormalities), cerebrovascular disease, conditions which predispose to hypotension (e.g. dehydration, hypovolaemia) or HTN (including accelerated or malignant), Parkinson's disease, suicidal attempts. Patient at risk of seizures, including those w/ history of seizures, head trauma, brain damage. Not intended for treatment in elderly w/ dementia-related psychosis. Severe hepatic impairment. Elderly. Pregnancy and lactation.

Patient Counselling: This drug may cause somnolence and impairment of judgement, thinking or motor skills, if affected, avoid driving, operating machinery or performing hazardous tasks.

Monitoring Parameters: Regularly monitor BP, pulse, resp rate and level of consciousness.

#### INTERACTIONS:

May reduce plasma levels w/ CYP3A4 inducers (e.g. carbamazepine). May increase plasma levels w/ CYP3A4 inhibitors (e.g. clarithromycin, ketoconazole) or CYP2D6 inhibitors (e.g. fluoxetine, quinidine). Concurrent admin w/ anticholinergic agents may disrupt body temp regulation. Additive effects w/ hypotensive agents. Increased sedative and orthostatic hypotensive effects w/ lorazepam and other benzodiazepines. Overlapping adverse reactions (e.g. sedation) w/ CNS agents.

#### ADVERSE REACTIONS:

GI disorders (e.g. constipation, dyspepsia, nausea, vomiting); headache, anxiety, insomnia, lightheadedness, drowsiness, wt gain; agranulocytosis, leucopenia, neutropenia, thrombocytopenia; akathisia, tardive dyskinesia, pathological gambling.

Potentially Fatal: Neuroleptic malignant syndrome.

#### 24. ASPIRIN TABLETS

#### SALIENT ACTIONS:

Aspirin is an analgesic, anti-inflammatory and antipyretic. It inhibits cyclooxygenase, which is responsible for the synthesis of prostaglandin and thromboxane. It also inhibits platelet aggregation.

# INDICATION & DOSAGE REGIMENS:

1. Prophylaxis of myocardial infarction: Adult: 75-325 mg once daily.

2. Stent implantation: Adult: 325 mg 2 hr before procedure followed by 160-325 mg/day thereafter.

3. Juvenile rheumatoid arthritis: Child: 80-100 mg/kg daily in 5 or 6 divided doses. Up to 130 mg/kg daily in acute exacerbations if necessary.

4. Mild to moderate pain and fever: Adult: 325-650 mg repeated every 4-6 hr according to response. Max: 4

5. Pain and inflammation associated with musculoskeletal and joint disorders: Adult: Initial: 2.4-3.6 g/day in divided doses. Usual maintenance: 3.6-5.4 g/day. Monitor serum concentrations. Administration Should be taken with food.

## CONTRAINDICATIONS:

Hypersensitivity (attacks of asthma, angioedema, urticaria or rhinitis), active peptic ulceration; pregnancy (3rd trimester), children <12 yr, patients with haemophilia or haemorrhagic disorders, gout, severe renal or hepatic impairment, lactation.

#### PRECAUTIONS:

History of peptic ulcer or those prone to dyspepsia and those with gastric mucosal lesion, asthma or allergic disorders, dehydrated patients, uncontrolled hypertension, impaired renal or hepatic function, elderly.

## INTERACTIONS:

Alcohol, corticosteroids, analgin, phenylbutazone and oxyphenbutazone may increase risk of GI ulceration. Aspirin increases phenytoin levels. May antagonize actions of uricosuries and spironolactone, may potentiate effects of anticoagulants, methotrexate and oral hypoglycaemics.

# ADVERSE DRUG REACTIONS:

GI disturbances; prolonged bleeding time, rhinitis, urticaria and epigastric discomfort; angioedema, salicylism, tinnitus; bronchospasm, Gastric erosion, ulceration and bleeding; severe, occasionally fatal exacerbation of airway obstruction in asthma; Reye's syndrome (children <12 yr). Hepatotoxicity; CNS depression which may lead to coma; CV collapse and resp failure.

# 25. ATENOLOL Tab 25 mg

#### SALIENT ACTIONS:

Atenolol is a competitive cardioselective  $\beta_1$ -blocker. It does not have effect on  $\beta_2$ -receptors except in high doses. Its cardioselectivity is dose-related. Atenolol reduces resting and exercise-induced heart rate as well as myocardial contractility. Peripheral β-blockade may result in vasoconstriction. Atenolol reduces BP and heart rate which results in reduced myocardial work and O2 requirement leading to improved exercise tolerance and reduced frequency and intensity of 145iarrh attack.

# INDICATIONS & DOSAGE REGIMENS:

- I. Hypertension: 25-100 mg daily as a single dose, depending on response. Takes 1-2 wk for full effect to be observed.
- 2. Angina pectoris: 50-100 mg daily given as single or divided doses. Max dose: 200 mg daily.

3. Prophylaxis of migraine:: 50-100 mg daily.

## CONTRAINDICATIONS:

Hypersensitivity. Sinus bradycardia, sinus node dysfunction, heart block >1st degree, compensated cardiac failure, cardiogenic shock, bronchospastic diseases, peripheral vascular diseases. Pregnancy.

## PRECAUTIONS:

Compensated heart failure. Variant angina, acute MI, DM; peripheral vascular disorders; hepatic and renal dysfunction; elderly patients, children. Lactation. If atenolol and clonidine are co-admin, then gradual withdrawal of clonidine should take place a few days after withdrawal of atenolol.

## INTERACTIONS:

Decreased effect with aluminum and calcium salts, barbiturates, cholestyramine, NSAIDs, ampicillin, rifampicin, May increase effects of drugs which slow AV conduction (digoxin, verapamil, diltiazem).

#### ADVERSE DRUG REACTIONS:

Bronchospasm; cold extremities, fatigue, dizziness, insomnia, lethargy, confusion, headache, depression, nightmares, nausea, 146iarrhea, constipation, impotence and paraesthesia, Heart failure, 2<sup>nd</sup> or 3<sup>rd</sup> degree AV block.

## 26. ATOMOXETINE HCL TABLET

#### SALIENT ACTIONS:

Atomoxetine hydrochloride selectively inhibits noradrenaline reuptake w/ minimal affinity for other noradrenergic receptors or for other neurotransmitter receptors or transporters. It is used in the treatment of attention deficit hyperactivity disorder.

#### INDICATION & DOSAGE:

#### Attention deficit hyperactivity disorder

Adult: Initially, 40 mg/day may increase gradually after at least 7 days to 80 mg/day, up to 100 mg/day may be used after 2-4 wk.

Child:  $\geq 6 \ yr \leq 70 \ kg$ : Initially, 0.5 mg/kg/day, may increase gradually to approx 1.2 mg/kg/day. Max: 1.4 mg/kg or 100 mg, whichever is lower;  $\geq 70 \ kg$ : Initially, 40 mg/day, may increase gradually after at least 7 days to 80 mg/day, up to 100 mg/day may be used after 2-4 wk.

#### CONTRAINDICATIONS:

Angle-closure glaucoma. Severe CV or cerebrovascular disorders. Pheochromocytoma or history of pheochromocytoma. Not to be used w/ or w/in 14 days of discontinuing treatment w/ MAOIs.

#### PRECAUTIONS:

Patients w/ HTN, tachycardia; known or suspected prolonged QT interval; history of psychotic illness or bipolar disorder. Pregnancy and lactation.

Monitoring Parameters Monitor for signs of clinical worsening, suicidality or unusual behavioural changes at the start of therapy and during dose changes. Monitor height and wt gain especially during the initial period of treatment; dose reduction or treatment interruption may be needed in childn whose growth or wt gain is not satisfactory.

#### INTERACTIONS:

May cause additive effect when used w/ drugs that increase BP. May potentiate the effect of salbutamol on the CVS. May increase risk of cardiac events when used w/ drugs that affect cardiac conduction or electrolyte balance, or that inhibit CYP2D6 (e.g. fluoxetine, paroxetine, quinidine). Increased risk of QT prolongation w/ QT prolonging drugs (e.g. class Ia and III antiarrhythmics, moxifloxacin, erythromycin, TCAs, lithium, cisapride). Increased risk of seizures w/ drugs that are known to lower seizure threshold (e.g. phenothiazines, neuroleptics, mefloquine, bupropion, tramadol).

Potentially Fatal: Increased neurotoxic effect w/ MAOIs.

### ADVERSE REACTIONS:

GI disturbances, anorexia and wt loss, fatigue, sleep disturbances, dizziness, cough, sinusitis or rhinorrhoea, urinary hesitancy or retention, reduced libido and sexual dysfunction; skin rashes, increased sweating and hot flushes. Psychotic or manic symptoms (e.g. mania, agitation, hallucinations or delusional thinking) and hostility, aggressive behaviour or emotional lability, suicidal behaviour.

Potentially Fatal: Sudden death, stroke, MI, QT prolongation, hepatic failure.

#### 27. ATORVASTATIN Tab 10 mg/20 mg

#### SALIENT ACTIONS:

Atorvastatin competitively inhibits HMG-CoA reductase, the enzyme that catalyses the conversion of HMG-CoA to mevalonic acid. This results in the induction of the LDL receptors, leading to lowered LDL-cholesterol concentration.

#### INDICATIONS & DOSAGE REGIMENS:

1. Mixed dyslipidaemia 2. Nonfamilial hypercholesterolaemia

Adult: Initially, 10 or 20 mg daily, may increase at 4-wkly intervals. May initiate with 40 mg once daily in patients who require >45% reduction in low-density lipoprotein cholesterol. Max dose: 80 mg/day.

3. Heterozygous familial hypercholesterolaemia

Adult: Initially, 10 or 20 mg daily. Usual range depending on response: 10-80 mg daily. Child: 10-17 yr: Initially, 10 mg daily, adjust dose based on response. Max: 20 mg daily. Administration May be taken with or without food. (Avoid excessive consumption (>1 L/day) of grapefruit juice.)

#### CONTRAINDICATIONS:

Hypersensitivity, active liver disease or unexplained persistent elevations of serum transaminase, porphyria, pregnancy, lactation.

## PRECAUTIONS:

Patients who consume substantial quantities of alcohol. History of liver disease. Patients with risk factors for myopathy or rhabdomyolysis. Hypothyroidism should be properly managed prior to starting statin therapy. Children <10 yr. Premenarcheal females.

#### INTERACTIONS:

Increased AUC for norethindrone and ethinyl estradiol. Concomitant multiple doses of atorvastatin and digoxin increased steady-state digoxin levels. Increased risk of rhabdomyolysis when used concurrently with fibrates. Co-admin with antacid suspensions and colestipol decreased atorvastatin levels.

#### ADVERSE DRUG REACTIONS:

Headache, flatulence, diarrhoea, nausea, vomiting, anorexia, xerostomia, angioedema, myalgia, rash/pruritus, alopecia, allergy, infection, chest pain, Thrombocytopenia. Rhabdomyolysis with acute renal failure.

## 28. AZATHIOPRINE I.P. 50MG TAB

#### SALIENT ACTIONS:

Azathioprine is an imidazolyl derivative of mercaptopurine which inhibits RNA and DNA synthesis, and antagonises purine synthesis. It interferes w/ cellular metabolism by inhibiting coenzyme functioning and formation; may also inhibit mitosis.

## INDICATIONS & DOSAGE:

Prophylaxis of rejection in organ and tissue transplant

Adult: 1-5 mg/kg daily. Adjust according to clinical response and haematological tolerance.

Child: Same as adult dose.

Renal impairment: Reduce dose.

Hepatic impairment: Reduce dose.

Auto-immune diseases

Adult: 1-3 mg/kg daily. Discontinue treatment if there is no improvement after 3-6 mth.

Child: Same as adult dose.

Renal impairment: Reduce dose.

Hepatic impairment: Reduce dose.

Rheumatoid arthritis

Adult: Initially, 1 mg/kg daily in 1-2 divided doses for 6-8 wk, may increase by 0.5 mg/kg 4 wkly until response or up to 2.5 mg/kg daily. Maintenance: Reduce dose by 0.5 mg/kg 4 wkly to achieve lowest effective dose.

Child: Same as adult dose.

Renal impairment: Reduce dose.

Hepatic impairment: Reduce dose.

Renal homotransplantation

Adult: Initially, 3-5 mg/kg daily as a single dose starting on the day of transplantation, may be given 1-3 days prior to transplantation in some cases. Maintenance: 1-3 mg/kg daily.

Child: Same as adult dose.

Renal impairment: Reduce dose.

Hepatic impairment: Reduce dose.

## CONTRAINDICATIONS:

History of treatment w/ alkylating agents (e.g. chlorambucil, cyclophosphamide).

## PRECAUTIONS:

Patient w/ thiopurine methyltransferase (TPMT) enzyme deficiency. Renal and hepatic impairment. Pregnancy and lactation.

Monitoring Parameters Monitor CBC w/ differential and platelet regularly, LFTs, total bilirubin, CrCl, symptoms of infection; TPMT genotyping or phenotyping.

#### INTERACTIONS:

Increased risk of infection w/ intra-uterine device and live vaccine. May potentiate neuromuscular blockade produced by depolarising agents (e.g. succinylcholine). May reduce neuromuscular blockade by non-depolarising agents (e.g. tubocurarine). May reduce anticoagulant effect of warfarin. Risk of haematologic abnormalities w/ ACE inhibitors, co-trimoxazole. Increased myelosuppressive effects w/ indometacin and

cimetidine. Decreased rate of catabolism w/ xanthine oxidase inhibitors (e.g. allopurinol). Ribavirin may reduce efficacy and increase toxicity of azathioprine.

## ADVERSE REACTIONS:

Bone marrow depression (dose-related) characterised by anaemia, leucopenia, thrombocytopenia and rarely, aplastic anaemia, agranulocytosis, pancytopenia; reversible myelosuppression, megaloblastic anaemia, myelotoxicity, liver damage, GI disturbances, reversible alopecia, rashes, muscle and joint pains, rigors, fever, pneumonitis, tachycardia, pancreatitis, renal dysfunction, hypotension, Sweet's syndrome (acute febrile neutrophilic dermatosis). Rarely, Stevens-Johnson syndrome, toxic epidermal necrolysis. Potentially Fatal: Progressive multifocal leucoencephalopathy. Rarely, veno-occlusive liver disease, hepatosplenic T-cell lymphoma (HSTCL), post-transplant lymphoma.

# 29. AZILSARTAN MEDOXOMIL 40 MG TAB

#### SALIENT ACTIONS:

It selectively antagonises the effects of angiotensin II by blocking its binding to the

AT1 receptor in multiple tissues. Angiotensin II is the principal pressor agent of the renin-angiotensin system, with effects that include vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation and renal reabsorption of sodium. Blockade of the AT1 receptor inhibits the negative regulatory feedback of angiotensin II on renin secretion, but the resulting increases in plasma renin activity and angiotensin II circulating levels do not overcome the antihypertensive effect of azilsartan.

### INDICATIONS & DOSAGE:

Treatment of essential HTN.

Initially 40 mg once daily. May be increased to a max of 80 mg once daily.

#### CONTRAINDICATIONS:

Hypersensitivity. Pregnancy (2nd & 3rd trimesters).

#### PRECAUTIONS:

Activated renin-angiotensin-aldosterone system. Kidney transplantation. HTN w/ severe renal impairment. Severe hepatic impairment. Vol- &/or salt-depletion. Primary hyperaldosteronism. Hyperkalaemia. Aortic & mitral valve stenosis, obstructive hypertrophic cardiomyopathy. Concomitant w/ lithium. May affect ability to drive or operate machinery. Lactation.

#### INTERACTIONS:

Lithium; NSAIDs inclusing COX-2 inhibitors, acetylsalicylic acid (>3 g/day), non-selective NSAIDs; K-sparing diuretics, K supplements, K-containing salt substitutes & other substances that may increase K levels.

#### ADVERSE REACTIONS:

Dizziness, diarrhoea, increased creatine phosphokinase.

# 30. AZITHROMYCIN Tab 250 mg/ 500 mg, Syrup 100 mg/ 5ml, 15 ml botttle SALIENT ACTIONS:

Azithromycin blocks transpeptidation by binding to 50s ribosomal subunit of susceptible organisms and disrupting RNA-dependent protein synthesis at the chain elongation step.

#### INDICATIONS & DOSAGE REGIMENS:

1. Skin and soft tissue infections 2. Respiratory tract infections

Adult: 500 mg once daily for 3 days. Alternatively, 500 mg as a single dose on the 1st day followed by 250 mg once daily for 4 days. Child: >6 mth: 10 mg/kg; 15-25 kg: 200 mg; 26-35 kg: 300 mg; 36-45 kg: 400 mg. Doses to be taken once daily for 3 days.

- 3. Uncomplicated genital infections due to Chlamydia trachomatis: Adult: 1 g as a single dose.
- 4. Uncomplicated gonorrhea: Adult: 2 g as a single dose.
- 5. Prophylaxisof disseminated *Mycobacterium avium* complex (MAC) infections: *Adult:* 1.2 g once every wk. For treatment or secondary prophylaxis: 500 mg once daily with other antimycobacterials. *Child:* >6 mth: 10 mg/kg once daily for 3 days.
- 6. Granuloma inguinale: Adult: Initially, 1 g followed by 500 mg daily. Alternatively, 1 g once a wk for at least 3 wk, until all lesions have completely healed.

## **CONTRAINDICATIONS:**

Hypersensitivity.

## PRECAUTIONS:

Impaired liver and renal function; pregnancy and lactation; children.

#### INTERACTIONS:

Antacids containing aluminium and magnesium salts reduce rate of absorption. Increased risk of ergot toxicity, Potentially Fatal: Increased serum concentrations of digoxin and ciclosporin.

## ADVERSE DRUG REACTIONS:

Mild to moderate nausea, vomiting, abdominal pain, dyspepsia, flatulence, diarrhoea, cramping; angioedema, cholestatic jaundice; dizziness, headache, vertigo, somnolence; transient elevations of liver enzyme values.

#### 31. BACLOFEN TAB

#### SALIENT ACTIONS:

Baclofen inhibits both monosynaptic and polysynaptic reflexes in the spinal cord by acting as inhibitory neuronal transmitter or by blocking excitatory synaptic transmission through hyperpolarisation of afferent terminals.

#### INDICATIONS & DOSAGE:

Severe chronic spasticity

Adult: Initially, 15 mg daily in divided doses; increase gradually according to response. Suggested regimen: 5 mg tid for 3 days, increase to 10 mg tid for 3 days, then similar increments and intervals until either a dose of 20 mg tid is reached or until the desired therapeutic effect is obtained. W/draw gradually if there is no response w/in 6 wk of achieving max dosage.

Child: 0 to <18 yr 0.3 mg/kg daily, preferably in 4 divided doses; increase gradually at intervals of approx 1 wk until the desired therapeutic effect is obtained. Maintenance: 0.75-2 mg/kg daily. Max: <8 yr 40 mg daily; 8 to <18 yr 60 mg daily.

Elderly: Lower initial dose.

Renal impairment: Dose reduction may be required.

#### CONTRAINDICATIONS:

Epilepsy refractory to therapy, peptic ulceration.

#### PRECAUTIONS:

Patient w/ psychotic disorders, schizophrenia, confusional states, Parkinson's disease, cerebrovascular or resp insufficiency, history of autonomic dysreflexia, history of gastro duodenal ulcers, pre-existing sphincter hypertonia. Avoid abrupt withdrawal. Renal and hepatic impairment. Elderly, childn. Pregnancy and lactation. Patient Counselling This drug may cause dizziness, sedation, somnolence and visual disturbances, if affected, do not drive or operate machinery. Monitoring Parameters Monitor EEG regularly in patients w/ epilepsy.

#### INTERACTIONS:

Risk of hypotension, dyspnoea and other CNS effects w/ morphine. Enhanced effect w/ TCAs. Increased risk of hypotension w/ antihypertensives. May increase the undesirable effects of levodopa (e.g. mental confusion, hallucinations, agitation).

#### ADVERSE REACTIONS:

Nausea, sedation, somnolence, lightheadedness, dizziness, lassitude, fatigue, confusion, muscular pain/weakness, hypotension, euphoria, hallucinations, depression, headache, tinnitus, convulsions, paraesthesias, slurred speech, dry mouth, taste alterations, vomiting, diarrhoea or constipation, ataxia, nystagmus, tremors, insomnia, visual disturbances, rashes, pruritus, urinary disturbances, increased sweating, CV and resp depression, blood sugar changes, altered liver function values, paradoxical increase in spasticity; problems in erection and ejaculation (intrathecal). Rarely, hypothermia.

#### 32. BENFOTIAMINE TAB

#### SALIENT ACTIONS:

Benfotiamine is an allithiamine that boosts Advanced Glycation Endproduct (AGE)-inhibiting thiamine pyrophosphate and cell-shielding transketolase activity.

Indication & dosage:

Alcoholic neuropathy, Diabetic neuropathy

Adult: 100 mg 4 times daily.

#### CONTRAINDICATIONS:

Hypersentivity.

#### PRECAUTIONS:

NA

## INTERACTIONS:

NA

#### ADVERSE REACTIONS:

GI upset

#### 33. BENZONATATE 100MG

#### SALIENT ACTIONS:

Benzonatate is thought to act as a local anesthetic, decreasing the sensitivity of stretch receptors in the lower airway and lung, thereby reducing the drive to cough after taking a deep breath.

#### INDICATIONS & DOSAGE:

An antitussive: bronchitis, emphysema, influenza, and pneumonia

Initial dose is one 100 mg perle (gelcap) by mouth, 3 times a day. Dosage may be increased as necessary, up to a maximum of 600 mg per day.

## CONTRAINDICATIONS:

Hypersensitivity.

## PRECAUTIONS:

NA

#### INTERACTIONS:

NA

#### ADVERSE REACTIONS:

drowsiness, dizziness, and dysphagia.

## 34. BETAHISTINE HYDROCHLORIDE Tab 8 mg

#### SALIENT ACTIONS:

Betahistine improves the microcirculation in the labyrinth which reduces endolymphatic pressure.

#### INDICATIONS & DOSAGE REGIMENS:

Meniere's disease: Initially, 16 mg tid. Maintenance: 24-48 mg daily. Administration Should be taken with food.

## CONTRAINDICATIONS:

Phaeochromocytoma. Porphyria.

#### PRECAUTIONS:

Active peptic ulcer, bronchial asthma, pregnancy and lactation.

#### INTERACTIONS:

May antagonize antihistamines. May decrease bronchodilator effects of β-2 agonists.

#### ADVERSE DRUG REACTIONS:

Rash, pruritus, urticaria, dyspepsia, nausea, peptic ulcer disease, headache, dizziness, insomnia.

#### 35. BISACODYL Tab 5 mg

## SALIENT ACTIONS:

Bisacodyl acts mainly in the large intestine by increasing its motility to effect bowel evacuation.

Onset: 6-12 hr (oral).

## INDICATIONS & DOSAGE REGIMENS:

1. Constipation: Adult: 5-10 mg at night. Child: >4 yr: 5 mg at night time.

2. Bowel evacuation: Adult: Initially, 10-20 mg the night before the procedure followed by 10 mg suppository admin rectally the next morning. Child: >10 yr: Same as adult dose. 4-10 yr: 5 mg the night before the procedure and 5 mg suppository admin rectally the following morning.

#### CONTRAINDICATIONS:

Acute surgical abdomen or intestinal obstruction, severe dehydration, faecal impaction, chronic use.

#### PRECAUTIONS:

Swallow the tab whole. Pregnancy; inflammatory bowel disease.

#### INTERACTIONS:

Do not give antacids or milk within 1 hr of taking the drug (enteric coated).

### ADVERSE DRUG REACTIONS:

Abdominal discomfort (colic, cramps). Suppositories may cause irritation and proctitis.

#### 36. BISOPROLOL FUMARATE TAB

#### SALIENT ACTIONS:

Bisoprolol selectively and competitively blocks  $\beta_1$ -receptors but has little or no effect on  $\beta_2$ -receptors except at high doses

#### INDICATIONS & DOSAGE:

Oral

Hypertension

Adult: 5-10 mg once daily. Max: 20 mg/day.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation
<40	Initial: 2.5 mg/day.

Hepatic impairment: Severe: Initially, 2.5 mg/day. Max: 10 mg/day.

Oral

Angina pectoris

Adult: 5-10 mg once daily. Max: 20 mg/day.

Renal impairment:

CrCl (ml/min) Dosage Recommendation <40 Initial: 2.5 mg/day.

Hepatic impairment: Severe: Initially, 2.5 mg/day. Max: 10 mg/day.

Oral

Heart failure

Adult: Initially, 1.25 mg once daily doubled after 1 wk if tolerated, then increased gradually at 1-4-wk intervals. Max: 10 mg once daily.

## CONTRAINDICATIONS:

Cardiogenic shock, overt cardiac failure, 2nd or 3rd degree AV block, SA block, sick sinus syndrome, symptomatic bradycardia and hypotension, untreated phaeochromocytoma, metabolic acidosis, severe, peripheral arterial disease, severe bronchial asthma or severe COPD.

#### PRECAUTIONS:

Patients w/ compensated heart failure, bronchospastic disease, myasthenia gravis, DM. Patients undergoing major surgery involving general anaesth. May mask signs and symptoms of hypoglycaemia and hyperthyroidism. Avoid abrupt withdrawal as it may exacerbate angina, MI and ventricular arrhythmias or may precipitate thyroid storm. Renal and hepatic impairment. Pregnancy and lactation.

Monitoring Parameters: Monitor ECG, heart rate and BP, Regularly monitor blood glucose in patients w/ DM.

#### INTERACTIONS:

May potentiate AV conduction time and may increase negative inotropic effect w/ class I antiarrhythmic drugs (e.g. quinidine, disopyramide, propafenone). Concomitant catecholamine-depleting drugs (e.g. reserpine, guanethidine) may produce excessive sympathetic activity. May exacerbate rebound HTN upon discontinuance of clonidine treatment. Increased risk of bradycardia w/ digitalis glycosides. Reduced hypotensive effect w/ NSAIDs.

## ADVERSE REACTIONS:

Bradycardia, worsening of pre-existing heart failure, hypotension, dizziness, headache, GI disturbances (e.g. nausea, vomiting, diarrhoea, constipation), cold or numb extremities, asthenia, fatigue, upper resp infection, rhinitis, sinusitis, dyspnoea.

#### 37. BUCLIZINE HCL IP 25MG TAB

#### SALIENT ACTIONS:

Buclizine is a piperazine antihistamine with antimuscarinic and moderate sedative properties. It is used mainly for its antiemetic action and in the treatment of migraine in combination with analgesics.

#### INDICATIONS & DOSAGE:

Oral

Prophylaxis of motion sickness

Adult: As hydrochloride: 25 or 50 mg given 30 min before travelling, repeated after 4-6 hr, if necessary.

Oral

Migraine

Adult: As hydrochloride: 12.5 mg taken as soon as symptoms arise.

Child: 10-14 yr: 6.25 mg at the start of the symptoms. >14 yr: follow adult dose.

Ora!

Nausea and vomiting

Adult: As hydrochloride: 25 or 50 mg tid.

Oral

Pruritic skin disorders

Adult: As hydrochloride: 25-50 mg daily.

### CONTRAINDICATIONS:

Hypersensitivity; neonates.

#### PRECAUTIONS:

Driving or operating machinery; open-angle glaucoma; urinary retention; prostatic hyperplasia, pyloroduodenal obstruction, epilepsy; renal and hepatic impairment; pregnancy.

## INTERACTIONS:

Potentially Fatal: Effect of alcohol, sedatives and other CNS depressants potentiated.

ADVERSE REACTIONS:Drowsiness, dizziness, incoordination; blurred vision; urinary retention; vomiting; rash; dry mouth; headache, nausea, epigastric pain, wt gain and diarrhoea.

## 38. BUPROPION HCL ER TAB USP 150MG

## SALIENT ACTIONS:

Bupropion is a relatively weak inhibitor of the neuronal uptake of norepinephrine and dopamine, w/ minimal effect on serotonin reuptake. The mechanism by which it aids in smoking cessation is presumed to be mediated by its noradrenergic and/or dopaminergic actions.

#### INDICATIONS & DOSAGE:

Oral

Smoking cessation

Adult: As modified-release preparation: Initially, 150 mg once daily for 6 days then increased to 150 mg bid, give 8 hr between doses for 7-9 wk. Discontinue treatment if abstinence is not achieved by 7th wk. Max: 300 mg daily.

Elderly: 150 mg once daily for 7-9 wk.

Renal impairment: 150 mg once daily.

Hepatic impairment: Mild to moderate: 150 mg once daily. Severe hepatic cirrhosis: Contraindicated.

Oral

Depression

Adult: Initially, 100 mg bid for at least 3 days, may increase to 100 mg tid if necessary. Increased further to 150 mg tid if no improvement has been observed after several wk of therapy. Max: 150 mg tid. As modified-release preparation: 150 mg once daily in the morning, increased to 150 mg bid after 3 days if necessary, may further increase to 200 mg bid after several wk if needed. Max: 450 mg as a single dose.

Elderly: As immediate-release tab: Initially, 37.5 mg bid. As sustained-release tab: Initially, 100 mg daily. Dose may be increased by 37.5-100 mg every 3-4 days as tolerated. Max: 300 mg daily in divided doses.

Renal impairment: Reduce dose or dosing frequency.

Hepatic impairment: Mild to moderate: Reduce dose or dosing frequency. Severe: As immediate-release preparation: Max: 75 mg once daily. As modified-release preparation: Max: 100 mg once daily or 150 mg every other day.

#### CONTRAINDICATIONS:

Current or history of seizure disorder, eating disorders (e.g. bulimia or anorexia nervosa); CNS tumour, epilepsy; history of bipolar disorder (when used as an aid in smoking cessation). Abrupt withdrawal of alcohol, benzodiazepines, barbiturates, antiepileptic drugs. Severe hepatic cirrhosis. Concomitant admin or w/in 14 days of MAOIs withdrawal.

## PRECAUTIONS:

Patient w/ bipolar disorders (in the treatment of depression); recent history of MI or unstable heart disease; other risk factors for seizures (e.g. alcohol abuse, diabetes, history of head trauma). Renal or mild to moderate hepatic impairment. Elderly. Pregnancy and lactation. Patient Counselling This drug may cause dizziness and lightheadedness, if affected, do not drive or operate machinery. Monitoring ParametersMonitor BP and LFT before and during treatment; monitor wkly if used w/ nicotine products. Monitor for worsening and emergence of suicidal thoughts and behaviours.

#### INTERACTIONS:

Observe extreme caution w/ concurrent admin of drugs that lower seizure threshold (e.g. other antidepressants, antipsychotics, theophylline, systemic corticosteroids). Increased risk of side effects w/ levodopa or amantadine. Decreased exposure w/ CYP2B6 inducers (e.g. ritonavir, lopinavir, efavirenz). May increase exposure of CYP2D6 substrates (e.g. venlafaxine, fluoxetine, antipsychotics, β-blockers, type 1C antiarrhythmics. Potentially Fatal: Concurrent use w/ MAOIs may cause acute toxicity symptoms and increased risk of fatality.

## ADVERSE REACTIONS:

Headache, dry mouth, nausea, insomnia, dizziness, pharyngitis, constipation, agitation, anxiety, abdominal pain, tinnitus, tremor, nervousness, somnolence, irritability, vasodilation, photosensitivity, hypertonia, suicidal ideation, emotional lability, hostility, palpitation, myalgia, twitch, sweating, rash, nausea, migraine, insomnia, pharyngitis, urinary frequency or retention, hot flushes, dysphagia, flushing, anorexia, chills, facial eodema, photosensitivity, hypotension, stroke, tachycardia, gastric reflux, gingivitis, increased salivation, jaundice, mouth ulcers, stomatitis, thirst, ecchymosis, leg cramps, decreased libido, depersonalisation, dysphoria, vertigo, phlebitis, pulmonary embolism, colitis, aesophagitis, GI hemorrhage, hepatitis, intestinal perforation, pancreatitis, stomach ulcer, hyperglycaemia, hypoglycaemia, anaemia, muscle weakness, fever, rhabdomyolysis, euphoria, delirium, pneumonia, Stevens-Johnson syndrome, mydriasis, deafness, increased intraocular pressure, abnormal ejaculation, cystitis, vaginitis, and salpingitis.

# 39. CABERGOLINE 0.25MG TAB

#### SALIENT ACTIONS:

Cabergoline is a long-acting dopamine D2-agonist. It inhibits prolactin secretion through hypothalamic inhibitory control exerted through the release of dopamine.

## INDICATIONS & DOSAGE:

Oral

Inhibition of physiological lactation

Adult: 1 mg as a single dose on the 1st day postpartum.

Oral

Suppression of lactation

Adult: 250 mcg 12 hrly for 2 days.

Hyperprolactinaemia-associated disorders

Adult: Initially, 0.5 mg wkly, increase gradually, preferably in increments of 0.5 mg wkly at mthly intervals until optimal response. Wkly dose may be given in 1 or 2 divided doses on separate days. Usual dose: 1 mg wkly (range: 0.25-2 mg, up to 4.5 mg wkly). Oral

As monotherapy in Parkinson's disease

Adult: Initially, 1 mg daily, gradually increase by 0.5-1 mg at 1 or 2 wk interval until optimal response.

Recommended dose: 2-3 mg daily.

Oral

Adjunct to levodopa treatment in Parkinson's disease

Adult: Initially, 1 mg daily, gradually increase by 0.5-1 mg at 1 or 2 wk interval until optimal response. Recommended dose: 2-3 mg daily.

### CONTRAINDICATIONS:

Uncontrolled HTN; history of pulmonary, pericardial, and retroperitoneal fibrotic disorders; cardiac valvular disorders. Toxaemia of pregnancy, history of puerperal psychosis. Concomitant use w/ dopamine antagonists. PRECAUTIONS:

Patients w/ severe CV disease, Raynaud's syndrome, peptic ulcer, GI bleeding. Renal or hepatic impairment. Pregnancy and lactation. Patient Counselling May impair ability to drive or operate machinery. Monitoring Parameters Monitor BP; serum prolactin level (mthly until normalised); echocardiogram (at baseline and 6-12 mthly); ESR, chest X-ray, and serum creatinine level; signs and symptoms of pleuropulmonary disease, ureteral/abdominal vascular obstruction. Perform pregnancy test prior to initiation of therapy.

## INTERACTIONS:

Increased risk of orthostatic hypotension when used w/ antihypertensives. Additive therapeutic effect w/ levodopa. Increased systemic bioavailability w/ macrolide antibiotics (e.g. erythromycin).

Potentially Fatal: Diminished therapeutic effect w/ dopamine antagonist (e.g. phenothiazines, butyrophenones, thioxanthines, metoclopramide).

## ADVERSE REACTIONS:

Abdominal pain, angina, breast pain, confusion, constipation, depression, dyspepsia, epigastric pain, gastritis, hallucinations, headache, nausea, syncope, postural hypotension, somnolence, allergic skin reactions, alopecia, cardiac valvulopathy, constrictive pericarditis, drowsiness, dyskinesia, erythromelalgia, hypersexuality, hypotension, increased libido, leg cramps, pericardial effusion, pathological gambling, peripheral oedema, pleural effusion/fibrosis, pleuritis, pulmonary/retroperitoneal fibrosis. Rarely, digital vasospasm, epistaxis, hot

flushes, muscle weakness, palpitation, paraesthesia, transient hemianopia, vomiting.

#### 40. CALCITRIOL CAP

#### SALIENT ACTIONS:

Calcitriol promotes Ca absorption in the intestines and retention at the kidneys thus increasing serum Ca levels. It also increases renal tubule phosphate resorption, consequently decreasing serum phosphatase levels, PTH levels and bone resorption.

#### INDICATIONS & DOSAGE:

Oral

Renal osteodystrophy

Adult: For correction of Ca and phosphorus metabolism abnormalities: Initially, 0.25 mcg daily. Patient w/ normal or slightly reduced Ca levels: 0.25 mcg every other day. If no response w/in 2-4 wk, increase daily dose by 0.25 mcg at 2-4 wk intervals. Immediately stop treatment if serum Ca levels rise to 1 mg/100 mL (250 mcmol/L) above normal (9-11 mg/100 mL or 2,250-2,750 mcmol/L), or serum creatinine rises to >120 mcmol/L.

Oral

Postmenopausal osteoporosis

Adult: 0.25 mcg bid.

## CONTRAINDICATIONS:

Diseases associated w/ hypercalcaemia, evidence of metastatic calcification and vit D toxicity.

#### PRECAUTIONS:

Patient w/ malabsorption syndrome. Renal or hepatic impairment. Pregnancy and lactation. Patient Counselling Maintain adequate fluid intake. Avoid uncontrolled intake of additional Ca-containing preparations. Monitoring Parameters Periodically monitor serum Ca, Mg, phosphorus and alkaline phosphatase and 24-hr urinary Ca and phosphorus. During initial phase, determine serum Ca and phosphorus at least twice wkly.

### INTERACTIONS:

Increased risk of hypercalcaemia w/ thiazide diuretics. Hypercalcaemia in patients on digitalis may precipitate cardiac arrhythmias. Mg-containing drugs (e.g. antacids) may cause hypermagnesaemia in patients undergoing chronic renal dialysis. Bile acid sequestrants including colestyramine and sevelamer may impair intestinal absorption of calcitriol. CYP450 enzyme-inducing anticonvulsants (e.g. carbamazepine, phenobarbital, phenytoin) may reduce effects of vit D. Corticosteroids w/ glucocorticoid activity may counteract the effects of calcitriol in bone and mineral metabolism.

## ADVERSE REACTIONS:

Weakness, headache, somnolence, nausea, vomiting, dry mouth, constipation, muscle and bone pain, metallic taste, anorexia, abdominal pain and epigastric discomfort; polyuria, polydipsia, wt loss, nocturia, conjunctivitis (calcific), pancreatitis, photophobia, rhinorrhoea, pruritus; hyperthermia, decreased libido; elevated BUN, albuminuria; hypercholesterolaemia, elevated AST and ALT, ectopic calcification, HTN, cardiac arrhythmias, nephrocalcinosis, sensory disturbance, dehydration, apathy, occasional mild pain on inj site. Rarely, overt psychosis.

# 41. CALCIUM 500 mg + VITAMIN D3 250 IU Tab

#### SALIENT ACTIONS:

Calcium carbonate is a calcium supplement that is used in deficiency states and as an adjunct in the prevention and treatment of osteoporosis. Vitamin D3 is a fat-soluble sterol, it aids in the regulation of calcium and phosphate homeostasis and bone mineralisation.

#### INDICATIONS & DOSAGE REGIMENS:

Supplementation of calcium and vitamin D3

Adult: As effervescent tablet containing calcium carbonate 1500 mg and vitamin D<sub>3</sub> 10 mcg: 1 tablet bid, to be dissolved in a glass of water and taken immediately.

## CONTRAINDICATIONS:

Patients with hypercalcaemia and/or hypercalciuria. Nephrolithiasis, hypervitaminosis D, hypophosphataemia. **PRECAUTIONS:** 

Impaired calcium absorption in achlorhydria which is common in elderly. Increased risk of hypercalcaemia and hypercalciuria in hypoparathyroid patients receiving high doses of vitamin D. Caution when using in patients with history of kidney stones. Renal impairment; frequent monitoring of serum calcium and phosphorus is recommended.

## INTERACTIONS:

May affect the absorption of tetracycline when used together. Concurrent use with systemic corticosteroids may reduce calcium absorption. Thiazide diuretics may decrease urinary excretion of calcium. Concurrent use with ion-exchange resins may reduce GI absorption of vitamin D. Hypercalcaemia may increase the toxicity of cardiac glycosides during treatment with calcium and vitamin D, monitor ECG and serum calcium levels. Bisphosphonate or sodium fluoride should be given at least 3 hr before calcium-containing preparations.

ADVERSE DRUG REACTIONS:

Constipation, flatulence, nausea, abdominal pain and diarrhoea. Pruritus, rash and urticaria.

# 42.CAMPHOR 25 mg + CHLOROTHYMOL 5 mg + EUCALYPTOL 125 mg + MENTOL 55 mg + TERPINEOL 120 mg Tab SALIENT ACTIONS:

contain aromatic ingredients that provide relief from various respiratory ailments. Camphor applied externally acts as a rubefacient and mild analgesic. It is also a principal ingredient of many nasal decongestants for inhalation. Menthol is chiefly used to relieve symptoms of bronchitis, sinusitis and similar conditions. For this purpose, it may be used as an inhalation or as an ointment with camphor and eucalyptus oil for application to the chest and nostrils. Eucalyptus oil has been used as an inhalation often with other volatile substances. Eucalyptol kills bacteria and eases breathing difficulties in people with croup, asthma and bronchitis. It is also used externally for chest congestion, to ease aches and pains, and as a deodorant. Terpineol has anti-infective properties. Chlorothymol is a multipurpose phenolic antiseptic. It finds special use in symptomatic relief from common cold.

#### INDICATIONS & DOSAGES REGIMENS:

Prompt relief of symptoms of common cold, sinusitis, pharyngitis and other conditions accompanied by congestion of the upper respiratory tract.

## CONTRAINDICATIONS:

contraindicated in patients with hypersensitivity to any ingredient of the formulation.

#### PRECAUTION:

Direct contact with eyes and nostrils is to be strictly voided. In case of exposure to the eyes or nostril, rinse/wash thoroughly with cold water, is not intended for oral administration and should be never exposed to flame or kept near microwave.

#### INTERACTIONS:

None

#### ADVERSE DRUG REACTIONS:

None reported.

# 43. CARBAMAZEPINE Tab 100 mg / 200 mg, Syrup 100 mg/5ml, 100 ml bottle SALIENT ACTIONS:

Carbamazepine reduces polysynaptic responses and blocks post-tetanic potentiation. It is effective in partial and generalised convulsions as well as in mixed types but not in petit mal seizures. It reduces or abolishes pain in trigeminal and glossopharyngeal neuralgia.

#### INDICATIONS & DOSAGE REGIMENS:

- 1. Epilepsy: Adult: Initially, 100-200 mg once or bid gradually increased by increments of 100-200 mg every 2 wk. Maintenance: 0.8-1.2 g daily in divided doses. Max dose: 2 g daily. Child: ≤1 yr: 100-200 mg daily, 1-5 yr: 200-400 mg daily, 5-10 yr: 400-600 mg daily, 10-15 yr: 0.6-1 g daily. Alternatively, 10-20 mg/kg daily in divided doses.
- 2. Trigeminal neuralgia: *Adult*: Initially, 100 mg once or bid gradually increased as necessary. Maintenance: 400-800 mg daily in 2-4 divided doses. Max: 1.2 g daily.
- 3. Prophylaxis of bipolar disorder: *Adult:* Initially, 400 mg daily in divided doses gradually increased if necessary. Maintenance: 400-600 mg daily. Max: 1.6 g daily.

### CONTRAINDICATIONS:

Hypersensitivity; bone marrow depression; porphyria, pregnancy.

#### PRECAUTIONS:

Lactation; CV disease, hepatic or renal disorders, history of blood disorders or haematological reactions to other drugs; glaucoma; skin disorders; elderly, patients on MAO inhibitors; abrupt withdrawal of treatment.

#### INTERACTIONS:

Reduces tolerance to alcohol; shortens T<sub>1/2</sub> of doxycycline. Decreased efficacy of oral contraceptives when used

with carbamazepine. Increased plasma concentrations of carbamazepine by propoxyphene. Serum level decreases with phenytoin, phenobarbital, primidone, Neurotoxic reactions when combined with lithium.

#### ADVERSE DRUG REACTIONS:

Dizziness, drowsiness, ataxia; dry mouth, abdominal pain, nausea, vomiting, anorexia; leucopenia, proteinuria, renal failure, heart failure and hyponatraemia, Agranulocytosis, aplastic anaemia, hepatic failure, severe exfoliative dermatitis and Stevens-Johnson syndrome.

## 44. CAROVERINE 20MG CAP

#### SALIENT ACTIONS:

Caroverine is a smooth muscle relaxant with calcium-channel blocking and glutamate-antagonist properties. It is used in conditions associated with painful smooth muscle spasm, cerebral circulatory disorders and tinnitus.

## INDICATIONS & DOSAGE:

Oral

Smooth muscle spasms

Adult: 20-40 mg 3-4 times daily. Max: 200 mg/day.

Max Dosage: 200 mg daily.

## CONTRAINDICATIONS:

Hypersensitivity.

#### PRECAUTIONS:

Disability, Heart disease, Liver dysfunction, Muscle weakness, Problems in emptying your urinary bladder, Stomach inflammation

### INTERACTIONS:

NA

#### ADVERSE REACTIONS:

Headache, Blurred vision, Drowsiness, Dry mouth, Increased heart rate.

# 45. CEFADROXYL Tab 125 mg/250 mg/500 mg, Syrup 125 mg/5ml, 30 ml botttle SALIENT ACTIONS:

Cefadroxil binds to one or more of the penicillin-binding proteins (PBPs) which inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell wall, thus inhibiting biosynthesis and arresting cell wall assembly resulting in bacterial cell death. Cefadroxil is not active against *Proteus, Pseudomonas, Enterobacter, Morganella, Serratia* and *Listeria monocytogenes*.

## INDICATIONS & DOSAGE REGIMENS:

- 1. Uncomplicated lower urinary tract infections: *Adult:* 1-2 g daily as a single or 2 divided doses. *Child:* >6 yr: 500 mg bid; 1-6 yr: 250 mg bid; <1 yr: 25 mg/kg daily in divided doses.
- 2. Skin and skin structure infections: Adult: 1 g/day in single or divided doses. Child: 30 mg/kg/day in equally divided doses every 12 hr.
- 3. Pharyngitis: Adult: For treatment of group A  $\beta$ -haemolytic streptococcal pharyngitis and tonsillitis: 1 g/day in single or divided doses for 10 days. Child: 30 mg/kg/day in equally divided doses every 12 hr for at least 10 days.
- 4. Tonsillitis: Adult: For treatment of group A β-haemolytic streptococcal pharyngitis and tonsillitis: 1 g/day in single or divided doses for 10 days. Child: 30 mg/kg/day in equally divided doses every 12 hr for at least 10 days.

## CONTRAINDICATIONS:

Hypersensitivity to cephalosporins.

## PRECAUTIONS:

Impaired renal function; pregnancy and lactation.

## INTERACTIONS:

Prothrombin time prolonged; bleeding may occur when taken with anticoagulants. Decreased elimination with probenecid.

## ADVERSE DRUG REACTIONS:

Nausea, vomiting, diarrhoea, abdominal discomfort; skin rash, angioedema; elevated liver enzyme values; superinfection with resistant organisms especially candida, Anaphylactic reaction; pseudomembranous colitis.

## 46. CEFIXIME TRIHYDRATE Tab 200 mg, 50 mg/5ml, 30 ml bottle

#### SALIENT ACTIONS:

Cefixime binds to one or more of the penicillin-binding proteins (PBPs) which inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell wall, thus inhibiting biosynthesis and arresting cell wall assembly resulting in bacterial cell death.

## INDICATIONS & DOSAGE REGIMENS:

- 1. Susceptible infections: Adult: 200-400 mg/day as a single dose or in 2 divided doses. Child: 8 mg/kg/day as a single dose or in 2 divided doses
- 2. Uncomplicated gonorrhea: Adult: 400 mg as a single dose.

#### **CONTRAINDICATIONS:**

Hypersensitivity to cephalosporin.

#### PRECAUTIONS:

History of allergy to penicillins; pregnancy, lactation; renal failure; GI disease.

#### INTERACTIONS:

Increased concentrations with probenecid, may increase prothrombin time with anticoagulants.

#### ADVERSE DRUG REACTIONS:

Diarrhoea, nausea, vomiting, abdominal pain; headache, dizziness, thrombocytopenia, eosinophilia, Pseudomembranous colitis.

#### 47. CEFPROZIL 250MG TAB

#### SALIENT ACTIONS:

Cefprozil inhibits bacterial cell wall synthesis by binding to 1 or more of the penicillin-binding proteins (PBPs) which in turn inhibit the final transpeptidation step of peptidoglycan synthesis in bacterial cell walls, thus inhibiting cell wall biosynthesis and arresting cell wall assembly resulting in bacterial cell death.

## INDICATIONS & DOSAGE:

Oral

Respiratory tract infections, Skin and skin structure infections

Adult: 500 mg daily as a single or in 2 divided doses, increased to 500 mg bid if necessary. Duration: 10 days. Child: 6 mth to 2 yr For otitis media: 15 mg/kg 12 hrly. For acute sinusitis: 7.5 mg/kg or 15 mg/kg 12 hrly. For pharyngitis or tonsillitis: 7.5 mg/kg 12 hrly. >2 yr For skin and skin structure infections: 20 mg/kg daily. Max: 1 g daily.

#### CONTRAINDICATIONS:

Hypersensitivity to cefprozil or to other cephalosporins.

#### PRECAUTIONS:

History of hypersensitivity to penicillins and GI disease esp colitis. Renal impairment. Pregnancy and lactation. Monitoring Parameters Monitor renal function and for signs of anaphylaxis during 1st dose.

#### INTERACTIONS:

May enhance the nephrotoxic effect of aminoglycosides. May enhance the anticoagulant effect of vit K antagonists. May diminish the therapeutic effect of BCG, typhoid vaccine and Na picosulfate. May increase serum concentrations w/ probenecid.

## ADVERSE REACTIONS:

Diarrhoea, vomiting, abdominal pain, dyspepsia, flatulence, glossitis, mouth pain; rash, serum sickness like reactions, erythema, exanthema, erythema multiforme, erythema nodosum, Stevens-Johnson syndrome, toxic epidermal necrolysis; dizziness, hyperactivity, headache, nervousness, insomnia, confusion, somnolence; increased AST (SGOT), ALT (SGPT), serum alkaline phosphatase, bilirubin and serum LDH levels; eosinophilia, decreased leukocyte count, agranulocytosis, aplastic anaemia, pancytopenia, haemolytic anaemia, haemorrhage; elevated BUN and serum creatinine, renal dysfunction, toxic nephropathy; vaginitis, genital pruritus, leucorrhoea, vag candidiasis, diaper rash, superinfection. Rarely, urticaria, pruritus, lightheadedness, cholestatic jaundice, neutropenia, thrombocytopenia, thrombocytosis, decreased haematocrit; fever, chills, tinnitus, sweating, visual field defects, angioedema, crying, generalised pain, back pain, leg pain; prolonged partial thromboplastin time, prothrombin time and prothrombin ratio.

Potentially Fatal: Anaphylaxis, pseudomembranous colitis.

# 48. CETRIZINE DIHYDROCHLORIDE Tab 10 mg, Syrup 5mg / 5 ml, 30 ml bottle

## SALIENT ACTIONS:

Cetirizine is a potent and highly selective antagonist of the peripheral histamine H<sub>1</sub>-receptor on effector cells in

the GI tract, blood vessels and respiratory tract.

# INDICATIONS & DOSAGE REGIMENS:

1. Allergic conditions: Adult: 10 mg once daily or 5 mg bid. Child: 6 mth-2 yr: 2.5 mg once daily (up to 2.5 mg bid in children ≥12 mth); 2-5 yr: 5 mg once daily or 2.5 mg bid; >6 yr: 10 mg once daily or 5 mg bid.

## CONTRAINDICATIONS:

Hypersensitivity; lactation.

#### PRECAUTIONS:

Hepatic or renal impairment; elderly; tasks requiring mental alertness eg, driving or operating heavy machinery; pregnancy.

#### INTERACTIONS:

Risk of increased INR and epistaxis when taken together with warfarin. Potentially Fatal: CNS depressants and anticholinergics may potentiate CNS depression of cetirizine.

## ADVERSE DRUG REACTIONS:

Somnolence, insomnia, malaise, headache, dizziness; GI discomfort, dry mouth, abdominal pain, diarrhoea, nausea, vomiting; occasional hypersensitivity; epistaxis, pharyngitis, bronchospasm.

# 49.CHLORDIAZEPOXIDE Tab 10 mg

## SALIENT ACTIONS:

Chlordiazepoxide enhances activity of the inhibitory transmitter GABA in different parts of CNS by increasing neuronal-membrane permeability to chloride ions resulting to hyperpolarisation and stabilisation. It has some muscle relaxant and anticonvulsant activity.

## INDICATION & DOSAGE REGIMENS:

- 1. Anxiety: Adult: 30 mg daily in divided doses, up to 100 mg daily in severe conditions.
- 2. Muscle spasms: Adult: 10-30 mg daily in divided doses.
- 3. Insomnia: Adult: 10-30 mg before bedtime.

## CONTRAINDICATIONS:

Acute pulmonary insufficiency, resp depression, patients with marked neuromuscular resp weakness; hypersensitivity to benzodiazepines; chronic psychosis; porphyria; pregnancy and lactation.

#### PRECAUTIONS:

Alcohol; sedation, dependence. Elderly and debilitated patients. Liver or kidney dysfunction. Avoid prolonged usage.

#### INTERACTIONS:

Cimetidine increases serum conc of chlordiazepoxide. Potentiates action of major neuroleptics. Potentially Fatal: Alcohol potentiates CNS-depressant effect of chlordiazepoxide.

## ADVERSE DRUG REACTIONS:

Physical and psychological dependence; withdrawal syndrome; impairs psychomotor performance, aggression (in predisposed individuals esp in combination with alcohol); sedation; blood dyscrasias, jaundice, hepatic dysfunction. Potentially Fatal: May rarely cause hypoplastic or haemolytic anaemia.

# 50. CHLOROQUINE PHOSPHATE Tab 250 mg SALIENT ACTIONS:

Chloroquine is used for malarial prophylaxis (as a suppressive) and in managing acute attacks of malaria. It is highly active against erythrocytic forms of P. vivax, P. malariae and P. falciparum. It influences Hb digestion by increasing intravesicular pH in malaria parasite cells and interferes with the nucleoprotein synthesis of the patient. It is also effective in extra intestinal amoebiasis. In RA chloroquine and more effectively hydroxychloroquine have a disease-modifying effect.

# INDICATIONS & DOSAGE REGIMENS:

- 1. Acute malaria: Adult: As base: Initially, 600 mg followed by 300 mg 6-8 hr later on day 1. On days 2 and 3, single doses of 300 mg/day. Child: Initially, 10 mg base/kg (max 600 mg base) followed by 5 mg base/kg (max 300 mg base) after 6 hrs. Single doses of 5 mg base/kg on days 2 and 3.
- 2. Prophylaxis of malaria: Adult: As base: 300 mg once wkly, starting 1 wk before exposure, continuing throughout on a wkly basis and for at least 4 wk after exposure. Child: 5 mg/kg weekly.
- 3. Discoid and systemic lupus erythematosus: Adult: As base: Initially, 150 mg once daily, reduce gradually after maximal response. Max dose: 2.5 mg/kg daily. Child: 3 mg/kg daily.
- 4. Hepatic amoebiasis: Adult: As base: 600 mg daily for 2 days then 300 mg daily for 2 or 3 wk given with emetine or dehydroemetine. Child: 6 mg/kg daily. Max dose: 300 mg daily.

5. Rheumatoid arthritis: Adult: As base: 150 mg daily. Max: 2.5 mg/kg daily. Discontinue treatment if there is no improvement after 6 mth. Child: Up to 3 mg/kg/day. Discontinue treatment if there is no improvement after 6 mth.

#### CONTRAINDICATIONS:

Hypersensitivity, known or suspected resistant P. falciparum infection, porphyria, retinal damage, concurrent hepatotoxic drugs.

#### PRECAUTIONS:

Psoriasis, diseases of the haematopoietic or CNS systems, myasthenia gravis, hepatic or renal impairment, G6PD deficiency, epilepsy, children. Pregnancy and lactation. Slow infusion is used upon IV admin to prevent cardiotoxicity.

#### INTERACTIONS:

Concomitant therapy with phenylbutazone predisposes to dermatitis, antagonises effect of neostigmine and pyridostigmine, reduces bioavailability of ampicillin. Cimetidine inhibits metabolism of chloroquine raising plasma levels. Potentially Fatal: Increased risks of inducing ventricular arrhythmias with halofantrine or other arrhythmogenic drugs eg, amiodarone. Increased risk of convulsions with mefloquine. Antacids reduce absorption of chloroquine hence admin should be separated by 4 hrs. Rarely Stevens-Johnson syndrome, when administered with pyrimethamine/sulphadoxine. Increased toxicity with quinacrine.

#### ADVERSE DRUG REACTIONS:

Retinopathy, hair loss, photosensitivity, tinnitus, myopathy (long-term therapy). Psychosis, seizures, leucopenia and rarely aplastic anaemia, hepatitis, GI upsets, dizziness, hypokalaemia, headache, pruritus, urticaria, difficulty in visual accommodation, Cardiac and respiratory arrest, CV collapse, convulsions, coma.

#### 51. CHLORTHALIDONE 12.5MG TAB

#### SALIENT ACTIONS:

Chlorthalidone is a thiazide-like diuretic that reduces BP possibly by inhibiting sodium reabsorption at the beginning of the distal convulated tubule.

## INDICATIONS & PRECAUTION:

oral

Hypertension

Adult: Per tab contains Atenolol (mg)/Chorthalidone (mg): 50/25 or 100/25. Initially one tab of 50/25 once daily

#### CONTRAINDICATIONS:

anuria, hypersentivity

## PRECAUTIONS:

Chlorthalidone can cause hyperuricaemia and precipitate gout. Monitor renal functions, potassium levels, and signs of fluid and electrolytes imbalance. Discontinue if progressive renal impairment is evident.

#### INTERACTIONS:

May alter insulin and dosage of oral hypoglycaemic agents required in diabetics. May reduce renal clearance of lithium and increases risk of lithium toxicity. May cause hypokalaemia therefore increase risk of digitalis toxicity. Risk of hypercalcaemia with paricalcitol. Increased risk of hypokalaemia with ritodrine, amphotericin B. Increased responsiveness to tubocurarine.

#### ADVERSE REACTIONS:

Chlorthalidone: Orthostatic hypotension, GI disturbances, jaundice, pancreatitis, vertigo, lethargy, paraesthesia, photosensitivity, rash, muscle cramps, hypokalaemia, hyponatraemia, hyperglycaemia, hyperuricaemia or gout, leucopenia, agranulocytosis, aplastic anaemia, thrombocytopenia.

Potentially Fatal: Hypersensitivity reaction including toxic epidermal necrolysis.

## 52. CHOLECALCIFEROL CAP

## SALIENT ACTIONS:

Vitamin D3 is a fat-soluble sterol, it aids in the regulation of calcium and phosphate homeostasis and bone mineralisation.

## INDICATION & DOSAGE:

vitamin D<sub>3</sub> suppliment

10 mcg: 1 tablet bid, to be dissolved in a glass of water and taken immediately.

#### CONTRAINDICATIONS:

Patients with hypercalcaemia and/or hypercalciuria. Nephrolithiasis, hypervitaminosis D, hypophosphataemia.

#### PRECAUTIONS:

Impaired calcium absorption in achlorhydria which is common in elderly. Increased risk of hypercalcaemia and hypercalciuria in hypoparathyroid patients receiving high doses of vitamin D. Caution when using in patients with history of kidney stones. Renal impairment; frequent monitoring of serum calcium and phosphorus is recommended.

#### INTERACTIONS:

Concurrent use with ion-exchange resins may reduce GI absorption of vitamin D. Hypercalcaemia may increase the toxicity of cardiac glycosides during treatment with calcium and vitamin D,

#### ADVERSE REACTIONS:

Constipation, flatulence, nausea, abdominal pain and diarrhoea. Pruritus, rash and urticaria.

#### 53. CILNIDIOINE TAB

#### SALIENT ACTIONS:

Cilnidipine is a dihydropyridine calcium-channel blocker. It inhibits cellular influx of calcium, thus causing vasodilatation. It has greater selectivity for vascular smooth muscle. It has little or no action at the SA or AV nodes and -ve inotropic activity is rarely seen at therapeutic doses.

#### INDICATIONS & DOSAGE:

Oral

Hypertension

Adult: 5-10 mg once daily, increase to 20 mg once daily if necessary.

#### CONTRAINDICATIONS:

Cardiogenic shock; recent MI or acute unstable angina; severe aortic stenosis.

#### PRECAUTIONS:

Hypotension, poor cardiac reserve, heart failure. Sudden withdrawal may exacerbate angina. Discontinue in patients who experience ischemic pain following administration. Pregnancy, lactation.

#### INTERACTIONS:

Other antihypertensives; aldesleukin; antipsychotics that cause hypotension; may modify insulin and glucose responses; quinidine; carbamazepine; phenytoin; rifampicin; cimetidine; erythromycin.

#### ADVERSE REACTIONS:

Dizziness; flushing; headache; hypotension; peripheral oedema; tachycardia; palpitations; GI disturbances; increased micturition frequency; lethargy; eye pain; depression; ischaemic chest pain; cerebral or myocardial ischaemia; transient blindness; rashes; fever; abnormal liver function; gingival hyperplasia; myalgia; tremor; impotence.

#### 54. CILOSTAZOL 100MG TAB

#### SALIENT ACTIONS:

Cilostazol inhibits phosphodiesterase-III (PDE-III), thereby suppressing cyclic adenosine monophosphate (cAMP) degradation. Increase in cAMP in platelets and blood vessels leads to inhibition of platelet aggregation, vasodilation and inhibition of vascular smooth muscle cell proliferation.

#### INDICATIONS & DOSAGE:

Oral

Intermittent claudication

Adult: 100 mg bid. Discontinue if there is no clinical improvement after 3 mth.

Renal impairment:

CrCl (ml/min) Dosage Recommendation ≤25 Contraindicated.

Hepatic impairment: Moderate to severe: Contraindicated.

Special Populations: Patients taking CYP3A4 or CYP2C19 inhibitors: 50 mg bid.

#### CONTRAINDICATIONS:

CHF of any severity, QT interval prolongation, predisposition to bleeding (e.g. active peptic ulceration, proliferative diabetic retinopathy, recent haemorrhagic stroke [w/in 6 mth], poorly controlled HTN); unstable angina pectoris, MI or coronary intervention w/in the last 6 mth. History of ventricular tachycardia, ventricular fibrillation, multifocal ventricular ectopics, severe tachyarrhythmia. Moderate to severe hepatic impairment or severe renal impairment (CrCl ≤25 mL/min). Concomitant use w/ ≥2 additional antiplatelet or anticoagulant drugs.

#### PRECAUTIONS:

Patient w/ atrial or ventricular ectopy, AF, atrial flutter. Patients taking CYP3A4 or CYP2C19 inhibitors. Pregnancy and lactation. Patient Counselling This drug may cause dizziness, if affected, do not drive or operate machinery. Monitoring Parameters Monitor platelet and WBC counts periodically.

#### INTERACTIONS:

Increased plasma concentration w/ CYP3A4 and CYP2C19 inhibitors (e.g. ketoconazole, omeprazole). Potentially Fatal: Increased risk of bleeding when used concomitantly w/≥2 additional antiplatelet or anticoagulant drugs (e.g. aspirin, clopidogrel, heparin).

#### ADVERSE REACTIONS:

Dizziness, headache, palpitations, diarrhoea, nausea, vomiting, oedema, cardiac arrhythmias, chest pain, rhinitis, ecchymosis, rash, haemorrhage. Rarely, haematological abnormalities including agranulocytosis, leucopoenia, thrombocytopenia.

Potentially Fatal: Pancytopenia, aplastic anaemia.

#### 55. CINNARIZINE Tab 25 mg

#### SALIENT ACTIONS:

Cinnarizine has calcium-channel blocking activity selective for arterial smooth muscle. It also has some antihistamine activity. Cinnarizine acts as a labyrinthine sedative. It also improves microcirculation by reducing ischaemia-induced blood viscosity.

## INDICATION & DOSAGE REGIMENS

- 1. Peripheral vascular disease: Adult: 75 mg bid or tid.
- 2. Motion sickness: Adult: 30 mg taken 2 hr before travel and 15 mg every 8 hr during the journey if necessary. Child: 5-12 yr: 1/2 of adult dose.
- 3. Cerebrovascular disorders: Adult: 75 mg 1-3 times daily.
- 4. Vertigo and vestibular disorders: Adult: 30 mg tid. Child: 5-12 yr: 1/2 of adult dose. Administration Should be taken with food.

#### CONTRAINDICATIONS:

Proven hypersensitivity to the drug. Parkinson's disease. Childn and neonates.

#### PRECAUTIONS:

Hypotension; pregnancy; lactation; elderly. May impair ability to drive or operate machineries.

## INTERACTIONS:

CNS depressant effect enhanced with alcohol. Action potentiated by domperidone.

#### ADVERSE DRUG REACTIONS:

Extrapyramidal symptoms sometimes associated with severe depression. Drowsiness, headache, GI upsets, unsteadiness, headache; rarely skin and hypersensitivity reactions, dry mouth, blurred vision, urinary difficulty or retention, constipation and increased gastric reflux, fatigue. Hypolipidaemic effect.

#### 56. CIPROFLOXACIN Tab 500 mg

## SALIENT ACTIONS:

Ciprofloxacin promotes breakage of double-stranded DNA in susceptible organisms and inhibits DNA gyrase, which is essential in reproduction of bacterial DNA.

#### INDICATIONS & DOSAGE REGIMENS:

- 1. Susceptible infections 2. Typhus 3. Urinary tract infections 4. Chanroid 5. Lower respiratory tract infections
- 6. Septicaemia 7. Typhoid and paratyphoid fever 8. Gastroenteritis
- Adult: 250-750 mg bid depending on the severity and nature of infection. Child: 5-15 mg/kg bid.
- 9. Gonorrhoea: Adult: 250-500 mg as a single dose.
- 10. Prophylaxis of meningococcal meningitis: Adult: 500 mg as a single dose.
- 11. Prophylaxis of surgical infections: Adult: 750 mg as a single dose 60-90 minutes before procedure.

#### CONTRAINDICATIONS:

Hypersensitivity. Not to be used concurrently with tizanidine. Avoid exposure to strong sunlight or sun lamps during treatment.

## PRECAUTIONS:

Epilepsy, history of CNS disorders; severe renal or hepatic dysfunction; G6PD deficiency; maintain adequate hydration; myasthaenia gravis. Caution when used in patients with QT prolongation or risk factors e.g. bradycardia, pre-existing cardiac disease or uncorrected electrolyte disturbances. Discontinue treatment if patients experience tendon pain, inflammation or rupture. Avoid usage in methicillin-resistant staphylococcus

aureus (MRSA) infections due to high level of resistance. May impair ability to drive or operate machinery. Safety and efficacy have not been established in pregnant and lactating women. Not to be used in children <18 yr; except where benefit clearly exceeds risk.

#### INTERACTIONS:

Decreased absorption with concurrent sucralfate, magnesium-aluminum antacids, calcium, iron, zinc and multivitamins. Increased methotrexate and caffeine levels when taken concurrently with ciprofloxacin. Probenecid reduces renal clearance of ciprofloxacin. Potentiates oral anticoagulants and glibenclamide. Concurrent use with corticosteroids may increase tendon rupture. Concurrent use with ciclosporin may cause transient increases in serum creatinine.

#### ADVERSE DRUG REACTIONS:

GI disturbances; headache, tremor, confusion, convulsions; rashes; joint pain; phototoxicity. Transient increases in serum creatinine. Haematological, hepatic and renal disturbances. Vasculitis, pseudomembranous colitis and tachycardia. Phototoxicity, Anaphylactoid reaction; cardiopulmonary arrest.

# 57. CISSUS QUADRANGULARIS CAP

## **SALIENT ACTIONS:**

It contains a rich source of carotenoids, triterpenoids and ascorbic acid. Compounds that act as receptor antagonists of glucocorticoids have reduced the healing time of broken bones.

#### INDICATIONS & DOSAGE:

metabolic syndrome and high cholesterol, bone fractures, osteoporosis, scurvy, cancer, upset stomach, , peptic ulcer disease (PUD), painful menstrual periods, asthma, malaria, and pain, bodybuilding supplements.

## CONTRAINDICATIONS & PRECAUTIONS:

Pregnancy and breast-feeding: There is not enough reliable information about the safety of taking Cissus quadrangularis

Diabetes: Cissus quadrangularis might lower blood sugar. Taking Cissus quadrangularis along with medications for diabetes might lower blood sugar too much. Watch for signs of low blood sugar (hypoglycemia) and monitor your blood sugar levels closely if you have diabetes and use Cissus quadrangularis.

Surgery: Cissus quadrangularis might lower blood sugar and could interfere with blood sugar control during and after surgical procedures. Stop using Cissus quadrangularis at least 2 weeks before a scheduled surgery.

#### ADVERSE REACTIONS:

headache, dry mouth, diarrhea, and insomnia

#### 58. CITICOLINE SODIUM IP 500MG TAB

### SALIENT ACTIONS:

Citicoline increases blood flow and O<sub>2</sub> consumption in the brain. It is also involved in the biosynthesis of lecithin.

## INDICATIONS & DOSAGE:

Oral

Cerebrovascular disorders, Head injury, Parkinsonism

Adult: 200-600 mg daily in divided doses.

## CONTRAINDICATIONS:

Hypersensitivity

#### PRECAUTIONS:

Caution should be exercised in patients with history of mental illness, during pregnancy and breastfeeding.

#### INTERACTIONS:

NA

## ADVERSE REACTIONS:

Sleeplessness, headache, diarrhea, low or high blood pressure, nausea, blurred vision, chest pain

## 59. CLARITHROMYCIN IP TABLET

## SALIENT ACTIONS:

Clarithromycin inhibits protein synthesis in susceptible organisms by penetrating the cell wall and binding to 50S ribosomal subunits. It has activity against a variety of aerobic and anaerobic gm+ve and gm-ve bacteria.

#### INDICATIONS & DOSAGE:

Orai

Respiratory tract infections

Adult: 250 mg bid, increased to 500 mg bid for severe infections, if necessary, for 7-14 days.

Child: 7.5 mg/kg bid for 5-10 days.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation
<30	Half the dose or double the dosing interval.

Oral

Skin and soft tissue infections

Adult: 250 mg bid, increased to 500 mg bid for severe infections, if necessary, for 7-14 days.

Child: 7.5 mg/kg bid for 5-10 days.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation
<30	Half the dose or double the dosing interval.

Oral

Susceptible infections

Adult: 250 mg bid, increased to 500 mg bid for severe infections, if necessary, for 7-14 days.

Child: 7.5 mg/kg bid for 5-10 days.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation
<30	Half the dose or double the dosing interval.

Oral

Eradication of H. pylori associated with peptic ulcer disease

Adult: 500 mg bid, in combination w/ another antibacterial and either a PPI or H<sub>2</sub>-receptor antagonist for 7-14 days.

Child: ≥1 yr 7.5 mg/kg bid, may be given w/ another antibacterial and a PPI for 7 days.

Renal impairment:

CrCl (ml/r	min) Dosage Recommendation
<30	Half the dose or double the dosing interval.

#### CONTRAINDICATIONS:

Patient w/ known hypersensitivity to clarithromycin or any other macrolide antibiotic, history of QT prolongation or ventricular cardiac arrhythmia, including torsades de pointes, hypokalaemia, history of cholestatic jaundice or hepatic dysfunction associated w/ prior use of clarithromycin. Patient receiving terfenadine, astemizole, pimozide, cisapride, ergotamine or dihydroergotamine, and colchicine.

#### PRECAUTIONS:

Patient w/ coronary artery disease, severe cardiac insufficiency, hypomagnesaemia, bradycardia (<50 bpm). May exacerbate symptoms of myasthenia gravis. Renal and hepatic impairment. Pregnancy and lactation. Monitoring Parameters Monitor CBC w/ differential, BUN and creatinine.

#### INTERACTIONS:

Reduced efficacy w/ CYP3A inducers (e.g. phenytoin, carbamazepine). Strong inducers of CYP450 system (e.g. efavirenz, rifampicin) may accelerate metabolism, thus lower plasma levels of clarithromycin. Inhibition of metabolism w/ ritonavir. Torsades de pointes may result from concomitant quinidine or disopyramide. Increased phosphodiesterase inhibitor exposure w/ sildenafil, tadalafil or vardenafil. Increased risk of digoxin toxicity. Decreased concentration of zidovudine. Concomitant use w/ atazanavir, itraconazole or saquinavir may result to bi-directional drug interactions. Hypotension, bradyarrhythmias, and lactic acidosis may result when taken w/ verapamil. Increased risk of myopathy, including rhabdomyolysis w/ HMG-CoA reductase inhibitors. Increased risk of hypoglycaemia w/ oral hypoglycaemic drugs (e.g. pioglitazone) and insulin. Risk of serious haemorrhage and elevation of INR and prothrombin time w/ oral anticoagulants. Increased ototoxicity w/ aminoglycosides. Increased and prolonged sedation w/ triabenzodiazepines (e.g. midazolam).

Potentially Fatal: Concurrent use w/ ergot alkaloids (e.g. ergotamine or dihydroergotamine) is associated w/ acute ergot toxicity characterised by vasospasm and ischaemia of the extremities. Concomitant use w/ astemizole, cisapride, pimozide and terfenadine may result in QT prolongation or ventricular cardiac arrhythmia. Increases serum levels and toxicity of colchicine.

#### ADVERSE REACTIONS:

Smell and taste disturbances, stomatitis, glossitis, tongue and tooth discolouration, headache, arthralgia, myalgia, hypoglycaemia, leucopenia, thrombocytopenia, interstitial nephritis, muscle weakness, agranulocytosis, elevated serum amylase levels, QT prolongation, torsades de pointes, corneal opacities, fever,

pulmonary infiltration w/ eosinophilia, delirium, visual hallucinations, pancreatitis.

Potentially Fatal: Hepatic failure, pseudomembranous colitis, anaphylaxis, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug rash w/ eosinophilia and systemic symptoms (DRESS) syndrome and Henoch-Schonlein purpura.

# 60. CLOBAZAM Tab 10 mg

## SALIENT ACTIONS:

Clobazam binds to one or more specific GABA receptors at several sites within the CNS including the limbic system and reticular formation. Increased permeability of neuronal membrane to chloride ions results in GABA's inhibitory effect leading to hyperpolarisation and stabilisation.

## INDICATIONS & DOSAGE REGIMENS:

Short-term management of anxiety, Adjunct in epilepsy: Adult: 20-30 mg as a single dose at night or as daily divided doses, increased to 60 mg/day in severe conditions. Child: 3-12 yr: 125 mcg/kg bid increased every 5 days. Usual maintenance dose: 250 mcg/kg bid. Max: 500 mcg/kg bid.

#### CONTRAINDICATIONS:

Hypersensitivity; history of drug dependence; myasthaenia gravis; pregnancy (1st trimester), lactation; serious liver damage; sleep apnoea syndrome; impaired respiratory function.

## PRECAUTIONS:

May impair ability to perform skilled tasks and hazardous activities; elderly; renal or hepatic impairment; alcoholics; obesity; withdrawal should be gradual.

#### INTERACTIONS:

Increased hepatic clearance of clobazam when administered with phenytoin, phenobarbital or carbamazepine. Cimetidine may increase levels of clobazam, Concurrent alcohol, hypnotics and sedative antidepressants can potentiate CNS side effects of clobazam.

#### ADVERSE DRUG REACTIONS:

Constipation, anorexia, nausea; dizziness, fine tremors; worsening of respiratory symptoms in predisposed individuals; ataxia, drowsiness, headache, confusion; loss of libido, motor dysfunction; dependence; visual disturbances and weight gain, Respiratory depression.

## 61. CLOFAZIMINE IP 100MG CAP

## SALIENT ACTIONS:

Clofazamine inhibits mycobacterial growth by binding preferentially to mycobacterial DNA. It also has some anti-inflammatory activity.

#### INDICATIONS & DOSAGE:

Oral

Multibacillary leprosy

Adult: 300 mg clofazimine with 600 mg rifampicin, both given once a mth together with daily doses of 50 mg clofazimine and 100 mg dapsone for 12 mth.

Child: 10-14 yr: 150 mg clofazimine with 450 mg rifampicin and 50 mg dapsone once a mth, taken with 50 mg dapsone daily and 50 mg clofazimine on alternate days. Treatment is given for 12 mth.

Oral

Erythema nodosum leprosum (Type 2)

Adult: Treatment depends on severity. 100-200 mg daily for up to 3 mth. Doses >200 mg daily are not recommended. Gradually taper the dose to 100 mg daily as soon as the reactive episode is controlled. In general, continue with basic antileprosy treatment.

Oral

Dapsone-resistant leprosy

Adult: 100 mg daily with 1 or more other antileprosy drugs for 3 yr, then continue as a monotherapy at 100 mg daily.

#### CONTRAINDICATIONS:

Hypersensitivity. Lactation.

#### PRECAUTIONS:

Pregnancy. Patients with GI symptoms.

## ADVERSE REACTIONS:

Red-brownish black discolouration of skin especially areas exposed to sunlight, hair, sweat, sputum, urine, faeces. Rash, pruritus, photosensitivity, diarrhoea, nausea, abdominal pain, vomiting, weight loss, headache,

drowsiness, dizziness, taste disorders, dryness of the skin, ichthyosis, decreased tear and sweat production. Potentially Fatal: Crystal depletion in the wall of small bowel mesenteric lymph nodes, liver and spleen. Severe abdominal symptoms including bowel obstruction, GI bleeding and splenic infarction.

### 62. CLOMIPRAMINE HCL TAB

#### SALIENT ACTIONS:

Clomipramine is a potent inhibitor of serotonin re-uptake in the brain. Significant antagonism at cholinergic and  $\alpha_1$ -receptors. Weak antagonism at dopamine receptors. It has also antidepressant, sedative and anticholinergic effects.

## INDICATIONS & DOSAGE:

Oral

Adjunct for cataplexy associated with narcolepsy

Adult: Initially, 10 mg daily gradually increased to 10-75 mg daily.

Elderly: Dose reduction may be needed.

Max Dosage:

Oral

Obsessive compulsive disorder

Adult: Initially, 25 mg daily, gradually increased to 100-150 mg daily over 2 wk. Max: 250 mg daily. Child: ≥10 yr: Initially, 25 mg daily, increased gradually over 2 wk. Max: 3 mg/kg/day or 100 mg daily, whichever is smaller. Give in divided doses. Once titrated, dose may be given as a single dose at bedtime. Elderly: Initially, 10 mg daily.

Oral

Panic disorder

Adult: Initially, 25 mg daily, gradually increased to 100-150 mg daily over 2 wk. Max: 250 mg daily. Child: ≥10 yr: Initially, 25 mg daily, increased gradually over 2 wk. Max: 3 mg/kg/day or 100 mg daily, whichever is smaller. Give in divided doses. Once titrated, dose may be given as a single dose at bedtime. Elderly: Initially, 10 mg daily.

Oral

Phobias

Adult: Initially, 25 mg daily, gradually increased to 100-150 mg daily over 2 wk. Max: 250 mg daily. Child: ≥10 yr: Initially, 25 mg daily, increased gradually over 2 wk. Max: 3 mg/kg/day or 100 mg daily, whichever is smaller. Give in divided doses. Once titrated, dose may be given as a single dose at bedtime. Elderly: Initially, 10 mg daily.

Oral

Depression

Adult: Initially, 10 mg daily; may increase gradually to 30-150 mg daily if needed. Up to 250 mg daily or more may be required in more severe cases.

Elderly: Initially, 10 mg daily; may increase gradually over 10 days to 30-75 mg daily.

Max Dosage: 100-150 mg daily.

#### CONTRAINDICATIONS:

Hypersensitivity. Concomitant use of MAOIs; recovery phase following MI, heartblock or other arrhythmias; mania; childn.

## PRECAUTIONS:

Cardiovascular insufficiency; narrow-angle glaucoma; urinary retention; history of epilepsy; renal or hepatic dysfunction; electroconvulsive therapy; hypotension; hyperthyroidism or concomitant treatment with thyroid preparations; suicidal tendencies; surgery; pregnancy and lactation; tasks requiring mental alertness; elderly; avoid abrupt withdrawal.

## INTERACTIONS:

Barbiturates increase metabolism of tricyclic antidepressants; conversely cimetidine, guanethidine, haloperidol and phenothiazines block the tricyclic metabolism. CNS effects of alcohol enhanced.

Potentially Fatal: If clomipramine is to be substituted for MAOIs, at least 3 wk should elapse after discontinuing MAOIs. Risk of hypertension and arrhythmias if co-administered with adrenaline and noradrenaline.

#### ADVERSE REACTIONS:

Dryness of mouth; disturbances in micturition; drowsiness, increased sweating; sexual dysfunction; confusion, paraesthesia, ataxia, tremors; extrapyramidal symptoms; tinnitus, dizziness, fatigue, headache; wt gain esp in women; gynaecomastia and galactorrhoea.

Potentially Fatal: Death, rare (except in patients with preexisting significant heart block and patients on MAOI therapy). Induction of mania in individuals with underlying manic-depressive illness or worsening of psychoses in already psychotic individuals.

# 63. CLONAZEPAM Tab 0.5 mg / 1 mg SALIENT ACTIONS:

Clonazepam is an effective anticonvulsant. It raises the threshold for propagation of seizure activity and prevents generalisation of focal or local activity. Clinically, it improves focal epilepsy and generalised seizures. It is also believed to enhance the activity of GABA, and acts as anxiolytic.

## INDICATIONS & DOSAGE REGIMENS:

1. Epilepsy: Adult: Initially, 1 mg given at night for 4 nights, gradually increased over 2-4 wk. Maintenance: 4-8 mg daily. Max: 20 mg/day Child: 1-5 yr: 250 mcg daily; 5-12 yr: 500 mcg daily. Maintenance (given in 2-4 divided doses): Infants: 0.5-1 mg daily; 1-5 yr: 1-3 mg daily; 5-12 yr: 3-6 mg daily. Max: 200 mcg/kg/day 2. Panic disorder: Adult: Initially, 250 mcg bid, increased after 3 days up to 1 mg daily. Max: 4 mg daily.

CONTRAINDICATIONS:
Hypersensitivity to benzodiazepines, acute pulmonary insufficiency, acute narrow angle glaucoma.

## PRECAUTIONS:

Neonates, chronic pulmonary insufficiency, hepatic/renal dysfunction, porphyria, elderly; pregnancy and lactation.

#### INTERACTIONS:

Carbamazepine, phenobarbitone or phenytoin may accelerate clonazepam metabolism, Increased sedative effect with alcohol, general anaesthetics and TCAs.

## ADVERSE DRUG REACTIONS:

Drowsiness, fatigue, muscular hypotonia, coordination disturbances, dizziness, vertigo, anorexia, visual disturbances, libido changes, Salivary or bronchial hypersecretion leading to respiratory problems (children). May produce diminished reflexes or coma. Rarely, blood dyscrasias.

## 64. CLONIDINE HCL IP 100MCG TAB

#### SALIENT ACTIONS:

Clonidine stimulates  $\alpha_2$ -adrenoceptors in the brain stem which results in reduced sympathetic outflow from the CNS, and a decrease in peripheral resistance, heart rate, BP and renal vascular resistance.

#### INDICATION & DOSAGE:

Oral

#### Hypertension

Adult: Initially, 50-100 mcg tid, increased every 2nd or 3rd day according to response. Maintenance: 300-1,200 mcg daily, some may require ≥1,800 mcg daily. Max: 2,400 mcg daily.

Renal impairment: Dosage adjustment needed.

Oral

## Prophylaxis of migraine

Adult: 50 mcg bid, increased to 75 mcg bid if no remission after 2 wk.

Renal impairment: Dosage adjustment needed.

Oral

## Menopausal flushing

Adult: 50 mcg bid, increased to 75 mcg bid if no remission after 2 wk.

Renal impairment: Dosage adjustment needed.

## CONTRAINDICATIONS:

Severe bradyarrhythmia secondary to 2nd- or 3rd-degree AV block or sick sinus syndrome.

#### PRECAUTIONS:

Patient w/ cerebrovascular disease, ischaemic heart disease including MI, occlusive peripheral vascular disorders (e.g. Raynaud's disease), or those w/ history of depression. Avoid abrupt withdrawal. Renal impairment. Pregnancy and lactation. Patient Counselling May impair ability to drive or operate machinery. May cause dryness of eyes in patients who wear contact lenses. Monitoring Parameters Monitor BP (standing and sitting/supine), mental status, heart rate.

#### INTERACTIONS:

Increased hypotensive effect w/ other antihypertensives e.g. diuretics, β-blockers, vasodilators, Ca antagonists, ACE inhibitors. Reduced antihypertensive effect and induced orthostatic hypotension w/ TCAs or neuroleptics

 $w/\alpha$ -receptor blocking properties. Reduced therapeutic effect w/NSAIDs. Potentiation of bradycardic rhythm disturbances  $w/\alpha$  substances  $w/\alpha$  negative chronotropic or dromotropic effect (e.g.  $\beta$ -blocker, digitalis glycosides. May potentiate CNS depressant effect of barbiturates or other sedating drugs. May prolong the duration of pharmacologic effect of epidural local anaesth (epidural).

#### ADVERSE REACTIONS:

Headache, dizziness, drowsiness, dry mouth, constipation, depression, anxiety, nausea, fatigue, anorexia, parotid pain, paraesthesia, delusional perception, sleep disturbances, vivid dreams, impotence and loss of libido, urinary retention or incontinence, orthostatic hypotension, itching or burning sensations in the eye, accommodation disorder, decreased lacrimation, fluid retention, pruritus and rashes (transdermal), bradycardia (including sinus bradycardia w/ AV block), other ECG disturbances, heart failure, hallucinations, cramp, Raynaud's syndrome, gynaecomastia, transient abnormalities

## 65. CLOPIDOGREL Tab 75 mg

## SALIENT ACTIONS:

Clopidogrel inhibits adenosine diphosphate (ADP) from binding to its receptor sites on the platelets and subsequent activation of glycoprotein GP IIb/IIIa complex thus preventing fibrinogen binding, platelet adhesion and aggregation.

#### INDICATIONS & DOSAGE REGIMENS:

- 1. Prophylaxis of thromboembolic disorders: Adult: 75 mg once daily.
- 2. Acute coronary syndrome :Adult: For ST-elevation myocardial infarction: In combination with aspirin: 75 mg once daily.

#### CONTRAINDICATIONS:

Hypersensitivity. Active pathological bleeding. admin within 7 days after MI and ischaemic stroke, coagulation disorders. Lactation.

#### PRECAUTIONS:

Patients at risk of increased bleeding from trauma, surgery, or other pathological conditions; ulcer; renal and hepatic impairment; history of bleeding or haemostatic disorders. Pregnancy.

#### INTERACTIONS:

Co-admin with NSAIDs may increase the risk of stomach and intestinal bleeding. High-dose clopidogrel may lead to increased warfarin levels thus increasing the risk of bleeding. High-dose clopidogrel may also inhibit P450 (2C9), thus interfering with the metabolism of phenytoin, tamoxifen, torasemide, fluvastatin and some NSAIDs. Avoid concurrent use of drugs that inhibit CYP2C19, including omeprazole, esomeprazole, cimetidine, fluconazole, ketoconazole, voriconazole, etravirine,

#### ADVERSE DRUG REACTIONS:

Dyspepsia, abdominal pain, nausea, vomiting, flatulence, constipation, gastritis, gastric and duodenal ulcers. GI upset, diarrhoea, paraesthesia, vertigo, headache, dizziness, pruritus and rashes, Bleeding disorders including GI and intracranial haemorrhage. Blood dyscrasias.

## 66. CLOPIDOGREL 75 mg Tab + ASPIRIN 75 mg

## SALIENT ACTIONS:

Aspirin inhibits the formation of thromboxane A2 in the platelets. This inhibits platelet aggregation and coagulation. This action lasts until the enzyme cyclo-oxygenase is regenerated in the platelets. Clopidogrel is metabolised an active thiol metabolite which selectively inhibits the binding of adenosine diphosphate (ADP) to its platelet receptor and the subsequent ADP-mediated activation of the glycoprotein GP IIb/IIIa complex, thereby inhibiting platelet aggregation.

#### INDICATIONS & DOSAGE REGIMENS:

- 1. Prophylaxis of ischaemic events: Adult: Each tablet contains clopidogrel 75 mg and aspirin 75 mg: 1 tablet once daily.
- 2. Acute coronary syndrome: Adult: Loading dose: 4 tablets; maintenance: ! tablet daily.

#### CONTRAINDICATIONS:

Hypersensitivity to aspirin, NSAIDs or clopidogrel; active peptic ulceration; children <12 yr; patients with haemophilia or haemorrhagic disorders; gout; severe renal or hepatic impairment; lactation.

## PRECAUTIONS:

History of peptic ulcer or those prone to dyspepsia and those with gastric mucosal lesion or heavy ethanol consumption; asthma or allergic disorders; tinnitus; dehydrated patients; uncontrolled hypertension; impaired renal or hepatic function; children and elderly; pregnancy. Patients at risk of increased bleeding from trauma,

surgery, or other pathological conditions. Increased risk of Reye's syndrome when used in patients with chicken pox, influenza or flu symptoms.

#### INTERACTIONS:

Aspirin: Corticosteroids, phenylbutazone and oxyphenbutazone may increase risk of GI ulceration. Use with coumarins, anagrelide, agatroban, LMWH, bivalirudin, dasatinib, iloprost, lepirudin and tenecteplase may increase the risk of bleeding. Clopidogrel: Co-administration of clopidogrel with NSAIDs may increase the risk of stomach and intestinal bleeding. There is an increased risk of bleeding with coumarins, agatroban, dasatinib, heparin, LMWH, gingko biloba and iloprost. Increased risk of bleeding if clopidogrel and drotrecogin alfa are given within 7 days. May increase bupropion level and side effects (lightheadedness, GI discomfort). Potentially Fatal: Aspirin and clopidogrel: Increased risk of bleeding with dabigatran.

## ADVERSE DRUG REACTIONS:

Aspirin: GI disturbances, epigastric discomfort, prolonged bleeding time, rhinitis, urticaria; angioedema, salicylism, tinnitus. Clopidogrel: Dyspepsia, abdominal pain, nausea, vomiting, flatulence, constipation, gastritis, gastric and duodenal ulcers. Serious events include bleeding and GI haemorrhage. GI upset, diarrhoea, paraesthesia, vertigo, headache, dizziness, leucopaenia, eosinophilia, rash and pruritus. Potentially Fatal: Aspirin: Gastric erosion, ulceration and bleeding; severe, occasionally fatal exacerbation of airway obstruction in asthma; Reye's syndrome (childn <12 yrs). Hepatotoxicity; CNS depression, which may lead to coma; CV collapse, resp failure; paroxysmal bronchospasm and dyspnoea. Clopidogrel: Bleeding disorders including GI intracranial haemorrhage and thrombotic thrombocytopenic purpura.

## 67. CLOTRIMAZOLE IP 100MG TAB

#### SALIENT ACTIONS:

Clotrimazole is a broad-spectrum antifungal which binds to phospholipids in the cell membrane altering cell wall permeability causing a loss in essential intracellular elements.

### INDICATION & DOSAGE:

Oral

Oropharyngeal candidiasis

Adult: Per lozenge contains 10 mg clotrimazole: Suck 1 lozenge 5 times daily for 14 days. For prevention in patients receiving immunosuppressant therapy: 1 lozenge tid for the immunosuppressant treatment duration.

## CONTRAINDICATIONS:

Hypersensitivity.

## PRECAUTIONS:

Avoid contact with eyes upon topical application. Childn <3 yrs. Pregnancy, lactation.

## INTERACTIONS:

Antagonism with polyene antibiotics.

## ADVERSE REACTIONS:

Topical: Erythema, stinging, irritation; hypersensitivity reactions; contact dermatitis. Oral: GI disturbances, dysuria, mental depression, elevated liver enzymes.

#### 68. CLOZAPINE TAB

#### SALIENT ACTION:

Clozapine is a dibenzodiazepine derivative and an atypical antipsychotics prototype. Its therapeutic efficacy is proposed to be mediated through antagonism of the  $D_2$  and 5-HT $_{2A}$  receptors. It also acts as an antagonist at  $\alpha$ -adrenergic, histamine  $H_1$ , cholinergic and other dopaminergic and serotonergic receptors.

## INDICATIONS & DOSAGE:

Oral

Schizophrenia

Adult: 12.5 mg 1-2 times on day 1 followed by 25 mg 1-2 times on day 2, increased gradually in increments of 25-50 mg up to a daily dose of 300 mg w/in 14-21 days. Subsequent increments of 50-100 mg may be made 1-2 times wkly. Usual dose: 200-450 mg daily. Max: 900 mg daily.

Elderly: ≥60 yr Initially, 12.5 mg on day 1 increased subsequently in increments of 25 mg daily.

Renal impairment; Severe: Contraindicated.

Oral

Psychoses in Parkinson's disease

Adult: Initially, 12.5 mg at bedtime, increased in increments of 12.5 mg up to twice wkly, not >50 mg daily at the end of the 2nd wk. Usual dose: 25-37.5 mg daily. Max: 100 mg daily.

Renal impairment: Severe: Contraindicated.

### CONTRAINDICATIONS:

Patient w/ paralytic ileus, uncontrolled epilepsy, history of circulatory collapse, alcoholic or toxic psychoses, drug intoxication, coma or severe CNS depression, severe cardiac disease (e.g. myocarditis), bone marrow suppression, myeloproliferative disorders or any abnormalities of WBC or differential blood count, history of drug-induced neutropenia or agranulocytosis. Severe renal impairment.

#### PRECAUTIONS:

Patient w/ risk factors for stroke, history of long QT syndrome, history of seizures or conditions that lower the seizure threshold, history of cardiac impairment or abnormal cardiac findings on examination, benign prostatic hyperplasia, angle-closure glaucoma, history of colonic disease or lower abdominal surgery. Avoid abrupt withdrawal. Elderly w/ dementia-related psychosis. Hepatic or mild to moderate renal impairment. Pregnancy and lactation. Patient Counselling This drug may cause sedation and lowers seizure threshold, if affected, avoid driving or operate machinery. Avoid cigarette smoking. Monitoring Parameters Monitor cardiac and vital signs, leucocyte and differential blood counts every wk for 18 wk then at least every 2 wk; clinical monitoring for hyperglycaemia.

## INTERACTIONS:

Increased risk and/or severity of bone marrow suppression w/ bone marrow suppressants (e.g. carbamazepine, chloramphenicol), sulfonamides (e.g. co-trimoxazole), pyrazolone analgesics (e.g. phenylbutazone), penicillamine, cytotoxic agents or long-acting depot inj of antipsychotics. Concomitant use w/ benzodiazepines may increase risk of circulatory collapse which may lead to cardiac and/or resp arrest. Additive CNS depression and cognitive and motor performance interference w/ MAOIs and CNS depressants including antihistamines, benzodiazepines and opioid analgesics. May potentiate effects of anticholinergics or antihypertensives. Increased plasma concentration of highly protein bound substances (e.g. warfarin, digoxin). Decreased plasma concentrations w/ phenytoin. Concomitant use w/ lithium can increase the risk of development of neuroleptic malignant syndrome. Decreased clozapine levels w/ CYP1A2 inducers (e.g. omeprazole). Increased clozapine levels w/ CYP1A2 inhibitors (e.g. fluvoxamine, caffeine, ciprofloxacin).

#### ADVERSE REACTIONS:

Sedation, wt gain, reversible neutropenia, eosinophilia, tachycardia, orthostatic hypotension, dizziness, hypersalivation at night, headache, nausea, vomiting, constipation, urinary incontinence and retention, fatigue, transient fever, abnormalities of glucose homoeostasis and the onset of DM, obsessive compulsive symptoms. Rarely, anaemia, thrombocytopenia, thrombocythaemia, extrapyramidal disorders including tardive dyskinesia, circulatory collapse w/ cardiac and resp arrest, HTN, dysphagia, parotid gland enlargement, confusion, delirium, thromboembolism, acute pancreatitis, hepatitis and cholestatic jaundice.

Potentially Fatal: Agranulocytosis, myocarditis, cardiomyopathy, cardiac arrhythmias, pericarditis/pericardial effusion, neuroleptic malignant syndrome, pulmonary embolism, lower resp tract infection.

# 69. CO-TRIMOXAZOLE (sulphamethaxozole 400 mg + trimethoprim 80 mg / sulphamethaxozole 800 mg + trimethoprim 160 mg) Tab, Syrup sulphamethoxozole 200 mg + trimethoprim 40 mg SALIENT ACTIONS:

Co-trimoxazole exhibits the synergistic actions of its components (sulfamethoxazole and trimethoprim) by 10-fold. Sulfamethoxazole inhibits dihydrofolic acid formation from PABA, thus interfering with synthesis and growth of bacterial folic acid. Trimethoprim inhibits enzymes folic acid pathway, preventing the reaction of the dihydrolic acid to tetrahydrofolate. Co-trimoxazole possesses bactericidal effects against E coli, Klebsiella spp, Enterobacter spp, M morganii, P mirabilis, P vulgaris, H influenzae, Strep pneumoniae, Pneumocystis (carinii) jiroveci, Cyclospora spp.

#### INDICATIONS & DOSAGE REGIMENS:

- 1. Susceptible infections: 2. Urinary tract infections: 3, Gastrointestinal infections: 4. Respiratory tract infections: Adult: 960 mg bid, up to 2.88 g daily given in 2 divided doses in severe cases. Child: 6 wk-5 mth: 120 mg bid; 6 mth-5 yr: 240 mg bid; 6-12 yr: 480 mg bid.
- 5. Pneumocystis (carinii) jiroveci pneumonia :Adult: Up to 120 mg/kg/day in 2-4 divided doses for 14-21 days. Child: >4 wk: Up to 120 mg/kg daily given in 2-4 divided doses for 14-21 days.
- 6. Prophylaxis of susceptible infections in AIDS patients: Adult: 960 mg daily. Child: 450 mg/m² (max: 960 mg) bid for 3 days in each wk, either consecutively or on alternate days.

# CONTRAINDICATIONS:

Hypersensitivity; severe renal or hepatic insufficiency; infants <4 wk; megaloblastic anaemia; pregnancy and lactation.

#### PRECAUTIONS:

G6PD deficiency; potential folate deficiency; hepatic and renal impairment; elderly; porphyria; thyroid dysfunction; maintain adequate hydration.

#### INTERACTIONS:

Reduced ciclosporin concentrations in blood when used concurrently. Increases toxicity of methotrexate. Inhibits phenytoin clearance. Potentiates warfarin and oral hypoglycaemics. Potentially Fatal: Co-admin with pyrimethamine causes megaloblastic anaemia. Enhancement of renal damage by ciclosporin.

#### ADVERSE DRUG REACTIONS:

Renal failure, nausea, vomiting, diarrhoea, anorexia; skin rashes, urticaria. Potentially Fatal: Stevens-Johnson syndrome, agranulocytosis, toxic epidermal necrolysis, hepatic necrosis.

#### 70. CYCLOPHOSPHAMIDE TAB

#### SALIENT ACTIONS:

Cyclophosphamide is a prodrug which is converted in the body to the active metabolites. It acts at any stage of the cell cycle. It prevents cell division by cross-linking deoxyribonucleic acid (DNA) strands and reducing DNA synthesis. It also exerts a potent immunosuppressive effect.

#### INDICATIONS & DOSAGE:

Oral

Malignancies

Adult: Low dose regimen: 2-6 mg/kg wkly in divided dose. Alternatively, 100-300 mg daily in divided doses or 50-250 mg/m² daily, or 80-300 mg/m² daily in divided doses.

Oral

Nephrotic syndrome

Child: 2 mg/kg daily for 8-12 wk. Max cumulative dose: 168 mg/kg. Max duration: 90 days.

#### CONTRAINDICATIONS:

Patient w/ bone marrow aplasia, urinary outflow obstruction, UTI, acute infection, drug- or radiation-induced urothelial toxicity. Pregnancy.

#### PRECAUTIONS:

Patient w/ DM, severe immunosuppression, acute porphyria, pre-existing CV disease or those at risk for cardiotoxicity. Renal and hepatic impairment. Lactation. Patient Counselling This drug may cause visual impairment and dizziness, if affected, do not drive or operate machinery. Monitoring Parameters Monitor CBC w/ differential and platelets, serum electrolytes and creatinine, BUN, urinalysis. Monitor for signs/symptoms of haemorrhagic cystitis or other urinary/renal toxicity, cardiac, pulmonary and/or hepatic toxicity.

#### INTERACTIONS:

Increased risk of cardiotoxicity w/ doxorubicin or other cardiotoxic drugs. May increase incidence of mucositis w/ protease inhibitors. May increase haematotoxicity and/or immunosuppression w/ ACE inhibitors, natalizumab, paclitaxel, thiazide diuretics, zidovudine. May increase pulmonary toxicity w/ amiodarone. May increase nephrotoxicity w/ amphotericin B. May result to acute water intoxication w/ indometacin. May increase risk of hepatotoxicity w/ azathioprine. May increase incidence of hepatic veno-occlusive disease and mucositis w/ busulfan. May increase risk of haemorrhagic cystitis w/ previous or concomitant radiotherapy. May result to acute encephalopathy w/ metronidazole. May increase risk of thromboembolic complications. May alter the effect of warfarin. May increase immunosuppressive effect of ciclosporin. May result to prolonged apnoea w/ depolarising muscle relaxants (e.g. suxamethonium).

#### ADVERSE REACTIONS:

Alopecia, skin and nails hyperpigmentation, nausea and vomiting, mucositis, inappropriate antidiuretic hormone secretion, carbohydrate metabolism disturbances, gonadal suppression, interstitial pulmonary fibrosis. Potentially Fatal: Anaphylactic reactions, bone marrow failure, severe immunosuppression, urotoxicity, cardiotoxicity, hyponatraemia, haemorrhagic cystitis.

#### 71. DAPSONE 100MG TAB

#### SALIENT ACTIONS:

Dapsone inhibits folic acid synthesis by preventing normal bacterial utilization of PABA (PABA).

### INDICATION & DOSAGE:

Oral

Primary and secondary prophylaxis of Pneumocystis (carinii) jiroveci pneumonia

Adult: 50 mg daily, with pyrimethamine 50 mg once wkly. Alternatively, 100 mg with pyrimethamine 50 mg

twice wkly.

Child: 1 mth-18 yr: 2 mg/kg daily (max: 100 mg daily) or 4 mg/kg wkly (max: 200 mg wkly).

Multibacillary leprosy

Adult: 100 mg daily with clofazimine 50 mg daily, together with rifampicin 600 mg and clofazimine 300 mg once a mth for 12 mth. <35 kg: dapsone dose: 1-2 mg/kg/day.

Child: and child 10-14 yr old: daily doses of dapsone 50 mg, or 1 to 2 mg/kg if their body-weight is low.

Oral

Paucibacillary leprosy

Adult: 100 mg daily with 600 mg rifampicin once a mth, both given for 6 mth.

Child: Reduce dose as for multibacillary leprosy.

Oral

Dermatitis herpetiformis

Adult: Initially, 50 mg daily increased gradually to 300 mg daily if required.

# CONTRAINDICATIONS:

Hypersensitivity. Severe anaemia, porphyria.

## PRECAUTIONS:

G6PD deficiency, methaemoglobin or Hb M. Perform regular blood counts and monitor liver function regularly. Pregnancy and lactation.

## INTERACTIONS:

Decreased serum conc of dapsone when used with rifampicin. Increased plasma conc with probenecid, trimethoprim. Antagonize clofazimine.

## ADVERSE REACTIONS:

Anaemia, peripheral neuropathy, haemolysis and methaemoglobinaemia (dose-related), nephrotic syndrome, psychological changes, hepatitis. Others: Nausea, vomiting, anorexia, headache, maculopapular rash, toxic epidermal necrolysis, Stevens-Johnson syndrome. Topical: Dryness, redness, oiliness and peeling at application

Potentially Fatal: Agranulocytosis, serious cutaneous hypersensitivity reactions, exfoliative dermatitis.

# 72. DEFERASIROX TABLET

## SALIENT ACTIONS:

Deferasirox is an orally active chelator that is selective for Fe (III). It is a tridentate ligand that binds Fe w/ high affinity in a 2:1 ratio. It promotes excretion of Fe, primarily in the faeces and has low affinity for Zn and Cu.

# INDICATIONS & DOSAGE:

Oral

Chronic iron overload

Adult: For transfusion-related chronic Fe overload: Initially, 20 mg/kg once daily. Adjust dose in increments or decrements of 5-10 mg/kg, 3-6 mthly when needed. Max: 40 mg/kg daily. Discontinue treatment if serumferritin concentrations consistently fall below 500 mcg/L. For Fe overload of non-transfusion dependent thalassaemia syndromes: Initially, 10 mg/kg once daily, may increase to 20 mg/kg daily after 4 wk, if the baseline liver-Fe concentration is >15 mg Fe/g of liver dry wt. Adjust dose in increments or decrements of 5-10 mg/kg, 3-6 mthly when needed. Max: 20 mg/kg daily. Discontinue treatment if serum-ferritin concentrations consistently fall below 300 mcg/L.

Child: For transfusion-related chronic Fe overload: 2-5 yr Initially, 20 mg/kg once daily. May require higher titration doses. >5-17 yr Same as adult dose. For Fe overload of non-transfusion dependent thalassaemia syndromes: Max: 10 mg/kg daily.

Renal impairment:

CrCl (ml/min)Dosage Recommendation Contraindicated.

Hepatic impairment: Moderate: Considerably reduce dose followed by progressive increase up to a limit of 50%. Severe: Contraindicated.

# CONTRAINDICATIONS:

Patient w/ poor performance status, high-risk myelodysplastic syndromes, advanced malignancies. Platelet counts <50,000 cells/mm<sup>3</sup>. CrCl <60 mL/min. Severe hepatic impairment.

#### PRECAUTIONS:

Moderate hepatic impairment. Childn. Pregnancy and lactation. Monitoring Parameters Monitor serum ferritin

concentrations and tests for proteinuria mthly. Measure liver enzymes and bilirubin prior to, 2 wkly during the 1st mth and mthly thereafter. Perform auditory testing and ophthamologic examination before starting treatment and yrly, thereafter. Monitor renal function and CBC before starting treatment and regularly during therapy.

## INTERACTIONS:

May chelate Al when used w/ Al-containing antacids. Decreased exposure w/ colestyramine and potent inducers of UGT enzymes (e.g. carbamazepine, rifampicin, phenytoin). May increase serum concentration of CYP1A2 (e.g. duloxetine, theophylline) and CYP2C8 (e.g. repaglinide, paclitaxel) substrates, and decrease serum concentrations of CYP3A4 substrates (e.g. ciclosporin, hormonal contraceptives, simvastatin).

#### ADVERSE REACTIONS:

Nausea, vomiting, diarrhoea and abdominal pain; rashes, erythema multiforme; headache, pyrexia, pruritus, anxiety, sleep disorders, fatigue, dizziness, skin pigmentation disorders, infections, pharyngolaryngeal pain, oedema; leucocytoclastic vasculitis, urticaria, alopecia; increase in serum creatinine and liver enzyme values, renal tubulopathy, proteinuria; hearing loss and visual disorders, including cataracts.

Potentially Fatal: Upper GI ulceration and haemorrhage, acute renal failure, hepatitis and hepatic failure, serious hypersensitivity reactions e.g. angioedema and anaphylaxis, agranulocytosis, neutropenia, thrombocytopenia.

#### 73. DEFLAZACORT TABLET

## SALIENT ACTIONS:

Deflazacort is a glucocorticoid derived from prednisolone. It acts as anti-inflammatory and immunosuppressive agent.

#### INDICATION & DOSAGE:

Oral

Allergic and inflammatory disorders

Adult: Initially, up to 120 mg daily. Maintenance: 3-18 mg daily.

Child: 0.25-1.5 mg/kg daily or on alternate days.

#### CONTRAINDICATIONS:

Systemic infection (unless specific therapy is given). Concurrent admin of live virus vaccines in patients receiving immunosuppressive doses.

#### PRECAUTIONS:

Patient w/ infection, history of TB, cardiac disease or CHF (except in the presence of active rheumatic carditis), HTN, thromboembolic disorders, GI disorders (i.e. gastritis, diverticulitis, ulcerative colitis, peptic ulcer, pyogenic infections), DM (including family history), osteoporosis, myasthenia gravis, epilepsy, emotional instability, history of corticosteroid-induced myopathy, hypothyroidism, ocular herpes simplex. Avoid abrupt withdrawal after prolonged therapy. Renal and hepatic (including hepatic failure and cirrhosis) impairment. Childn. Pregnancy and lactation. Monitoring Parameters Monitor growth, height and wt esp in childn.

#### INTERACTIONS:

Decreased serum concentration when used w/ hepatic enzyme inducers (e.g. rifampicin, rifabutin, carbamazepine, phenobarbitone, phenytoin, primidone, aminoglutethimide). Increased serum concentration if concurrently used w/ hepatic enzyme inhibitors (e.g. ketoconazole). Antagonises the effect of hypoglycaemic agents, antihypertensive and diuretics. Enhances the hypokalaemic effect of acetazolamide, loop/thiazide diuretics, β<sub>2</sub>-agonists, xanthines and carbenoxolone. May increase the anticoagulant effect of coumarins. May prolong relaxation and acute myopathy when given w/ non-depolarising muscle relaxants. Increases the renal clearance of salicylates, steroid withdrawal may lead to salicylate intoxication. Increased serum concentrations w/ oral contraceptives. Reduced bioavailability w/ antacids. Increased risk of tendonitis and tendon rupture if concomitantly used w/ quinolones.

### ADVERSE REACTIONS:

Wt gain, hypothalamic-pituitary-adrenal (HPA) axis suppression, amenorrhoea, Cushingoid facies, growth suppression (childn), increased appetite, opportunistic infections, candidiasis, osteoporosis, myopathy, menstrual irregularity, heart failure, headache, vertigo, restlessness, depression, labile mood, irritability, euphoria, mania, delusions, hallucinations, schizophrenia, behavioural disturbances, anxiety, sleep disturbances, cognitive dysfunction including confusion and amnesia, increased intra-ocular pressure, glaucoma, chorioretinopathy, corneal/scleral thinning, posterior subcapsular cataract, dyspepsia, peptic ulceration, haemorrhage, nausea, acute pancreatitis (childn), hirsutism, striae, acne, skin atrophy, telangiectasia, oedema, impaired healing, leukocytosis. Rarely, muscle wasting, bruising, benign intracranial HTN.

# 74. DESLORATADINE TAB

# SALIENT ACTIONS:

Desloratadine is a long-acting, tricyclic, non-sedating, selective peripheral histamine H<sub>1</sub>-receptor antagonist which inhibits the release of pro-inflammatory mediators from human mast cells and basophils.

#### INDICATIONS & DOSAGE:Oral

Allergic conditions

Adult: 5 mg once daily.

Child: 6-11 mth 1 mg; 1-5 yr 1.25 mg; 6-11 yr 2.5 mg. Doses to be taken once daily.

Renal impairment: Initially, 5 mg every other day.

Hepatic impairment: Initially, 5 mg every other day.

#### CONTRAINDICATIONS:

hypersensitivity

#### PRECAUTIONS:

Hepatic and renal impairment. Pregnancy and lactation.

#### INTERACTIONS:

Potential increase in plasma concentrations w/ drugs affecting hepatic microsomal enzymes (e.g. azithromycin, cimetidine, erythromycin, fluoxetine, ketoconazole).

#### ADVERSE REACTIONS:

Pharyngitis, dry mouth, myalgia, fatigue, somnolence, headache, dizziness, insomnia, dysmenorrhoea, nausea, dyspepsia, diarrhoea, vomiting, anorexia, increased appetite, fever, UTI, varicella, upper resp tract infection, coughing, epistaxis, parasitic infection, bronchitis, otitis media, rhinorrhoea, emotional lability, irritability, maculopapular rash, erythema.

# 75. DESVENLAFAXINE 25 MG TAB

#### SALIENT ACTIONS:

Desvenlafaxine is the principal active metabolite of venlafaxine. The exact mechanism is unknown, but is thought to be related to the potentiation of serotonin and norepinephrine in the CNS, through inhibition of their reuptake.

# INDICATIONS & DOSAGE:

Oral

Depression

Adult: 50 mg once daily. Doses up to 400 mg once daily have been studied and shown to be effective, but no additional benefit was observed w/ doses >50 mg once daily.

Renal impairment:

CrCl (ml/min	Dosage Recommendation
<30 or ESRD	25 mg daily or 50 mg every other day. Supplemental doses should not be given after dialysis.
	Max: 50 mg once daily.

Hepatic impairment: Moderate to severe: 50 mg daily. Max: 100 mg once daily.

## CONTRAINDICATIONS:

Concurrent use or w/in 14 days of discontinuing MAOIs (e.g. linezolid, IV methylene blue). Initiation of MAOI at least 7 days after discontinuing desvenlafaxine.

# PRECAUTIONS:

Patient w/ pre-existing HTN or other conditions that may be compromised by increased BP, raised intraocular pressure, personal or family history of mania or hypomania; CV, cerebrovascular or lipid metabolism disorders; seizure disorder. Avoid abrupt withdrawal. Renal and moderate to severe hepatic impairment. Pregnancy and lactation. Patient Counselling May impair ability to drive or operate machinery. Monitoring Parameters Monitor renal function, BP, lipid panel (e.g. total cholesterol, LDL, triglycerides); signs/symptoms of serotonin syndrome; mental status for depression, suicidal ideation (esp at the beginning of therapy or when doses are increased or decreased); intraocular pressure (in patients w/ baseline elevations or history of glaucoma).

#### INTERACTIONS:

Increased risk of bleeding w/ aspirin or other NSAIDs, warfarin and other anticoagulants.

Potentially Fatal: Increased risk of serotonin syndrome w/ MAOIs (e.g. linezolid, IV methylene blue).

#### ADVERSE REACTIONS:

Suicidal thinking/behaviour, HTN, mydriasis, seizure, hyponatraemia, interstitial lung disease and eosinophilic pneumonia; nausea, dizziness, insomnia, hyperhidrosis, constipation, somnolence, decreased appetite, anxiety, sexual function disorders in males (e.g. anorgasmia, decreased libido, abnormal orgasm, delayed ejaculation,

erectile dysfunction, ejaculation disorder, ejaculation failure, sexual dysfunction).

Potentially Fatal: Serotonin syndrome or neuroleptic malignant syndrome-like reactions; haemorrhage.

# 76. DEXAMETHASONE PHOSPHATE Tab 0.5 mg SALIENT ACTIONS:

Dexamethasone is a corticosteroid having anti-inflammatory, immunosuppressant property.

### INDICATIONS & DOSAGE REGIMENS:

- 1. Antiinflammatory: Adult: 0.75 mg daily in 2-4 divided doses.
- 2. Screening test of cushing syndrome: Adult: 0.5 mg every6 hour.
- 3. Acute exacerbation of multiple sclerosis: Adult: 30 mg daily for 1 week

## CONTRAINDICATIONS:

Hypersensitivity, active untreated infections, viral/fungal diseases of eye.

#### PRECAUTIONS:

Hypothyroidism, cirrhosis, hypertension, CHF, ulcerative colitis, osteoporosis, glaucoma, cataract.

## INTERACTIONS:

hypokalemia with amphotericin B, loop diuretics, reduced efficacy of INH, salicylates, vaccines

# ADVERSE DRUG REACTIONS:

Growth retardation, osteoporosis, peptic ulcer glaucoma, subcapsular cataract, increased opportunistic infections.

#### 77. DEXKETOPROFEN TABLET

## SALIENT ACTIONS:

Dexketoprofen is an isomer of ketoprofen. It is a propionic acid derivative with analgesic, anti-inflammatory and antipyretic properties. It is a non-steroidal anti-inflammatory drug (NSAID) that reduces prostaglandin synthesis via inhibition of cyclooxygenase pathway (both COX-1 and COX-2) activity.

#### INDICATION & DOSAGE:

Oral

Mild to moderate pain

Adult: 12.5 mg every 4-6 hr or 25 mg every 8 hr. Max: 75 mg/day.

Elderly: Initial total daily dose should not exceed 50 mg/day. May increase to the doses recommended for general population only if well tolerated.

## **CONTRAINDICATIONS:**

Hypersensitivity to Dexketoprofen, or other NSAIDs. Patients with history of asthma attacks, bronchospasm, angioedema, urticaria, acute rhinitis or nasal polyps that were precipitated by Aspirin or other NSAIDs. Active/suspected/recurrent peptic ulcer or haemorrhage. Chronic dyspepsia; GI bleeding or other active bleedings; Crohn's disease or ulcerative colitis; bronchial asthma; severe heart failure; severe hepatic impairment; moderate to severe renal impairment; haemorrhagic diathesis and other coagulation disorders. Pregnancy and lactation.

#### PRECAUTIONS:

History of GI disease, GI symptoms; NSAIDS are associated with serious GI side effects e.g. bleeding, ulceration or perforation. May cause deterioration of renal function, fluid retention and oedema; caution in renal and/or hepatic impairment, HTN, heart failure. May inhibit platelet aggregation and prolong bleeding time, concomitant use with warfarin or heparin is not recommended. Non-selective NSAIDs are also associated with a small increased risk of thrombotic events (e.g. stroke, MI). Long term use may impair female fertility. Safety and efficacy in children and adolescent have not been established. Increased risk of NSAIDS adverse reactions in elderly patients.

# INTERACTIONS:

Concomitant use of salicylates, other NSAIDs, anticoagulant (e.g. warfarin, heparin) or corticosteroids may increase risk of bleeding and combination use is not recommended. Caution if used with thrombolytics, antiplatelets, selective serotonin reuptake inhibitors, pentoxyfylline due to elevated bleeding risk. May increase toxic effects of hydantoines and sulphonamides. May reduce effects of antihypertensives. Increased risk of red cell line toxicity with zidovudine, monitor complete blood count and reticulocyte count. Renal function may be worsened when used with ciclosporin or tacrolimus. May increase hypoglycaemic effect of sulfonylureas. Probenacid may increase plasma concentration of Dexketoprofen.

Potentially Fatal: NSAIDS may increase blood lithium levels; and increase haematological toxicity of methotrexate.

## ADVERSE REACTIONS:

Nausea, vomiting, dyspepsia, abdominal pain, diarrhoea, gastric, peptic ulcer, GI bleeding, dry mouth, flatulence, headache, dizziness, somnolence, insomnia, palpitations, paraesthesia, syncope, HTN, hypotension, bradypnoea, bronchosposm, fatigue, asthenia, malaise, rash, urticaria, acne, photosensitivity reactions, facial oedema, polyruria, nephritis or nephrotic syndrome, menstrual disorder, prostatic disorder, peripheral oedema, pancreatitis, abnormal LFT, increased plasma urea nitrogen, neutropenia, thrombocytopenia. Potentially Fatal: Anaphylactic shock, Steven-Johnson Syndrome and toxic epidermal necrolysis.

# 78. DEXLANSOPRAZOLE Capsule. 30 mg, 60 mg

# SALIENT ACTIONS:

Dexlansoprazole suppresses gastric acid secretion by specific inhibition of the enzyme system hydrogen/potassium adenosine triphosphatase (H+/K+ ATPase) present on the secretory surface of the gastric parietal cell.

# INDICATIONS & DOSAGES REGIMENS:

1. Healing of all grades of erosive esophagitis (EE).- 60 mg orally once a day x 8 wks

Treatment of heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD).
 30 mg orally once a day x 4 weeks

3. Maintenance of healing of EE and relief of heartburn. - 30 mg orally once a day x 4 wks

#### CONTRAINDICATIONS:

Known hypersensitivity (eg, anaphylaxis, acute interstitial nephritis) to dexlansoprazole or any component of the formulation; concomitant use with products that contain rilpivirine.

#### PRECAUTIONS:

1. Acute Interstitial Nephritis - generally attributed to anidiopathic hypersensitivity reaction

Cyanocobalamin (Vitamin B-12) Deficiency -lead to <u>malabsorption</u> of cyanocobalamin (Vitamin B-12) caused by hypo- or <u>achlorhydria</u>

3. Clostridium Difficile Associated Diarrhea- increased risk of *Clostridium difficile* associated diarrhea, especially in hospitalized patients.

#### INTERACTIONS:

1. Warfarin - increased inr and prothrombin time in Patients receiving ppis and warfarin concomitantly.

 Antacids- simultaneous administration of lansoprazole with aluminum and magnesium hydroxide or Magaldrate results in lower peak plasma levels, but does not significantly reduce bioavailability.

3. Tacrolimus- Concomitant administration of dexlansoprazole and tacrolimus may increase whole blood levels Oftacrolimus, especially in transplant patients who are intermediate or poor metabolizers of Cyp2c19.

4. Methotrexate - concomitant administration of ppis and methotrexate (primarily at high dose) may elevate And prolong serum levels of methotrexate and/or its metabolite hydroxymethotrexate

# ADVERSE EFFECTS

- 1. Gastrointestinal disorders Diarrhea, Abdominal Pain, Flatulence, Constipation
- 2. Nervous system disorders Headache

3. Blood and Lymphatic System Disorders: anemia, lymphadenopathy

- 4. Cardiac Disorders: acute myocardial infarction, angina, arrhythmia, bradycardia, edema, palpitations, tachycardia
- 5. Ear and Labyrinth Disorders: ear pain, tinnitus, vertigo

6. Endocrine Disorders: goiter

7. Hepatobiliary Disorders: biliary colic, cholelithiasis, hepatomegaly

# 79. DICLOFENAC POTTASIUM 50 mg + DICYCLOMINE HCL 10 mg Tab

## SALIENT ACTIONS:

Diclofenac has potent anti-inflammatory, analgesic and antipyretic actions. It inhibits the enzyme,

cyclooxygenase, thus resulting in reduced synthesis of prostaglandin precursors. Dicyclomine is antispasmodic having anticholinergic activity.

# INDICATIONS & DOSAGE REGIMENS:

1. Gastrointestinal spasm: one tablet twice a day.

# CONTRAINDICATIONS:

Active peptic ulcer; hypersensitivity to diclofenac or other NSAIDs. Treatment of perioperative pain in CABG surgery. 3rd trimester of pregnancy.

#### PRECAUTIONS:

History of GI ulceration; impaired cardiac, renal or hepatic function; hypertension; lactation. IV admin in patients with moderate or severe renal impairment; hypovolaemia or dehydration; asthma, porphyria. Monitor LFTs in patients on prolonged therapy. May prolong bleeding time; caution when used in patients with coagulation disorders or on anticoagulants. Prolonged therapy may increase risk of anaemia. 1st and 2nd trimester of pregnancy. Elderly, debilitated patients.

#### INTERACTIONS:

Not to be given IV to patients who are receiving other NSAIDs or anticoagulants including low dose heparin. Renal function may be worsened when used with ciclosporin or triamterene. Altered absorption when given with sucralfate, colestyramine or colestipol. Ophthalmic application of diclofenac may reduce the efficacy of ophthalmic acetylcholine and carbachol. Increased risk of GI ulceration and bleeding when used with corticosteroids, aspirin or anticoagulants. Potentially Fatal: Increases blood levels of digoxin, lithium and methotrexate. Potentiate potassium-sparing diuretics.

#### ADVERSE DRUG REACTIONS:

GI disturbances; headache, dizziness, rash; GI bleeding, peptic ulceration; abnormalities of kidney function. Pain and tissue damage at Inj site (IM); local irritation (rectal); transient burning and stinging (ophthalmic).

# 80. DIETHYLCARBAMAZINE CITRATE Tab 100 mg SALIENT ACTIONS:

Diethylcarbamazine is an anthelmintic that is used in the treatment of lymphatic filariasis. It is active against the microfilariae and adult worms of W. bancrofti, B. malayi, B. timori and Loa loa but only against the microfilariae of O. volvulus. It is also used in treatment of toxocariasis. Repeated courses may be necessary.

# INDICATIONS & DOSAGE REGIMENS:

1. Filariasis 2. Toxocariasis 3. Loiasis

Adult: Initially, 1 mg/kg daily, increased gradually to 6 mg/kg daily over 3 days then maintained for 3 wk. A corticosteroid may be given concurrently for the treatment of filarial infections.

4. Prophylaxis of loiasis : Adult: 300 mg wkly.

#### CONTRAINDICATIONS:

Pregnancy, hypersensitivity; lactation; infants, elderly or debilitated patients; impaired renal function; cardiac disease.

# PRECAUTIONS:

Patients with poor health.

# ADVERSE DRUG REACTIONS:

Fever, headache, vomiting, dizziness, drowsiness, nausea, chills.Potentially Fatal: Severe hypersensitivity reactions may occur especially in the treatment of onchocerciasis where rare Mazzotti reaction characterised by rash, itching, headache, muscle and joint pains, tachycardia, postural hypotension may start within 2 hr of drug administration. Encephalitis and retinal haemorrhage.

# 81. DIGOXIN Tab 0.25 mg

#### SALIENT ACTIONS:

Digoxin acts by inhibiting Na-K-ATPase enzyme, thereby increasing intracellular concentration of sodium and calcium. This causes increase in force of contraction.

#### INDICATIONS & DOSAGE REGIMENS:

Heart failure & supraventricular arrhythmia loading dose of 0.75 mg- 1.5 mg during first 24 hour period in a single dose or divided doses every 6 hour for greater risk cases. For mild heart filure, 250 mcg 1-2 times a day.

# CONTRAINDICATIONS:

Digoxin toxicity, ventricular tachycardia/ fibrillation, obstructive cardiomyopathy, WPW syndrome.

# PRECAUTION:

Hypokalemia, hypertension, , IHD, hypercalcemia, cardiac dysarrhythmias, hypomagnesemia, acute myocarditis, chronic cor pulmonale.

# INTERACTIONS:

Effectiveness reduced by phenytoin, neomycin, sulphasalazine, antacids. Blood levels increased by calcium channel blockers, spironolactone.

# ADVERSE DRUG REACTIONS:

Extra beat, anorexia nausea, vomiting, confusion, drowsiness, restlessness.

# 82. DILTIAZEM HCL (TAB 30 MG)

#### SALIENT ACTIONS:

#### Hypertension

Diltiazem hydrochloride extended-release capsules produce their antihypertensive effect primarily by relaxation of vascular smooth muscle with a resultant decrease in peripheral vascular resistance. The magnitude of blood pressure reduction is related to the degree of hypertension; thus hypertensive individuals experience an antihypertensive effect, whereas there is only a modest fall in blood pressure in normotensives.

#### Angina

Diltiazem hydrochloride has been shown to produce increases in exercise tolerance, probably due to its ability to reduce myocardial oxygen demand. This is accomplished via reductions in heart rate and systemic blood pressure at submaximal and maximal work loads.

Diltiazem has been shown to be a potent dilator of coronary arteries, both epicardial and subendocardial. Spontaneous and ergonovine-induced coronary artery spasms are inhibited by Diltiazem.

#### INDICATIONS:

1) The drug is indicated for angina:

- Stable angina (exercise-induced) diltiazem increases coronary blood flow and decreases myocardial oxygen consumption, secondary to decreased peripheral resistance, heart rate, and contractility. [3][4]
- Variant angina it is effective owing to its direct effects on coronary dilation.
- Unstable angina (preinfarction, crescendo) diltiazem may be particularly effective if the underlying mechanism is vasospasm.
- 2)Atrial fibrillation<sup>[6]</sup> or atrial flutter is another indication. The initial bolus should be 0.25 mg/kg, intravenous (IV).
- 3)Because of its vasodilatory effects, diltiazem is useful for treating hypertension. Calcium channel blockers are well tolerated, and especially effective in treating low-renin hypertension.<sup>[7]</sup>

#### DOSAGE REGIMENS:

### **Usual Adult Dose:**

Initial dose: 30 to 60 mg orally 3 to 4 times a day.

Maintenance dose: 180 to 360 mg orally/day in divided doses.

#### CONTRAINDICATIONS:

Diltiazem is relatively contraindicated in the presence of <u>sick sinus syndrome</u>, <u>atrioventricular node</u> conduction disturbances, <u>bradycardia</u>, impaired <u>left ventricle</u> function, <u>peripheral artery occlusive disease</u>, and <u>chronic obstructive pulmonary disease</u>.

#### PRECAUTIONS:

- In congestive heart failure, patients with reduced ventricular function may not be able to counteract the
  inotropic and chronotropic effects of diltiazem, the result being an even higher compromise of function.
- With SA node or AV conduction disturbances, the use of diltiazem should be avoided in patients with SA or AV nodal abnormalities, because of its negative chronotropic and dromotropic effects.
- Low blood pressure patients, with systolic blood pressures below 90 mm Hg, should not be treated with diltiazem.
- Diltiazem may paradoxically increase ventricular rate in patients with Wolff-Parkinson-White syndrome because of accessory conduction pathways.

#### INTERACTIONS:

Because of its inhibition of hepatic cytochromes CYP3A4, CYP2C9 and CYP2D6, there are a significant number of drug interactions, more than can be listed here. [8] Some of the more important interactions are listed below.

#### Beta-blockers

Intravenous diltiazem should be used with caution with beta-blockers because, while the combination is most potent at reducing heart rate, there are rare instances of dysrhythmia and AV node block.<sup>[9]</sup>

Quinidine[edit]

Quinidine should not be used concurrently with calcium channel blockers because of reduced clearance of both drugs and potential pharmacodynamic effects at the SA and AV nodes.<sup>[10]</sup>

## ADVERSE EFFECTS:

- · Body aches or pain
- congestion
- cough

- · dryness or soreness of the throat
- fever
- hoarseness
- runny nose
- · tender or swollen glands in the neck
- trouble swallowing
- · voice changes

# 83. DIPHENOXYLATE 2.5 mg + ATROPINE 0.025 mg Tab SALIENT ACTIONS:

Diphenoxylate is an opioid agonist used for the treatment of diarrhea that acts by slowing intestinal contractions and peristalsis allowing the body to consolidate intestinal contents and prolong transit time, thus allowing the intestines to draw moisture out of them at a normal or higher rate and therefore stop the formation of loose and liquid stools. It is the main active ingredient in the anti-peristaltic medication which also contains atropine.

# INDICATIONS & DOSAGE REGIMENS:

Irritable bowel syndrome: Diarrhoea resulting from cyclic or diarrhoea-predominant IBS One tablet (2.5 mg diphenoxylate and 0.025mg atropine) in adults, the usual dose is 5 mg (2 tablets) of diphenoxylate three to four times per day initially. Thereafter, the dose may be decreased to 2.5 mg (1 tablet) two to three times a day.

### CONTRAINDICATIONS:

Infective diarrhea, cardia arrhythmia.

#### PRECAUTIONS:

Allergy, liver disease (e.g., obstructive jaundice, cirrhosis), diarrhea caused by certain types of infections (Clostridium difficile-associated diarrhea following recent antibiotic therapy, bacterial infection of the gut caused by E. coli, Salmonella, Shigella).

#### INTERACTIONS:

The combination of diphenoxylate and monoamine oxidase inhibitors (MAO's), for example, isocarboxazid, phenelzine, tranylcypromine, and procarbazine can cause severe high blood pressure with the possibility of a cerebrovascular accident, bethanechol, cisapride, metoclopramide, and erythromycin, hyoscyamine, antihistamines such as hydroxyzine and diphenhydramine may exaggerate the effects of diphenoxylate and cause constipation.

#### ADVERSE DRUG REACTIONS:

Drowsiness, headache, nausea or vomiting, and dry mouth. Euphoria, depression, lethargy, restlessness, numbness of extremities, loss of appetite, and abdominal pain or discomfort have been reported less frequently.

# 84. DIAZEPAM TAB SALIENT ACTIONS:

Diazepam is a long-acting benzodiazepine w/ anticonvulsant, anxiolytic, sedative, muscle relaxant and amnestic properties. It increases neuronal membrane permeability to Cl ions by binding to stereospecific benzodiazepine receptors on the postsynaptic GABA neuron w/in the CNS and enhancing the GABA inhibitory effects resulting in hyperpolarisation and stabilisation.

EHSELICIA

#### INDICATIONS & DOSAGE:

Oral

Severe anxiety

Adult: 2 mg tid. Max: 30 mg/day.

Child: 1-2.5 mg 3-4 times daily, increase gradually as needed and tolerated.

Elderly: Should not exceed half the adult dose.

Renal impairment: Dose reduction may be required.

Hepatic impairment: Dose reduction may be required.

Oral

Insomnia associated with anxiety

Adult: 5-15 mg at bedtime.

Child: 1-2.5 mg 3-4 times daily, increase gradually as needed and tolerated.

Elderly: Should not exceed half the adult dose.

Renal impairment: Dose reduction may be required.

Hepatic impairment: Dose reduction may be required.

Oral

Premedication before anaesthesia

Adult: 5-20 mg. Child: 2-10 mg.

Elderly: Should not exceed half the adult dose.

Renal impairment: Dose reduction may be required. Hepatic impairment: Dose reduction may be required.

Oral

Sedation in minor surgical and medical procedures

Adult: 5-20 mg. Child: 2-10 mg.

Elderly: Should not exceed half the adult dose. Renal impairment: Dose reduction may be required. Hepatic impairment: Dose reduction may be required.

Oral

Adjunct in seizures

Adult: 2-60 mg/day in divided doses.

Elderly: Should not exceed half the adult dose.

Renal impairment: Dose reduction may be required. Hepatic impairment: Dose reduction may be required.

Oral

Muscle spasms

Adult: 2-15 mg/day in divided doses, may increase up to 60 mg/day in severe spastic disorders (e.g. cerebral palsy).

Child: 2-40 mg/day in divided doses.

Elderly: Should not exceed half the adult dose.

Renal impairment: Dose reduction may be required. Hepatic impairment: Dose reduction may be required.

Oral

Alcohol withdrawal syndrome

Adult: 5-20 mg, repeat after 2-4 hr if necessary. Alternatively, 10 mg 3-4 times daily on the 1st day, reducing to 5 mg 3-4 times daily as required.

Elderly: Should not exceed half the adult dose.

Renal impairment: Dose reduction may be required.

Hepatic impairment: Dose reduction may be required.

#### CONTRAINDICATIONS:

Patient w/ acute angle closure glaucoma, pre-existing CNS depression, coma, severe or acute resp insufficiency, sleep apnoea syndrome, myasthenia gravis, severe hepatic impairment. Childn <6 mth (oral).

#### PRECAUTIONS:

Patient w/ open angle glaucoma, chronic pulmonary insufficiency, muscle weakness, organic brain changes particularly arteriosclerosis, personality disorder, phobia or on obsessional state, chronic psychosis. Used in patient w/ depression or anxiety associated w/ depression esp those w/ suicidal or aggressive behaviour. History of drug and alcohol addiction. Avoid abrupt withdrawal. Renal and hepatic impairment. Elderly and debilitated patient. Pregnancy and lactation. Patient Counselling May impair ability to drive or operate machinery. May increase metabolism by smoking. Monitoring Parameters Monitor CV, resp and mental status.

# INTERACTIONS:

May significantly enhance CNS depressant effect w/ antivirals (e.g. amprenavir, ritonavir). May enhance CNS depressant effect w/ anaesth, narcotic analgesics, antidepressants, antipsychotics, anxiolytics, antiepileptics, antihistamines, antihypertensives, muscle relaxants (e.g. tizanidine, baclofen), nabilone. May decrease clearance w/ antibacterials that interfere w/ metabolism by hepatic enzymes (e.g. isoniazid and erythromycin), OC, cimetidine, omeprazole. May increase clearance w/ antibacterials which are known inducers of hepatic enzymes (e.g. rifampicin). May increase serum level w/ disulfiram. May reduce clearance of digoxin. May reduce therapeutic effect w/ theophylline. Reversible deterioration of parkinsonism w/ levodopa.

# ADVERSE REACTIONS:

Sedation, drowsiness, ataxia, muscle weakness, fatigue, confusion, depression, headache, vertigo, amnesia, paradoxical reactions (e.g. anxiety, hallucinations, insomnia, psychoses, sleep disturbances), visual disturbances, tremor, slurred speech or dysarthria, paradoxical excitation, resp depression, hypotension, changes in libido and

salivation, GI disturbances, urinary retention or incontinence; pain and thrombophlebitis (IV). Rarely, hypersensitivity, blood disorders, jaundice, increased liver enzyme values

# 85. DIVALPROEX SODIUM IP TABLET SALIENT ACTIONS:

This drug belongs to a class of drugs called anti-epileptics. A class of drugs refers to medications that work similarly. They have a similar chemical structure and are often used to treat similar conditions.

This drug works by increasing brain concentrations of a certain chemical, GABA, which reduces the excitability of your nervous system. This helps to treat seizures and manic episodes and prevent migraines.

#### INDICATIONS:

Divalproex sodium affects chemicals in the body that may be involved in causing seizures.

Divalproex sodium is used to treat various types of seizure disorders. Divalproex sodium is sometimes used together with other seizure medications.

Divalproex sodium is also used to treat manic episodes related to bipolar disorder (manic depression), and to prevent migraine headaches

#### DOSAGE REGIMENS:

The recommended initial dose is 15 mg/kg/day, increasing at one week intervals by 5 to 10 mg/kg/day until seizures are controlled or side effects preclude further increases. The maximum recommended dosage is 60 mg/kg/day. If the total daily dose exceeds 250 mg, it should be given in divided doses.

#### CONTRAINDICATIONS:

- · It should not be administered to patients with hepatic disease or significant hepatic dysfunction.
- It is contraindicated in patients known to have mitochondrial disorders caused by mutations
  in mitochondrial DNA polymerase γ (POLG; e.g., Alpers-Huttenlocher Syndrome) and children under two
  years of age who are suspected of having a POLG-related disorder
- It is contraindicated in patients with known hypersensitivity to the drug
- · It is contraindicated in patients with known urea cycle disorders
- It is contraindicated for use in prophylaxis of migraine headaches in pregnant women.

#### PRECAUTIONS

You should not use divalproex sodium if you are allergic to it, or if you have:

- liver disease;
- · a urea cycle disorder; or
- a genetic mitochondrial (MYE-toe-KON-dree-al) disorder such as Alpers' disease or Alpers-Huttenlocher syndrome, especially in a child younger than 2 years old.

Divalproex sodium can cause liver failure that may be fatal, especially in children under age 2 and in people with liver problems caused by a genetic mitochondrial disorder.

#### INTERACTIONS:

Drugs that affect the level of expression of hepatic enzymes, particularly those that elevate levels of glucuronosyltransferases (such as ritonavir), may increase the clearance of valproate. For example, phenytoin, carbamazepine, and phenobarbital (or primidone) can double the clearance of valproate. Thus, patients on monotherapy will generally have longer half-lives and higher concentrations than patients receiving polytherapy with antiepilepsy drugs.

In contrast, drugs that are inhibitors of cytochrome P450 isozymes, e.g., antidepressants, may be expected to have little effect on valproate clearance because cytochrome P450 microsomal mediated oxidation is a relatively minor secondary metabolic pathway compared to glucuronidation and beta-oxidation.

### ADVERSE EFFECTS:

signs of an allergic reaction: hives; fever, swollen glands, mouth sores, difficulty breathing; swelling of your face, lips, tongue, or throat

Diarrhea, dizziness, drowsiness, hair loss, blurred/double vision, change in menstrual periods, ringing in the ears, shakiness (tremor), unsteadiness, weight changes may occur.

# 86. DOMPERIDONE Tab 10 mg, Syrup 1mg/5ml, 3o ml bottle SALIENT ACTIONS:

Domperidone is a peripheral dopamine-receptor blocker. It increases oesophageal peristalsis, lower oesophageal sphincter pressure, gastric motility and peristalsis, thus facilitating gastric emptying and decreasing small bowel transit time.

#### INDICATIONS & DOSAGE REGIMENS:

- 1. Nausea and vomiting: Adult: 10-20 mg every 4-8 hr. Max: 80 mg/day.
- 2. Non ulcer dyspepsia: Adult: 10-20 mg tid and at night.
- 3. Migraine: Adult: 20 mg every 4 hr, in combination with paracetamol, as required.

#### CONTRAINDICATIONS:

Hypersensitivity. GI haemorrhage, obstruction and perforation, patients with prolactin releasing pituitary hormone, chronic admin or routine prophylaxis of postoperative nausea and vomiting.

#### PRECAUTIONS:

Phaeochromocytoma; children<2 yr, elderly; renal or hepatic impairment. Risk of cardiac arrhythmias and hypokalaemia if administered IV. Pregnancy and lactation.

#### INTERACTIONS:

Reduces absorption of digoxin. Increases absorption of aspirin, paracetamol and oral diazepam. Enhances CNS depression by phenothiazine. Antimuscarinic agents and opioids antagonise GI effects. May antagonise hypoprolactinaemic effect of drugs such as bromocriptine. Increased effects when used with CYP3A4 inhibitors such as erythromycin or ritonavir.

#### ADVERSE DRUG REACTIONS:

Drowsiness, extrapyramidal reactions, galactorrhoea, gynaecomastia; constipation or diarrhoea, lassitude, decreased libido, skin rash, itch. Potentially Fatal: Convulsions, arrhythmias and cardiac arrest, dysrrhythmias in patients with CV disease or hypokalaemia, patients on cancer chemotherapy. Seizures; hypertensive crisis in patients with phaeochromocytoma.

#### 87. DONEPEZIL TAB

# SALIENT ACTIONS:

Donepezil improves the function of nerve cells in the brain. It works by preventing the breakdown of a chemical called acetylcholine. People with dementia usually have lower levels of this chemical, which is important for the processes of memory, thinking, and reasoning.

#### INDICATIONS:

- It is used to treat dementia.
- It is used to treat Alzheimer's disease.

### DOSAGE REGIMENS:

Initial dose: 5 mg orally once a day, in the evening prior to retiring

Mild to moderate Alzheimer's disease:

-Maintenance dose: 10 mg orally once a day, after the patient has been on an initial dose of 5 mg once a day for 4 to 6 weeks

Moderate to severe Alzheimer's disease:

-Maintenance dose: 23 mg orally once a day, after the patient has been on a dose of 10 mg once a day for at least 3 months

#### CONTRAINDICATIONS:

Neuroleptic Malignant Syndrome, Atrioventricular Heart Block, Very Rapid Heartbeat - Torsades de Pointes, Sick Sinus Syndrome, Sinus Bradycardia, Asthma, Bronchi Muscle Spasm resulting from COPD, Stomach or Intestinal Ulcer, Bleeding of the Stomach or Intestines, Blockage of Urinary Bladder, rhabdomyolysis, seizures

## PRECAUTIONS:

This medicine may cause some people to become dizzy or drowsy, to have blurred vision, or to have problems with clumsiness or unsteadiness. Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are not alert, well-coordinated, and able to see clearly.

# INTERACTIONS:

- succinylcholine
- ketoconazole
- dimenhydrinate
- diphenhydramine
- hydroxyzine
- phenytoin
- carbamazepine
- phenobarbital
- · amitriptyline

- desipramine
- doxepin

## ADVERSE EFFECTS:

- severe vomiting;
- slow heartbeats;
- seizure (convulsions);
- painful or difficult urination;
- · new or worsening breathing problems; or

signs of stomach bleeding-severe heartburn or stomach pain, bloody or tarry stools, coughing up blood or vomit that looks like coffee grounds.

# 88. DOSULEPIN 50mg TAB

#### SALIENT ACTIONS:

Dosulepin and other antidepressants work by regulating the balance of neurotransmitter chemicals in the juncture between nerve cells. Imbalances in these substances, especially in serotonin, norepinephrine and dopamine are thought to cause mood and anxiety disorders. Dosulepin improves depression and anxiety by regulating the neurotransmitters, especially serotonin, dopamine and norepinephrine. It also affects other neurotransmitters, particular cholinergic substances. Many of the side effects of dosulepin are related to its anticholinergic actions.

#### INDICATIONS:

- · Dosulepin is used to treat depression.
- It is a tricyclic antidepressant, sometimes known as a mood elevator.
- It is used to relieve the symptoms of depression.
- In general this drug is used to improve mood and behaviour in people with depressive illness, particularly in those with anxiety. Dosulepin is also useful in treating people with depression where sleeping difficulties and loss of appetite are predominant symptoms.
- Benefits of being on this drug can include improved mood as assessed by various rating scales.

# DOSAGE REGIMENS:

- The effective dose of dosulepin varies widely between individuals. Most people start by taking 25 mg three times a day. The dose is gradually increased to 50 mg three times a day. It can also be taken as a single dose at bedtime. Some people may need up to 225 mg/day of dosulepin.
- Elderly people usually need a reduced dose. The usual daily dose for elderly people is 50-75 mg/day.

#### CONTRAINDICATIONS:

- Allergy
- Monoamine oxidase inhibitors (MAOI)
- Heart Attack
- Manic phase of bipolar disorder
- Liver disease

### PRECAUTIONS:

This medication should not be used if you have certain medical conditions.

- Known hypersensitivity (allergy) to dosulepin or any of the other ingredients in the medicine
- Severe liver disease
- Recently had a heart attack
- Decreased heart function due to problems with its electrical activity (heart block)
- Abnormal heart beat such as arrivthmias
- Mania

#### INTERACTIONS:

Monoamine oxidase inhibitors (MAOIs) used to treat depression or within two weeks of stopping treatment (e.g. isocarboxazid, moclobemide and phenelzine

# ADVERSE EFFECTS:

- · Dry mouth
- Drowsiness
- Blurred vision
- Constipation
- Nausea (feeling sick)
- Difficulty passing urine

- Feeling faint or dizzy on changing position (due to low blood pressure)
- Rapid heart beat

# 89. DOXOFYLLINE TAB

# SALIENT ACTIONS:

Doxofylline (also known as doxophylline) is a xanthine derivative drug used in the treatment of asthma.It has antitussive and bronchodilator [2] effects, and acts as a phosphodiesterase inhibitor.

# INDICATIONS:

Bronchial asthma & pulmonary disease w/ spastic bronchial component.

# DOSAGE REGIMENS:

Adult: 400mg once a day. Single dose administration in the evening reduces nocturnal symptoms and helps to keep the patients complaint free during the day. However, in certain cases 400mg twice daily is recommended on the basis of the clinical response.

Adult: PO- The recommended dose is up to 1,200 mg/day.

# CONTRAINDICATIONS:

Hypersensitivity

# PRECAUTIONS:

Information not available.

# INTERACTIONS:

Information not available.

# ADVERSE EFFECTS:

- Irritability
- Nausea
- Vomiting
- Insomnia
- Severe arrhythmias
- Seizure

# 90. DOXYCYCLINE Tab 100 mg

### SALIENT ACTIONS:

Doxycycline binds to 30S and 50S ribosomal subunits thus causing alterations on the cytoplasmic membrane of susceptible organisms.

# INDICATIONS & DOSAGE REGIMENS:

- 1. Susceptible infections: Adult: 200 mg on day 1 followed by 100 mg once daily. Maintain initial dose in severe infections.
- 2. Uncomplicated gonorrhea: Adult: 100 mg bid for 7 days or a single dose of 300 mg followed by another dose repeated 1 hr later.
- 3. Syphilis: Adult: 200 or 400 mg daily in divided doses for 10-15 days.
- 4. Relapsing fever and louse-borne typhus: Adult: 100 or 200 mg as a single dose.
- 5. Acne: Adult: 50 mg daily for 6-12 wk.

# CONTRAINDICATIONS:

Children <8 yr; pregnancy, lactation; porphyria; hypersensitivity to tetracyclines; severe hepatic dysfunction; prolonged exposure to sunlight or tanning equipment.

# PRECAUTIONS:

Impaired hepatic function; history or predisposition to oral candidiasis. Should be taken with at least a glass of water in an upright position to reduce the risk of oesophageal injury.

# INTERACTIONS:

Reduction in absorption and bioavailability when used with antacids, calcium, magnesium and iron. Chronic ethanol ingestion reduces serum concentrations. Metabolism increased by hepatic enzyme inducers such as rifampicin, phenytoin and carbamazepine. May reduce the efficacy of oral contraceptives.

# ADVERSE DRUG REACTIONS:

Permanent staining of teeth; rash, superinfection; nausea, GI upsets, glossitis; dysphagia; photosensitivity, hypersensitivity; haemolytic anaemia, thrombocytopenia, neutropenia and eosinophilia. Potentially Fatal: Anaphylaxis.

# 91. DOXYLAMINE SUCCINATE 10mg + PYRIDOXINE 10 mg Tab SALIENT ACTIONS:

Doxylamine is an antihistamine derived from monoethanolamine possessing antimuscarinic and pronounced sedative effects. Pyridoxine is a precursor of pyridoxal, which functions in the metabolism of carbohydrates, proteins and fats. It is essential in Hb formation and GABA synthesis within the CNS. It also aids in the release of glycogen stored in the liver and muscles.

# INDICATIONS & DOSAGE REGIMENS:

Pregnancy-associated nausea and vomiting: Each tab contains doxylamine 10 mg and pyridoxine 10 mg: 2 tab at bedtime. In severe cases or in cases with nausea/vomiting during the day: increase dosage by 1 tab in morning and/or afternoon.

## CONTRAINDICATIONS:

Severe liver disease; avoid alcohol; premature infants or full-term neonates.

#### PRECAUTIONS:

May impair ability to drive and operate machinery. Angle-closure glaucoma, urinary retention, prostatic hypertrophy or pyloroduodenal obstruction; epilepsy; hepatic impairment, elderly. Lactation.

#### INTERACTIONS:

Doxylamine enhances effects of CNS depressants eg alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and antipsychotics. Atropine, tricyclic antidepressants (TCAs), MAOIs. It can mask signs of ototoxicity caused by aminoglycosides. INH, penicillamine and OC require greater pyridoxine dose. Pyridoxine reduces the effects of levodopa, phenobarb and phenytoin.

# ADVERSE DRUG REACTIONS:

Acute dystonic reactions and long-lasting impaired consciousness in child. CNS depression including slight drowsiness to deep sleep, lassitude, dizziness, incoordination. Headache, psychomotor impairment and antimuscarinic effects. Rarely rashes and hypersensitivity reactions, blood disorders, convulsions, sweating, myalgia, extrapyramidal effects, tremor, confusion, tinnitus, hypotension, hair loss. Severe peripheral neuropathies with long-term admin of large doses of pyridoxine.

# 92. DROTAVERINE HCL 40MG TABLET

#### SALIENT ACTIONS:

Drotaverine is an effective medicine to treat spasm or twitches of the smooth muscles in the stomach and heart. It is used to relieve pain caused due to irritable bowel syndrome, headache, menstrual periods, and is also used to relieve cervical spasm during labor.

# INDICATIONS & DOSAGE REGIMENS:

As an antispasmodic

Adult: 40-80 mg tid.

Child: 1-6 yr: 20 mg 3-4 times daily; >6 yr: 40 mg tid.

# CONTRAINDICATIONS:

- Allergy
- Sever liver/kidney damage
- Heart Failure

#### PRECAUTIONS:

# Pregnancy

This medicine is not recommended for use by pregnant women unless necessary and the benefits outweigh the risks.

# Breast-feeding

This medicine is not recommended for use if you are breastfeeding as the risks of adverse effects on the infant are significantly high.

## INTERACTIONS:

- Atropine
- Diclofenac
- Levodopa
- Diazepam

## ADVERSE EFFECTS:

- · Nausea and Vomiting
- Dry mouth
- · Change in pulse rate

- Dizziness
- Headache
- Difficulty in breathing
- Allergic skin reaction
- · Swelling of face, lips, eyelids, tongue, hands and feet
- · Fall in blood pressure

# 93. DULOXETINE HCL 20MG CAP

### **SALIENT ACTIONS:**

Antidepressant

#### INDICATIONS:

- Major Depressive Disorder
- · Generalized Anxiety Disorder
- Diabetic Peripheral Neuropathy
- Fibromyalgia
- · Chronic Musculoskeletal Pain

#### DOSAGE REGIMENS:

Administer 60 mg once daily. Begin treatment at 30 mg for one week, to allow patients to adjust to the medication before increasing to 60 mg once daily.

#### CONTRAINDICATIONS:

- hypersens. to drug/class/compon.
- CrCl <30</li>
- hepatic impairment
- alcohol abuse

#### PRECAUTIONS:

- avoid abrupt withdrawal
- caution if concurrent CNS depressant use
- · caution if smoking habit changes
- caution in pts <25 yo</li>
- · caution in elderly pts
- · caution if pregnancy 3rd trimester
- caution if bleeding risk
- caution if hypomania or mania hx
- caution if GI motility disorder
- · caution if glaucoma, angle-closure
- caution if seizure hx
- caution if volume depletion
- caution if HTN

# INTERACTIONS:

- isocarboxazid
- linezolid
- methylene blue
- phenelzine
- procarbazine

#### ADVERSE EFFECTS:

- suicidality
- depression exacerbation
- hypomania/mania
- serotonin syndrome
- abnormal bleeding/altered platelet fxn
- anaphylaxis/anaphylactoid rxn
- Stevens-Johnson syndrome
- erythema multiforme
- glaucoma, angle-closure
- seizures
- nsomnia

- vomiting
- dizziness
- diarrhea
- diaphoresis
- erectile dysfxn
- agitation
- · oropharyngeal pain
- libido decr.
- blurred vision
- tremor

# 94. DYDROGESTERONE TABLET

## SALIENT ACTIONS:

Dydrogesterone has selective progestational activity and does not inhibit ovulation.<sup>[13]</sup> The greater rigidity of dydrogesterone also positively affects its selectivity, while natural progesterone is less selective, existing in different conformations that more easily bind to different receptors. As a consequence of its better bioavailability and the progestational activity of its main metabolites (20-, 21- and 16-hydroxy derivatives), the equivalent dose of dydrogesterone is 10–20 times lower than that of oral micronized progesterone.

#### INDICATIONS:

Dydrogesterone has proven effective in the following conditions associated with progesterone deficiency:[18]

• Infertility due to [19] luteal insufficiency [20]

Threatened miscarriage<sup>[21]</sup>

- Habitual or recurrent miscarriage. [22]
- Menstrual disorders<sup>[23]</sup>
- Premenstrual syndrome<sup>[24]</sup>
- Endometriosis<sup>[25]</sup>

Dydrogesterone has also been registered as hormone replacement therapy (HRT)<sup>[26]</sup> to counter-check the negative effects of unopposed estrogen on the endometrium in women with an intact uterus.

#### DOSAGE REGIMENS:

Drug dosage varies as per the medical condition.

- Painful menstruation and irregular menstrual periods: 10 mg twice daily from starting from the 5th day of the menstrual cycle to the 25th day.
- Endometriosis: 10 mg twice or thrice daily starting from the 5th day of the menstrual cycle to the 25th day.
- Dysfunctional bleeding/ unexpected bleeding:
- 10 mg twice daily for a week for stopping bleeding.
- 10 mg twice daily starting from the 11th day of the menstrual cycle to 25th day to prevent heavy bleeding.
- Secondary Amenorrhea: Should be given in combination with estrogen therapy. 10 mg twice daily starting from the 11th day of the menstrual cycle to the 25th day.
- Abortion: In case of threatened abortion, 40 mg immediately and then 10 mg doses repeated every 8 hours till remission.
- In case of habitual abortion, 10 mg once daily till 12th week of pregnancy.
- Infertility: 10 mg once daily from 14th day of menstrual cycle to 25th day.
- In post-menopausal conditions: Should be given in combination with estrogen therapy in a dose of 2.5 mg to 10 mg once daily as per the severity of the condition.

#### CONTRAINDICATIONS:

Contraindicated in patients with undiagnosed, abnormal vaginal bleeding, blood clot disorder, stroke, incomplete abortion, breast cancer, brain cancer, breastfeeding mothers, liver dysfunction, and hypersensitivity. The drug is contraindicated in children under age 18 years.

While the drug is useful in sustaining pregnancy in patients with recurrent abortion, the drug is contraindicated in pregnant patients who are not at any risk of abortion or in patients with advanced pregnancy.

# PRECAUTIONS:

Caution should be exercised in patients with a history of blood clot disorder, kidney impairment, heart disease, epilepsy, asthma, migraine, fluid retention, and breastfeeding. Monitor closely eye vision and symptoms of blood clot disorders.

It may cause dizziness, do not drive a car or operate machinery while taking this medication.

Should be used with extreme care in patient with a history of clinical depression.

#### INTERACTIONS:

In HRT, dydrogesterone is administered together with an estrogen. Therefore, the interaction between dydrogesterone and estrogens has been assessed, and no clinically significant interaction has been observed.

## ADVERSE EFFECTS:

- Pulsating headache which can develop into a migraine
- Pain in breast and breast tenderness
- Occasional blood spotting
- Pain during periods
- Irregular period
- Heavy bleeding during periods
- Missed period
- Weight gain
- Depression
- Abnormal liver function which can progress into jaundice Nausea and abdominal discomfort
- Hypersensitivity

# 95. EMPAGLIFLOZIN TABLET

SALIENT ACTIONS: Empagliflozin is used along with diet and exercise, and sometimes with other medications, to lower blood sugar levels in patients with type 2 diabetes (condition in which blood sugar is too high because the body does not produce or use insulin normally). It is in a class of medications called sodiumglucose co-transporter 2 (SGLT2) inhibitors. Empagliflozin lowers blood sugar by causing the kidneys to get rid of more glucose in the urine. It is not used to treat type 1 diabetes (condition in which the body does not produce insulin and, therefore, cannot control the amount of sugar in the blood) or diabetic ketoacidosis (a serious condition that may develop if high blood sugar is not treated).

#### INDICATIONS:

- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus,
- to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.

## DOSAGE REGIMENS:

The recommended dose is 10 mg once daily in the morning, taken with or without food. In patients tolerating this drug, the dose may be increased to 25 mg

# CONTRAINDICATIONS:

- kidney disease (or if you are on dialysis); or
- diabetic ketoacidosis

#### PRECAUTIONS:

- Hypotension
- Acute Kidney Injury And Impairment In Renal Function
- Genital Mycotic Infections

# INTERACTIONS:

- insulin Or Insulin Secretagogues
- diuretics

# ADVERSE EFFECTS:

- urinating a lot, including at night
- increased thirst
- frequent, urgent, burning, or painful urination
- urine that is cloudy
- pelvic or back pain
- (in women) vaginal odor, white or yellowish vaginal discharge (may be lumpy or look like cottage cheese), or vaginal itching
- (in men) redness, itching, or swelling of the penis; rash on the penis; foul smelling discharge from the penis; or pain in the skin around the penis
- flu-like symptoms
- dry mouth, nausea and vomiting, stomach pain, unusual fatigue or tiredness, difficulty breathing, breath that smells fruity, decreased consciousness or confusion

# 96. ENALAPRIL MALEATE Tab 5 mg

#### SALIENT ACTIONS:

Enalapril is de-esterified into the active enalaprilat resulting in potent inhibition of ACE thus leading to reduced levels of angiotensin II and aldosterone. Clinically, BP is reduced, salt and water retention is corrected. Ventricular hypertrophy is reversed. Renal blood flow is increased but in patients with renal impairment there may be oliguria or acute renal failure.

#### INDICATIONS & DOSAGE REGIMENS:

- 1. Hypertension: Adult: Initially, 5 mg at bedtime. Maintenance: 10-20 mg once daily increased up to 40 mg in divided doses in severe hypertension. Max: 40 mg/day.
- 2. Heart failure: Adult: Initially, 2.5 mg daily. Maintenance: 20 mg once daily as a single or in 2 divided doses, up to 40 mg daily in 2 divided doses.

### CONTRAINDICATIONS:

Hypersensitivity. History of angioedema due to previous treatment with ACE inhibitors; bilateral renal artery stenosis. Pregnancy.

# PRECAUTIONS:

Impaired renal function. Hyperkalaemia, hypovolaemia, collagen vascular disease, valvular stenosis, during or immediately before or after anaesthesia, unilateral renal artery stenosis. Hypotension due to volume depletion, diuretic therapy. Monitor WBC count. Lactation, children.

#### INTERACTIONS:

Diuretics potentiate hypotensive action. May increase lithium levels. Other antihypertensives potentiate enalapril action. Potentially Fatal: Increased risk of bone marrow suppression when used with immunosuppressive drugs. Hyperkalaemia with potassium-sparing diuretics or potassium supplements especially in the presence of renal failure. Probenecid delays excretion. Potentiates analgesia and respiratory depression produced by morphine. NSAIDs may result in further deterioration of renal function.

## ADVERSE DRUG REACTIONS:

Initial hypotension may be severe and prolonged. Dizziness, headache, fatigue, persistent dry cough, abnormal taste, lassitude, rash, neutropenia, renal impairment or failure. Potentially Fatal: Angioedema.

#### 97. EPLERENONE 25MG TABLET

#### SALIENT ACTIONS:

Eplerenone binds to the mineralocorticoid receptor and blocks the binding of aldosterone, a component of the renin-angiotensin-aldosterone-system (RAAS). Aldosterone synthesis, which occurs primarily in the adrenal gland, is modulated by multiple factors, including angiotensin II and non-RAAS mediators such as adrenocorticotropic hormone (ACTH) and potassium. Aldosterone binds to mineralocorticoid receptors in both epithelial (e.g., kidney) and nonepithelial (e.g., heart, blood vessels, and brain) tissues and increases blood pressure through induction of sodium reabsorption and possibly other mechanisms.

#### INDICATIONS:

Congestive Heart Failure Post-Myocardial Infarction

It is indicated to improve survival of stable patients with left ventricular (LV) systolic dysfunction (ejection fraction ≤ 40%) and clinical evidence of congestive heart failure (CHF) after anacute myocardial infarction (MI).

#### Hypertension

It is indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular (CV) events, primarily strokes and MI.

## **DOSAGE REGIMENS:**

Eplerenone is usually administered together with other medication for heart failure e.g. beta blockers. The usual starting dose is one 25 mg tablet once daily, increasing after about 4 weeks to 50 mg once daily (either as one 50 mg tablet or two 25 mg tablets). The maximum dose regimen is 50 mg daily.

#### CONTRAINDICATIONS:

- serum potassium > 5.5 mEq/L at initiation,
- creatinine clearance ≤ 30 mL/min, or
- concomitant administration of strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir, and nelfinavir)

#### PRECAUTIONS:

Hyperkalemia

The risk of hyperkalemia is higher in patients with impaired renal function, proteinuria, diabetes and those concomitantly treated with ACEs, ARBs, NSAIDs and moderate CYP3A inhibitors. Minimize the risk of hyperkalemia with proper patient selection and monitoring.

## INTERACTIONS:

- CYP3A Inhibitors
- ACE Inhibitors And Angiotensin II Receptor Antagonists
- Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)
- Lithium

## ADVERSE EFFECTS:

- · swollen face, tongue or throat
- · difficulty swallowing
- · hives and difficulties breathing
- · elevated potassium level in your blood (symptoms include muscle cramps, diarrhoea, nausea, dizziness or headache)
- · dizziness
- fainting
- · infection
- · cough
- · constipation

# 98. ERYTHROMYCIN Tab 250 mg / 500 mg

# SALIENT ACTIONS:

Erythromycin inhibits protein synthesis by irreversibly binding to the 50S ribosomal subunit thus blocking the transpeptidation or translocation reactions of susceptible organisms resulting in stunted cell growth.

# INDICATIONS & DOSAGE REGIMENS:

- 1. Susceptible infections 2. Severe campylobacter enteritis 3. Pertussis 4. Trench fever 5. Chanroid
- 6. Chlamydial infections 7. Diphtheria 8. Legionnaire's disease 9. Pneumonia 10. Sinusitis 11. Bronchitis Adult: 1-2 g daily, increased up to 4 g daily for severe infections. Doses >1 g should be given in more than 2 divided doses.
- 12. Acne: Adult: Maintenance: 250 mg daily. Severe cases may require up to 500 mg bid.
- 13. Prophylaxis against pneumococcal infections: Adult: For patients who are unable to take penicillins or sulfonamides: 250 mg bid.
- 14. Prophylaxis of streptococcal infections in patients with evidence of rheumatic fever or heart disease Adult: For patients who are unable to take penicillins or sulfonamides: 250 mg bid.

# CONTRAINDICATIONS:

Hypersensitivity; porphyria; hepatic impairment; pregnancy.

# PRECAUTIONS:

Increased risk of cholestatic hepatitis when treatment is >10 days or in patients with previous history of erythromycin usage. History of hepatic disorders; arrhythmias; prolonged QT interval; lactation. Monitor liver function. Avoid estolate in liver impairment. Caution when using lactobionate in patients with severe renal impairment. May aggravate muscle weakness in patients with myasthenia gravis.

# INTERACTIONS:

May antagonise therapeutic effects lincomycin and clindamycin. Concurrent usage may lead to increased absorption of alcohol. Potentially Fatal: May potentiate actions of neuromuscular blockers, oral anticoagulants, ciclosporin, theophylline. Terfenadine, astemizole, cisapride toxicity increased.

# ADVERSE DRUG REACTIONS:

Rash, urticaria; nausea, vomiting, GI discomfort; ototoxicity; central neurotoxicity; agranulocytosis; arrhythmias; pancreatitis. Potentially Fatal: Hepatotoxicity, cholestatic jaundice; raised serum transaminases; eosinophilia.

# 99. ESCITALOPRAM OXALATE Tab 10 mg SALIENT ACTIONS:

Escitalopram selectively inhibits CNS neuronal re-uptake of serotonin (5-HT) and potentiates serotonergic activity. It has minimal effects on norepinephrine and dopamine neuronal re-uptake. Onset: 1-2 wk.

# INDICATIONS & DOSAGE REGIMENS:

1. Depression 2. Obsessive compulsive disorder 3. Anxiety

Adult: 10 mg once daily, increased if necessary. Max: 20 mg daily.

4. Panic disorder

Adult: Initially, 5 mg daily, increased to 10 mg daily after 7 days. Max: 20 mg daily.

#### CONTRAINDICATIONS:

Concomitant use with or within 2 wk of MAOI withdrawal. Special Precautions History of mania or seizure disorders; work requiring mental alertness; renal and hepatic impairment; pregnancy, lactation; withdraw gradually. Children and adolescents <18 yr

#### INTERACTIONS:

Increased risk of bleeding when used with aspirin, NSAIDs or drugs that affect coagulation. Serum levels may be reduced by CYP2C19 inducers (e.g. carbamazepine, rifampin, phenytoin) or CYP3A4 inducers (e.g. nafcillin, nevirapine). Serum levels may also be increased by CYP2C19 inhibitors (e.g. fluconazole, fluvoxamine, omeprazole) or CYP3A4 inhibitors (e.g. azole antifungals, clarithromycin). May increase serum levels of desipramine or metoprolol. Increased risk of serotonin syndrome when used with linezolid or sibutramine. Escitalopram may enhance the sedative effects of alcohol.

#### ADVERSE DRUG REACTIONS:

Nausea, diarrhoea, increased sweating, insomnia, impotence, ejaculation disorder, fatigue, somnolence; postural hypotension, sinusitis, taste disturbances. Increased appetite and wt gain.

#### 100. ETHAMSYLATE BP TAB 250MG

#### **SALIENT ACTIONS:**

Ethamsylate Injection is a medicine that is used for the treatment of Blood In Urine, Abnormal Bleeding From The Womb, Excessive Blood Loss During Periods In Women, Post-Abortion Bleeding, Postpartum Bleeding, Vomiting Of Blood and other conditions.

#### INDICATIONS:

Ethamsylate Injection is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms:

- Blood In Urine
- · Abnormal Bleeding From The Womb
- Excessive Blood Loss During Periods In Women
- Post-Abortion Bleeding
- Postpartum Bleeding
- Vomiting Of Blood
- Upper Gastrointestinal Bleeding
- Blood-Stained Mucus

# DOSAGE REGIMENS:

Adult: PO- Menorrhagia- The recommended dose is 500 mg 4 times/day during menstruation. Control of hemorrhage after surgery- The recommended dose is 250-500 mg 4-6 hourly as needed.

#### CONTRAINDICATIONS:

Contraindicated in patients with known hypersensitivity and porphyria (a blood disorder).

#### PRECAUTIONS:

Caution should be exercised in patients with history of coeliac disease, during pregnancy and breastfeeding.

#### INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

- Headache
- Allergic Rejection
- Nausea
- Skin Rash
- Vomiting
- Fever

# 101. ETHAMBUTOL Tab 400 mg / 800 mg

#### SALIENT ACTIONS:

Ethambutol interferes with RNA synthesis, causing suppression of Mycobacteria multiplication. It also has bacteriostatic action against M tuberculosis by acting on rapidly growing pathogens in cavity walls and is also

effective in slow-growing pathogens. Has some action against atypical opportunistic Mycobacteria e.g. M kansasii, M avium complex (MAC).

## **INDICATIONS & DOSAGE REGIMENS:**

1. Primary treatment of pulmonary and extrapulmonary tuberculosis

Adult: As hydrochloride: Initial 8 wk: 15 mg/kg/day or 30 mg/kg thrice wkly given with isoniazid, rifampicin and pyrazinamide. Child: For treatment of drug-resistant tuberculosis: 15-25 mg/kg daily or 50 mg/kg twice wkly. For congenitally acquired tuberculosis: Neonates: 15 mg/kg once daily and ≥1 mth: 15 mg/kg once daily or 30 mg/kg 3 times wkly for 2 mth initial treatment phase.

#### CONTRAINDICATIONS:

Hypersensitivity; optic neuritis. Lactation.

## PRECAUTIONS:

Impaired pre-treatment visual acuity, elderly, children. Perform liver, kidney and visual acuity tests regularly. Caution when assessing visual acuity in patients with cataracts, DM, recurrent eye inflammation to make sure that changes are not due to the underlying causes.

#### INTERACTIONS:

Absorption delayed or reduced by aluminum hydroxide. Synergistic effect with other antitubercular agents.

### ADVERSE DRUG REACTIONS:

Retrobulbar neuritis with a reduction in visual acuity, constriction of visual field, central or peripheral scotoma and green-red colour blindness. Retinal haemorrhage (rare); reduced renal clearance of urates (acute gout); GI disturbances eg, nausea, vomiting, abdominal pain, anorexia; rash, headache, dizziness, confusion, hallucinations, malaise, jaundice; thrombocytopenia; pulmonary infiltrates.

### 102. ETIZOLAM TAB 0.25MG

#### SALIENT ACTIONS:

Etizolam is an effective anti-anxiety medicine that is similar to benzodiazepine class of medicines. It is used for the management of anxiety and short-term treatment of insomnia (sleeplessness).

#### INDICATIONS:

- Anxiety
- Insomnia

# DOSAGE REGIMENS:

Adult: PO- The recommended dose is up to 3 mg/day.

#### CONTRAINDICATIONS:

- Myasthenia gravis
- Narrow angle glaucoma
- Porphyria
- Allergy

#### PRECAUTIONS:

- Caution should be exercised in patients with history of lung insufficiency, muscle weakness, impaired liver
  or kidney function, alcoholism or drug addiction, elderly, during pregnancy and breastfeeding.
- It may cause dizziness or drowsiness, do not drive a car or operate machinery while taking this medication.

#### INTERACTIONS:

- Cetirizine
- Cisapride
- Clozapine
- Ketoconazole
- Metoclopramide
- Morphine
- Disulfiram
- Clonidine

#### ADVERSE EFFECTS:

- Most Common: Drowsiness, sedation, muscle weakness and incoordination.
- Central Nervous System: Fainting, headache, confusion, depression, slurred speech, changes in libido and tremor.
- Miscellaneous: Visual disturbances, urinary retention or incontinence, gastrointestinal disturbances, changes in salivation and memory loss.

# 103. ETODOLAC 200MG TABLET SALIENT ACTIONS:

Etodolac is used to relieve pain from various conditions. It also reduces pain, swelling, and joint stiffness from arthritis. This medication is known as a nonsteroidal anti-inflammatory drug (NSAID). It works by blocking your body's production of certain natural substances that cause inflammation.

#### INDICATIONS:

- For acute and long-term use in the management of signs and symptoms of the following:
- 1. Osteoarthritis
- 2. Rheumatoid arthritis
- For the management of acute pain

## DOSAGE REGIMENS:

The recommended total daily dose of etodolac capsules for acute pain is up to 1000 mg, given as 200 to 400 mg every 6 to 8 hours.

The recommended starting dose of etodolac capsules for the management of the signs and symptoms of osteoarthritis or rheumatoid arthritis is: 300 mg b.i.d., t.i.d., or 400 mg b.i.d., or 500 mg b.i.d. A lower dose of 600 mg/day may suffice for long-term administration.

## CONTRAINDICATIONS:

Etodolac capsules are contraindicated in patients with known hypersensitivity to etodolac.

# PRECAUTIONS:

N/A

#### INTERACTIONS:

NSAIDs may diminish the antihypertensive effect of ACE-inhibitors.

#### ADVERSE EFFECTS:

Gastrointestinal experiences including: abdominal pain, constipation, diarrhea, dyspepsia, flatulence, gross bleeding/perforation, heartburn, nausea, GI ulcers (gastric/duodenal), vomiting.

Other events including: abnormal renal function, anemia, dizziness, edema, elevated liver enzymes, headaches, increased bleeding time, pruritis, rashes, tinnitus.

# 104. ETOPHYLLINE11 5 mg / 77 mg & THEOPHYLINE 35 mg /23 mg Tab SALIENT ACTIONS:

It inhibits phosphodiesterase, which degrades cyclic nucleotides, hence increased amount of intra cellular CAMP molecules causing smooth muscle relaxation.

Blockade of adenosine receptors (which enhance release of histamine and other inflammatory mediator and bronchospasm). Overall effect of the drug is to produce: Bronchodilation by bronchial muscle relaxation, Suppression of response of airways to stimuli, Cardiac stimulation (increases heart rate and cardiac output), and Respiratory stimulation. It also induces diuresis.

## INDICATIONS & DOSAGE REGIMENS:

- 1. Treatment of acute attacks or status asthamticus in conjunction with other drugs.
- 2. Suppression of attacks in chronic asthma.
- 3. Relief of dyspnoea, bronchospasm in other respiratory disorders like COPD, emphysema.
- 4. Acute left ventricular failure and pulmonary edema. Adults 400 1600 mg/day in 2 –3 divided doses. Children 3 –4 mg/kg/dose.

## CONTRAINDICATIONS:

Hypersensitivity, Uncontrolled arrhythmias, Hyperthyroidism, Active peptic ulcer, Uncontrolled seizure disorders, Porphyria.

# DRUG INTERACTIONS:

Potentially fatal: The drugs increasing theophylline levels by inhibiting cyto. P450 and cause toxicity of theophylline - Ciprofloxacin, erythromycin, clarithromycin, fluconazole, ketoconazole, Disulfiram, estrogen containing OCPs, pentoxphylline, ticlopidine, methotrexate, propofenone, diltiazem, and verapmil, Allopurinol, fluvoxamine, Halothane sensitizes the myocardium to catecholamines which are released by the phylline (hence risk of arrhythmias).

Non fatal: Drugs which increase theophylline clearance (by cytochrome P450 induction) - carbamazepine, phenytoin, phenobarbitone, rifampicin and alcohol and hence an increase in dose is required. Theophylline increases lithium excretion. Theophylline may antagonize non-polarizing relaxants. Propranolol antagonizes the effects of theophylline by beta-receptors blockade. Risk of hypokalemia if given with salbutamol, terbutaline.

#### ADVERSE EFFECTS:

GIT disturbances-Nausea, vomiting, abdominal pain diarrhoea and GI bleeding. CNS effects – insomnia, headache, and restlessness, Seizures. Palpitation, dieresis, Worsening of breathing problems, Tachycardia, arrhythmias. Signs of an allergic reaction - unexplained rash, hives, itching, unexplained swelling, wheezing, or difficulty breathing or swallowing.

# 105. ETORICOXIB Tab 90 mg / 120 mg

#### SALINET ACTIONS:

Etoricoxib selectively inhibits cyclooxygenase 2 (COX-2) enzymes.

# **INDICATION & DOSAGE REGIMENS:**

- 1. Osteoarthritis Adult: 60 mg OD.
- 2. Rheumatoid arthritis Adult: 90 mg OD
- Acute gout Adult: 120 mg OD. Max duration: 8 days.
   Special Populations: Patients with mild hepatic impairment: 60 mg once daily. Moderate hepatic impairment: 60 mg every other day. Avoid in severe hepatic impairment.

#### CONTRAINDICATION:

Inflammatory bowel disease, severe congestive heart failure, active peptic ulceration, cerebrovascular disease, CrCL <30 ml/min; lactation. Children and adolescent < 16 yr.

#### PRECAUTION.

Allergic disorders, coagulation defects; history of cardiac failure, left ventricular dysfunction, hypertension, or in patients with oedema due to other reasons; elderly, renal, cardiac or hepatic impairment. Withdraw treatment if GI lesions develop; Caution when admin to dehydrated patients. Regular BP monitoring advisable. May mask fever and other signs of infection. Pregnancy.

#### INTERACTION:

CYP3A4 inhibitors or inducers; rifampicin, ethinyloestradiol; oral salbutamol and minoxidil. Antidepressant SSRIs and venlafaxine increase risk of bleeding. Increase side effect with concomitant use of aspirin, ciclosporin, ketorolac or other NSAIDs, Lithium, methotrexate, coumarins, phenindione, phenytoin and sulphonylureas.

#### ADVERS EFFECT:

GI disorders; ischemic cardiac events; hypersensitivity reactions, headache, dizziness, nervousness, depression, drowsiness, insomnia, vertigo, tinnitus, photosensitivity; blood disorders, fluid retention, hypertension; dry mouth, taste disturbance, mouth ulcers; appetite and wt changes; chest pain, fatigue, paraesthesia, influenza-like syndrome, myalgia, Renal toxicity.

# 106. FEBUXOSTAT 40MG TAB

**SALIENT ACTIONS:**Febuxostatis used to lower uric acid levels in people with gout. Febuxostat works by reducing the amount of uric acid made by the body.

#### INDICATIONS:

Febuxostat is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout.

# DOSAGE REGIMENS:

The recommended starting dose of febuxostat is 40 mg once daily. For patients who do not achieve a serum uric acid (sUA) less than 6 mg/dL after two weeks with 40 mg, Febuxostat 80 mg is recommended.

## CONTRAINDICATIONS:

It is contraindicated in patients being treated with azathioprine or mercaptopurine

# PRECAUTIONS:

After initiation of Febuxostat, an increase in gout flares is frequently observed. This increase is due to reduction in serum uric acid levels, resulting in mobilization of urate from tissue deposits.

In order to prevent gout flares when Febuxostat is initiated, concurrent prophylactic treatment with an NSAID or colchicine is recommended

#### INTERACTIONS:

febuxostat altered the metabolism of theophylline (a substrate of XO) in humans

## ADVERSE EFFECTS:

- · chest pain or heavy feeling, pain spreading to the arm or shoulder, nausea, sweating, general ill feeling;
- sudden numbness or weakness, especially on one side of the body;
- · sudden headache, confusion, problems with vision, speech, or balance; or

nausea, stomach pain, low fever, loss of appetite, dark urine, clay-colored stools, jaundice

# 107. FERROUS FUMARATE 200 mg + FOLIC ACID 0.3 mg + VITAMIN B12 1 mcg + ZINC SULFATE 61.8 mg Tab

## SALIENT ACTIONS:

They are used together in pregnant women (2nd and 3rd trimesters) for the prevention of iron deficiency and megaloblastic anaemia of pregnancy.

#### INDICATIONS:

Prophylaxis of iron deficiency in pregnancy.

DOSAGE REGIMENS: For pregnant women from 13th wk of gestation onwards: 1 tablet daily.

#### CONTRAINDICATIONS:

Paroxysmal nocturnal haemoglobinuria, haemosiderosis, haemochromatosis.

# PRECAUTIONS:

Avoid use in patients with active peptic ulcer, repeated blood transfusion, regional enteritis and ulcerative colitis. Caution when used in patients with folate-dependent tumours. Not recommended for use during 1st trimester of pregnancy.

### INTERACTIONS:

Concurrent admin may reduce the efficacy of fluoroquinolones, levodopa, carbidopa, thyroxine and bisphosphonates. Iron may reduce the absorption of penicillamine by forming complexes. Concurrent admin with tetracycline may lead to reduced absorption of tetracycline and iron. Antacids may reduce the absorption of iron. Serum levels of anticonvulsants may be reduced by folic acid.

#### ADVERSE EFFECTS:

GI discomfort, anorexia, nausea, vomiting, constipation, diarrhoea. Stool darkening may occur.

# 108. FEXOFENADINE Tab 120 mg/ 180 mg SALIENT ACTIONS:

Fexofenadine, an active metabolite of terfenadine, is a competitive peripheral histamine H<sub>1</sub>-receptor antagonist on effector cells in the GI tract, blood vessels and respiratory tract.

#### INDICATIONS & DOSAGE REGIMENS:

- 1. Seasonal allergic rhinitis: Adult: 120 mg once daily. Child: 6-11 yr: 30 mg bid.
- 2. Chronic idiopathic urticaria :Adult: 180 mg once daily. Child: 6 mth-<2 yr: 15 mg bid; ≥2 yr: 30 mg bid. Renal impairment: Adult: Initially, 60 mg once daily. Child: 6 mth-<2 yr: 15 mg once daily and 2-11 yr: 30 mg once daily.

#### CONTRAINDICATION:

Hypersensitivity.

#### PRECAUTIONS:

Pregnancy Category (US FDA): C Special: Renal impairment. Pregnancy, lactation; children <6 yr.

#### INTERACTIONS:

Ketoconazole or erythromycin increase plasma levels of fexofenadine. Avoid concurrent usage of anticholinergics and CNS depressants. Increase arrhythmogenic effect of antipsychotic agents (phenothiazines). Bioavailability increased by Verapamil. Efficacy may be reduced by rifampin.

### ADVERSE EFFECTS:

Viral infection (cold/flu); headache, dizziness, drowsiness, fatigue; nausea, dyspepsia, dysmenorrhea.

# 109. FINASTERIDE IP 1 MG TABLET

### SALIENT ACTIONS:

This medication works by decreasing the amount of a natural body hormone (DHT). Decreasing the amount of DHT leads to increased hair regrowth and slower hair loss. Hair growth on other parts of the body is not affected by finasteride.

#### INDICATIONS:

This medication is used to treat male pattern baldness(androgenetic alopecia) at the crown and in the middle of the scalp. It should be used by adult men only.

#### **DOSAGE REGIMENS:**

The recommended dosage is 1 mg orally once a day.

#### CONTRAINDICATIONS:

Known allergy of finasteride.

#### PRECAUTIONS:

should never be taken by a woman or a child.

## INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

Decreased sexual ability/desire may occur

temporary impotence (whilst continuing on treatment) erectile dysfunction and low libido.

Less common side effects include breast tenderness and enlargement (gynecomastia) and itchy skin rash.

# 110. FLAVOXATE HCL 200 MG TABLET

## SALIENT ACTIONS:

Flavoxate is a smooth-muscle relaxant. It works by relaxing the muscles in the bladder. Flavoxate helps to reduce leaking of urine, feelings of needing to urinate right away, frequent trips to the bathroom, and bladder pain.

# INDICATIONS:

flavoxate HCL is indicated for symptomatic relief of dysuria, urgency, nocturia, suprapubic pain, frequency and incontinence as may occur in cystitis, prostatitis, urethritis, urethrocystitis/urethrotrigonitis.

### DOSAGE REGIMENS:

Adults and children over 12 years of age

One or two 100 mg tablets 3 or 4 times a day. With improvement of symptoms, the dose may be reduced.

#### CONTRAINDICATIONS:

stomach/intestinal blockage (e.g., pyloric/duodenal obstruction, ileus), bleeding from the stomach or intestines, bladder blockage.

## PRECAUTIONS:

It should be given cautiously in patients with suspected glaucoma

## INTERACTIONS:

anticholinergic drugs (e.g., atropine, belladonna alkaloids,

scopolamine, benztropine, trihexyphenidyl), antispasmodic drugs (e.g., clidinium, dicyclomine), bisphosphonate drugs (e.g., alendronate, etidronate, risedronate), potassium tablets/capsules.

#### ADVERSE EFFECTS:

Nausea, vomiting, dry mouth, headache, drowsiness, dizziness, blurred vision, and nervousness may occur.

# 111. FLUCONAZOLE Tab 150 mg

#### SALIENT ACTIONS:

Fluconazole decreases ergosterol synthesis by interfering with cytochrome P450 activity, thus inhibiting cell membrane formation of susceptible fungi including B dermatitidis, Candida spp, C immitis, C neoformans, Epidermophyton spp, H capsulatum, Mycosporum spp, Trichophyton spp, thus leading to cell death.

# INDICATION & DOSAGE REGIMENS:

- Superficial mucosal candidiasis: adult: (except genital candidiasis) usual dose: 50 mg to 100 mg daily if needed, 7-14 days (oropharyngeal candidiasis, except in severely immunocompromised patients), 14 days (atrophic oral candidiasis associated with dentures), 14-30 days (other mucosal candidiasis including oesophagitis).child: >4 wk: loading dose: 6 mg/kg followed by 3 mg/kg daily.
- 2. vaginal candidiasis, candidal balanitis: adult: 150 mg as a single dose.
- 3. Dermatophytosis, pityriasis versicolor, cutaneous candidiasis: adult: 50 mg daily for up to 6 wk.
- 4. Systemic candidiasis, cryptococcal infections: adult: 400 mg followed by 200-400 mg daily. Max: 800 mg daily in severe infections. ,at least 6-8 wk in cryptococcal meningitis.
- 5. To prevent relapse after a primary course of treatment for acute cryptococcal: meningitis in aids patients: 100-200 mg daily, child: >4 wk: 6-12 mg/kg daily; same doses may given every 72 hr in neonates up to 2 wk and every 48 hr in neonates 2-4 wk. Max: 400 mg daily.
- 6. Prophylaxis of fungal infections in immunocompromised patients: adult: 50-400 mg daily. Child: 3-12 mg/kg daily; for infants <2 wk, doses should be given every 72 hr; 2-4 wk, doses should be given every 48 hr. Max: 400 mg daily, or 12 mg/kg at recommended intervals in infants.

Renal impairment: Normal initial doses; adjust subsequent doses based on CrCl. Patients on dialysis: Single recommended dose after each session.

#### PRECAUTIONS:

Renal or hepatic impairment. May prolong QT interval. Pregnancy, lactation.

### INTERACTIONS:

Rifampicin reduces fluconazole levels. Reduces theophylline clearance. Affects efficacy of oral contraceptives. Increase serum levels of alprazolam, triazolam, midazolam, diazepam. Raise serum concentrations and efficacy of oral sulphonylureas, phenytoin, ciclosporin, calcium channel blockers, tacrolimus, warfarin, HMG-CoA reductase inhibitors (except pravastain and fluvastatin). Reduced metabolism of caffeine. Avoid concurrent use with clopidogrel. Potentially Fatal: Increased risk of cardiac arrhythmias with astemizole, cisapiride or terfenadine.

#### ADVERSE EFFECTS:

Nausea, abdominal pain, vomiting, diarrhoea, flatulence; elevated LFT; headache; rash, exfoliative dermatitis, Angioedema, anaphylactic reactions & thrombocytopenia. *Potentially Fatal:* Hepatotoxicity; rarely anaphylaxis; Stevens-Johnson syndrome.

#### 112. FLUNARIZINE TAB 10MG

#### SALIENT ACTIONS:

Flunarizine is a non-selective calcium antagonist with moderate other actions including antihistamine, serotonin receptor blocking and dopamine  $D_2$  blocking activity.

#### INDICATIONS:

Migraine prophylaxis; Prophylaxis of peripheral and cerebrovascular disorders; Prophylaxis of vertigo and vestibular disorders

#### DOSAGE REGIMENS:

5-10 mg/day at bedtime.

#### CONTRAINDICATIONS:

Flunarizine is contraindicated in patients with depression, in the acute phase of a stroke, and in patients with extrapyramidal symptomsor Parkinson's disease. [4] It is also contraindicated in hypotension, heart failure and arrhythmia.

#### PRECAUTIONS:

Avoid the use of alcohol while taking this medication since excessive drowsiness can occur. This medication should be used only if clearly needed during pregnancy or while breast-feeding.

## INTERACTIONS:

The effects of other sedating drugs and alcohol, as well as antihypertensives, can be increased.

## ADVERSE EFFECTS:

Drowsiness, weight gain, nausea, heartburn, dry mouth or anxiety

## 113. FLUOXETINE Tab 20 mg

#### SALIENT ACTIONS:

Fluoxetine is a potent and highly selective serotonin (5-HT) re-uptake inhibitor. No affinity for adrenoceptors or histamine, GABA-B, or muscarinic receptors.

#### INDICATIONS & DOSAGE REGIMENS:

1.Depression: Adult: 20-40 mg daily. Max: 80 mg daily. Child: 8-18 yr: 10-20 mg daily. Elderly: 10 mg daily, increase by 10-20 mg.2. Bulimia nervosa Adult: 60 mg daily.3. Obsessive compulsive disorder: Adult: 20 mg daily increased up to 60 mg daily unresponsive. Max: 80 mg daily. Children. 10-60 mg daily.4. Premenstrual dysphoric disorder: Adult: 20 mg daily continuously, or 20 mg daily, to be started 14 days before onset of menstruation and continue until 1st day of menses., repeat with each cycle.5. Panic disorder: Adult: 10 mg daily, Increase to 20 mg to 60 mg daily after a few wk.

## CONTRAINDICATIONS:

Severe renal or hepatic failure; hypersensitivity; lactation; concomitant MAOIs or within 2 wk of MAOI withdrawal.

#### PRECAUTIONS:

Unstable epilepsy, liver and renal impairment, cardiac disease, diabetes, electroconvulsive therapy, bleeding disorders, closed-angle glaucoma; pregnancy. May impair performace of skilled tasks; withdraw gradually. Close monitoring of clinical worsening and behavioural changes during the 1st few mth of treatment or when there are dose changes.

#### INTERACTIONS:

Increase plasma concentration by tightly protein bound drugs e.g. warfarin and digoxin. Prolonged  $T_{1/2}$  of

diazepam. Avoid use with clopidogrel.

Potentially Fatal: Serious reactions with MAOIs; at least 14 days should elapse after MAOIs withdrawal before starting fluoxetine treatment or at least 5 wk should elapse after fluoxetine treatment before starting MAOIs therapy. Two-fold increase in plasma levels of other antidepressants when combined with fluoxetine. Monitor lithium levels when combined.

#### ADVERSE EFFECTS:

Nervousness, insomnia, anxiety, headache, tremor, drowsiness, dry mouth, nausea, vomiting, sweating, diarrhoea. Seizures, mania, hypomania or mixed manic states reported. Hyponatremia; elevated hepatic enzymes. *Potentially Fatal:* systemic events vasculitis in patients with rash but may be serious involving lungs, kidney and liver.

#### 114. FLUVOXAMINE TAB. I.P.

#### SALIENT ACTIONS:

Fluvoxamine is used to treat obsessive-compulsive disorder (OCD). It helps decrease persistent/unwanted thoughts (obsessions) and urges to perform repeated tasks (compulsions such as hand-washing, counting, checking) that interfere with daily living. Fluvoxamine is known as a selective serotonin reuptake inhibitor (SSRI). This medication works by helping to restore the balance of a certain natural substance (serotonin) in the brain.

#### INDICATIONS:

to treat obsessive-compulsive problems.

# DOSAGE REGIMENS:

The recommended starting dose for Fluvoxamine Maleate Tablets in adult patients is 50 mg, administered as a single daily dose at bedtime.

The recommended starting dose for Fluvoxamine Maleate Tablets in pediatric populations (ages 8-17 years) is 25 mg, administered as a single daily dose at bedtime.

#### CONTRAINDICATIONS:

Coadministration of tizanidine, thioridazine, alosetron, or pimozide with Fluvoxamine Maleate Tablets is contraindicated.

#### PRECAUTIONS:

Avoid alcoholic beverages

#### INTERACTIONS:

other drugs that can cause bleeding/bruising (including antiplatelet drugs such as clopidogrel, NSAIDs such as ibuprofen, "blood thinners" such as warfarin).

# ADVERSE EFFECTS:

fainting, black stools, vomit that looks like coffee grounds, seizures, eye pain/swelling/redness, widened pupils, vision changes.

# 115. FOLIC ACID Tab 5 mg

## SALIENT ACTIONS:

Folic acid is essential for the production of certain coenzymes in many metabolic systems such as purine and pyrimidine synthesis. It is also essential in the synthesis and maintenance of nucleoprotein in erythropoesis. It also promotes WBC and platelet production in folate-deficiency anaemia.

# INDICATIONS & DOSAGE REGIMENS:

- 1. Folate-deficient megaloblastic anaemia: Adult: 5 mg daily for 4 month, up to 15 mg daily in malabsorption states
- 2. Prophylaxis of megaloblastic anaemia in pregnancy: Adult: 0.2-0.5 mg daily.
- 3. Prophylaxis of neural tube defect in pregnancy: Adult: 4 or 5 mg daily starting before pregnancy and continued through the 1st trimester.
- 4. Supplement for women of child-bearing potential: Adult: 0.4 mg daily.

## CONTRAINDICATIONS:

Undiagnosed megaloblastic anaemia; pernicious, aplastic or normocytic anaemia.

#### PRECAUTIONS:

Pregnancy Category (US FDA): A

# INTERACTIONS:

Antiepileptics, oral contraceptives, anti-TB drugs, alcohol, aminopterin, methotrexate, pyrimethamine, trimethoprim and sulphonamides decrease in serum folate concentration. Decreases serum phenytoin

concentrations.

#### ADVERSE EFFECTS:

GI disturbances, hypersensitivity reactions; bronchospasm.

# 116. FORTIFIED MICRONUTRIENTS(RICONIA LP TAB) SALIENT ACTIONS:

Riconia Tablet works by causing more fluid to be drawn into intestines and stimulating gut to push out its contents; affecting the mobilization of fat from liver; maintaining the normal glucose metabolism and peripheral nerve function; helping in bone and collagen synthesis; producing blood cells and platelets in the body; producing and storing iron; acting on megaloblastic bone marrow to produce a normoblastic marrow; activating enzymes and carbohydrate metabolism; increasing iron absorption in the body; completing the deficiency of essential mineral in body; completing the need of magnesium in the body; works for nerve conduction, muscle contraction, kidney function and heart beating; blocking or reducing the chances of radioactive iodine swallowing; building muscles and improving the muscle coordination; increasing the effects of insulin; breaking down proteins and other substances; increasing the action of antioxidants; works as a reducing agent; metabolizing carbohydrate thus maintains normal growth; facilitating retina formation required for low light and color vision; treating vitamin B12 deficiency; maintaining many tissues of the body to prevent vitamin B2 deficiency; converting food into glucose thus produces energy; replacing vitamin when this do not get enough from foods; producing antibodies and hemoglobin by keeping blood sugar level in normal range; blocking the damage caused by free radicals thus heals wounds; increasing absorption of calcium and phosphorus required for strong bones; slowing down the processes that damage cells; regulating the intestinal fluid transport, mucosal integrity, immunity, gene expression and oxidative stress;

#### INDICATIONS:

- Acid indigestion
- · Oral health care
- Hair loss
- Eye problems
- High blood pressure
- Circulation disorders
- Arthritis
- Deficiency of vitamin b12
- Low blood calcium levels
- Osteoporosis
- Gastric antacid
- Nutritional supplement
- Prevention of neural tube defects and fatty liver disease
- Parenteral nutrition
- Heart disease
- Alzheimer's disease
- Hair and nail quality
- Skin healing
- Anemia
- During pregnancy
- Copper deficiency
- Wound healing
- Osteoarthritis
- Treatment of megaloblastic anemias due to a deficiency of folic acid
- Treatment of anemias of nutritional origin, pregnancy, infancy, or childhood
- Manganese plasma levels

## DOSAGE REGIMENS:

One tablet a day.

## **CONTRAINDICATIONS:**

NIA

#### PRECAUTIONS:

N/A

#### INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

- Constipation
- Stomach upset
- Nausea
- Loss of appetite
- Unusual weight loss
- Mood changes

# 117. FOSAPREPITANT DIMEGLUMINE INJ

#### SALIENT ACTIONS:

Fosaprepitant is a selective high-affinity antagonist of human substance P/neurokinin 1 (NK1) receptors. inhibit emesis induced by cytotoxicchemotherapeutic agents, such as cisplatin, via central actions.

#### INDICATIONS:

- acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin.
- delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).

#### DOSAGE REGIMENS:

150 mg intravenously over 20 to 30 minutes approximately 30 minutes prior to chemotherapy

#### CONTRAINDICATIONS:

Coadministration of cisapride or pimozide; hypersensitivity to any component of the product.

#### PRECAUTIONS:

#### Hypersensitivity

Immediate hypersensitivity reactions, including flushing, erythema, dyspnea, and anaphylaxis, have occurred.

#### **Hepatic Function**

Use with caution in patients with severe hepatic impairment.

#### INTERACTIONS:

#### Colchicine

Plasma concentrations of colchicine may be elevated, increasing the risk of toxicity. Use with caution and closely monitor for colchicine toxicity. Colchicine dosage adjustment may be required for patients receiving fosaprepitant.

#### Contraceptives, hormonal

Contraceptive efficacy may be reduced. Use alternative methods of contraception during aprepitant treatment and for 1 mo after the last dose of aprepitant.

#### CYP2C9 substrates (eg, phenytoin, tolbutamide, warfarin)

Plasma concentrations of these drugs may be reduced. In patients receiving warfarin, closely monitor anticoagulation parameters for 14 days after initiation of the 3-day antiemetic regimen.

#### ADVERSE EFFECTS:

#### CNS

Asthenia/fatigue (3%): headache (2%).

#### Dermatologic

Angioedema, erythema, Stevens-Johnson syndrome, urticaria.

#### GI

Anorexia, constipation, dyspepsia (2%); diarrhea, eructation (1%).

## Lab Tests

Increased ALT (3%); increased AST (1%).

#### Miscellaneous

Hiccups (5%); infusion-site reactions (eg, erythema, induration, pain, pruritus, thrombophlebitis) (3%); increased blood pressure; hypersensitivity reactions (postmarketing).

# 118. GABAPENTIN(GABAPIN 300MG CAP)

#### SALIENT ACTIONS:

Gabapentin belongs to a class of drugs called anticonvulsants. A class of drugs is a group of medications that work in a similar way. These drugs are often used to treat similar conditions.

#### INDICATIONS:

Gabapentin is used to the following conditions:

- Seizures: Gabapentin is used to treat partial seizures. It's taken together with other seizure medications in adults and in children 3 years of age and older who have epilepsy.
- Postherpetic neuralgia: This is pain from nerve damage caused by shingles, a painful rash that affects
  adults. Shingles appears after infection with the varicella zoster virus. This virus occurs in people who have
  had chicken pox.
- Restless legs syndrome: This condition causes discomfort in the legs, resulting in a strong urge to move them. It typically occurs when a person is relaxing or sleeping.

#### DOSAGE REGIMENS:

Initial dose: 300 mg orally on day one, 300 mg orally 2 times day on day two, then 300 mg orally 3 times a day on day three

Maintenance dose: 300 to 600 mg orally 3 times a day Maximum dose: 3600 mg orally daily (in 3 divided doses)

#### CONTRAINDICATIONS:

Gabapentin is contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients.

#### PRECAUTIONS:

Antiepileptic drugs (AEDs), including gabapentin, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication.

## INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

- dizziness
- tiredness or drowsiness
- loss of coordination
- fever
- · jerky movements
- nausea and vomiting
- · trouble speaking
- · double vision
- unusual eye movements
- tremor
- swelling of legs and feet

# 119. GABAPENTIN 300 mg + MECOBALAMINE 500 mcg Tab SALIENT ACTIONS:

Mecobalamin is the neurologically active form of vitamin B12. Gabapentin is structurally related to the neurotransmitter GABA but is neither a GABA agonist nor antagonist. Gabapentin-binding sites have been identified throughout the brain tissues e.g. neocortex and hippocampus. However, the exact mechanism of action is still unknown.

#### INDICATIONS:

Neuropathic pain, Peripheral neuropathy

#### DOSAGE REGIMENS:

One tablet three times a day or as directed by physician

**CONTRAINDICATIONS:** Hypersensitivity, Lactation.

#### PRECAUTIONS:

Discontinuation or transfer from other antiepileptics, history of psychotic illness; renal impairment; pregnancy.

#### INTERACTIONS:

Cimetidine may reduce gabapentin clearance. Absorption reduced with antacids. Decreased GI tract absorption with neomycin, aminosalicylic acid, H<sub>2</sub>-blockers and colchicine. Reduced serum concentrations with oral contraceptives. Reduced effects in anaemia with parenteral chloramphenicol.

## ADVERSE EFFECTS:

Anorexia, nausea, vomiting and diarrhea Somnolence, dizziness, ataxia, weakness, paraesthesia, fatigue, headache; nystagmus, diplopia, wt gain, dyspepsia; rhinitis; tremor; leucopenia; altered LFTs; Stevens-Johnson syndrome.

# 120. GEFITINIB TABLET

## SALIENT ACTIONS:

Gefitinib belongs to a group of anti-cancer medicines known as tyrosine kinase inhibitors (TKI). These medicines work by blocking chemical messengers (called tyrosine kinases) which send signals to cells to grow. Geftinat stops cancer cells from growing and spreading.

## INDICATIONS:

Gefitinib is used for the treatment of Non small cell lung cancer that has spread into surrounding tissues (locally advanced cancer) or to other parts of the body in people with certain types of tumors. In order for Gefitinib to work, the cancer cells need to have receptors for a protein called Epidermal Growth Factor (EGFR).

# DOSAGE REGIMENS:

250 mg PO qDay until disease progression or unacceptable toxicity

# CONTRAINDICATIONS:

- Confirmed interstitial lung disease
- Severe hepatic impairment
- Gastrointestinal perforation
- Persistent ulcerative keratitis

# PRECAUTIONS:

Gefitinib is not recommended for use during pregnancy. It may cause harm to an unborn baby.

## INTERACTIONS:

Some liver enzyme inducer medications such as rifamycins (e.g., rifampin, rifabutin), Your dosage of gefitinib may need to be increased if you are using such medications.

# ADVERSE EFFECTS:

Rash; Acne; Weakness; Mouth sores; Dry skin; Itching; Mouth Sore; Decreased Appetite; Vomiting etc.

# 121. GINKGO DRY EXTRACT I. P TABLET

SALIENT ACTIONS: Ginkgo has been studied extensively for its antioxidant and neuroprotective effects, as well as for treatment of cerebral insufficiency, cognitive impairment, dementia, peripheral vascular disease, premenstrual syndrome, schizophrenia, tinnitus, and vertigo

## INDICATIONS:

Ginkgo has been studied extensively for its antioxidant and neuroprotective effects, as well as for treatment of cerebral insufficiency, cognitive impairment, dementia, peripheral vascular disease, premenstrual syndrome, schizophrenia, tinnitus, and vertigo

# DOSAGE REGIMENS:

daily doses of 120 to 720 mg of extract

# CONTRAINDICATIONS:

Individuals with known hypersensitivity reactions should avoid ginkgo use.

# PRECAUTIONS:

Because of the potential risk of increased bleeding or hemorrhage, ginkgo use should be avoided with antiplatelets (eg, aspirin) or anticoagulants (eg, warfarin), or if the patient has vitamin K deficiency. Patients with a history of, or a predisposition to, seizure activity should not take ginkgo. INTERACTIONS:

Plasma concentrations of nifedipine may be elevated with ginkgo use, increasing therapeutic and adverse reactions. Conversely, Ginkgo biloba may reduce plasma concentrations of omeprazole and tolbutamide, decreasing the therapeutic effects.

# ADVERSE EFFECTS:

possible reactions include headache, dizziness, heart palpitations, as well as GI and dermatologic reactions.

# 122. GLICLAZIDE 40MG TAB

# SALIENT ACTIONS:

Gliclazide Stimulates Insulin Secretion From Pancreatic B-Cells, Reduces Hepatic Gluconeogenesis, And Lowers Blood Glucose Concentrations. It Also Inhibits Platelet Aggregation At Therapeutic Doses. INDICATIONS:

Gliclazide Is An Anti-Diabetic Medicine . Gliclazide Is Used In The Management Of Type 2 Diabetes. DOSAGE REGIMENS:

The starting dose is usually 40-80mg once daily and may be increased to a total daily dose of 40-320mg.

#### CONTRAINDICATIONS:

Type 1 DM, Diabetes Complicated With Ketoacidosis; Hypersensitivity; Severe Renal And Hepatic Impairment. Pregnancy And Lactation.

#### PRECAUTIONS:

Monitor Blood Glucose Concentration. May Require Insulin During Metabolic Stress. Care When Transferring From Combination Therapy. Increased Risk Of Severe Hypoglycaemia In Elderly, Debilitated Patients, Patients With Hepatic Or Renal Impairment. Risk Of Hypogylcaemia When Caloric Intake Is Deficient, After Strenuous Exercise,

#### INTERACTIONS:

Nausea And Flushing With Alcohol. Hypoglycaemic Effect Increased By Salicylates, Phenylbutazone, Clofibrate, Sulphonamides, Oral Anticoagulants And MAOIs. Hypoglycaemic Effect Diminished By Rifampicin, Barbiturates, Alcohol, Diuretics, Diazoxide, Corticosteroids, B-Blockers, Oestrogens And Sympathomimetic Drugs; Dose Adjustment May Be Required.

#### ADVERSE EFFECTS:

- Dizziness
- Nausea or vomiting
- Diarrhea
- Confusion
- Weakness
- Sweating
- Changes in vision
- Decreased heartbeat
- Abdominal pain
- Constipation
- Skin rash
- · Elevated liver enzymes

# 123. GLIBENCLAMIDE 5 mg +METFORMIN 500 mg Tab SALIENT ACTIONS:

Glibenclamide stimulates insulin secretion from pancreatic  $\beta$ -cells, reduces hepatic gluconeogenesis and lowers blood-glucose concentrations. Metformin improves glucose tolerance in patients with type 2 DM, lowering both basal and postprandial blood glucose. It decreases hepatic gluconeogenesis, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.

## INDICATIONS & DOSAGE REGIMENS:

Glibenclamide 1.25 mg and metformin 250 mg/tablet.

Type 2 diabetes mellitus: Adult: Start with 1 tablet once or twice daily. Increase in steps of 1 tablet/day every 2 wk to the lowest effective dose need to achieve effective control of blood glucose. Max: 8 tablets/day.

#### CONTRAINDICATIONS:

Hypersensitivity. Lactation.

#### PRECAUTIONS:

Overdosage; elderly; dietary errors; mild to moderate renal and hepatic disorders. Impaired alertness. Avoid alcohol. Carefully monitor blood-glucose concentration.

Pregnancy category (US-FDA) - B

## INTERACTIONS:

Diminished hypoglycaemic effect of glibenclamide: Adrenaline, aminoglutethimide, chlorpromazine, corticosteroids, diazoxide, OC and thiazide diuretics. Increased hypoglycaemic effects of glibenclamide: ACE inhibitors, alcohol, analgesics, azole antifungals, coumarin, MAOIs, octreotide, tetracyclines, tricyclic antidepressants. Metformin: Additive effect with sulphonylureas. Antagonistic effects with diuretics, corticosteroids, phenothiazines. thyroid products, oestrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, Ca channel blockers and isoniazid. Metformin: Lactic acidosis with alcohol and potentiation of hypoglycaemic effect. Cimetidine and furosemide increase plasma-metformin levels. Drugs eliminated via renal tubular secretion may increase metformin levels. Potentially Fatal: Glibenclamide: Warfarin, salicylates, sulphonamides and alcohol potentiate hypoglycaemic effect. Glucocorticoids, diuretics and oestrogen reduce hypoglycaemic effect. Beta-blockers mask early symptoms of hypoglycaemia.

# ADVERSE EFFECTS:

Hypoglycemia; cholestatic jaundice; agranulocytosis; aplastic anemia; hemolytic anemia. Blood dyscrasias, liver

dysfunction, hypoglycemia, GI symptoms, and allergic skin reactions. Potentially Fatal: Glibenclamide: Prolonged hypoglycemia seen in elderly or debilitated patients with hepatic or renal diseases. Metformin: Lactic acidosis in presence of renal failure and alcoholism.

# 124. GLIMEPIRIDE Tab 2 mg

# SALIENT ACTIONS:

Glimepiride stimulates the insulin release from functioning pancreatic β-cells and inhibits gluconeogenesis at hepatic cells. It also increases insulin sensitivity at peripheral target sites.

# INDICATIONS & DOSAGE REGIMENS:

Type 2 diabetes mellitus: Adult: 1-2 mg daily. Maintenance: 4 mg daily. Max: 6 mg daily.

Renal impairment: Initiate at 1 mg daily; subsequent increments should be based on fasting blood glucose levels. Should be taken with food. (Take immediately before or during breakfast, or the 1st main meal of the day. Do not skip meals.)

# CONTRAINDICATIONS:

Diabetic ketoacidosis with or without coma.

#### PRECAUTIONS:

Pregnancy category (US-FDA) - C. Hepatic and renal impairment. SIADH in patients with CHF or hepatic cirrhosis. Monitor blood-glucose concentration. Pregnancy, lactation.

#### INTERACTIONS:

NSAIDs, salicylates, sulphonamides, chloramphenicol, coumarin, probenecid, CYP2C9 inhibitors, fibric acid derivatives, TCAs, MAOIs and β-adrenergic blockers may potentiate the hypoglycaemic action of glimepiride. Thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, oestrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, rifampicin, CYP2C9 inducers and isoniazid may reduce hypoglycaemic effect of glimepiride. May increase the serum levels of ciclosporin. Serum levels may be increased by fluconazole. May cause disulfiram-like reaction and hypoglycemia when used with ethanol. Hypoglycemic risk when used with chromium, garlic.

# ADVERSE EFFECTS:

Vomiting, GI pain, diarrhoea; pruritus, erythema, urticaria, morbilliform, maculopapular eruptions; leukopenia, agranulocytosis, thrombocytopenia, hemolytic anaemia, aplastic anaemia and pancytopenia; hyponatremia; changes in accommodation, blurred vision, jaundice.

# 125. GLUGOSAMNE SULPHATE CAP

# SALIENT ACTIONS:

Glucosamine Sulphate is an amino sugar, which builds up the volume of naturally present glucosamine in the body. This increased glucosamine level in turn, accelerates the biosinthesis of building blocks of cartilage, i.e., proteoglycans and collagens.

Indications: In painful conditions of osteoarthritis and rheumatoid arthritis, where aspirin and other NSAIDs fail to provide a satisfactory relief.

# DOSAGE REGIMENS:

500mg orally three times daily for upto three months. This intake may have to be adjusted for obese individuals (at approximately 20mg/kg body Weight) including those taking diuretics, thereafter 1000mg/day as a nutritional maintenance, as the arthritic condition improves.

Safety: Glucosamine sulphate has an excellent safety record in both animal and human investigations, should be considered as a supplement of choice for nutritional correction of rheumatic disorders, can be safely taken alongside orthopedic pain controlling medications.

# CONTRAINDICATIONS:

Not recoinmended in pregnancy & Laciation.

# DRUG INTERACTIONS:

No reports of drug Interactions were located.

#### ADVERSE EFFECTS:

Adverse effects are reported as minimal. The most common side effects were epigastric pain tenderness, heartburn, diarrhoea and nausea, Drowsiness, headache and insomnia ocurred rarely(less than 1 %).

# 126. GLYCERYL TRINITRATE TAB 0.5 MG

#### SALIENT ACTIONS:

The medication works by relaxing and widening the blood vessels of the heart so it does not need to work as

hard to pump blood. The tablets are used by patients with coronary artery disease to treat and prevent chest pain caused by angina pectoris.

#### INDICATIONS:

- Angina pectoris
- · Hypertension during surgeries
- Chronic anal fissures

#### DOSAGE REGIMENS:

Initial 2.5-6.5 mg PO q6-8hr

# CONTRAINDICATIONS:

Hypersensitivity. Severe Hypotension, Heart Failure, Marked Anaemia, Hypertrophic Obstructive Cardiomyopathy, Cerebral Haemorrhage Or Head Trauma, Low Cardiac Output Secondary To Hypovolaemia, Inferior MI With Right Ventricular Involvement, Raised Intracranial Pressure. Concomitant Use With Phosphodiesterase Type-5 Inhibitors.

#### PRECAUTIONS:

Severe Hepatic Or Renal Impairment, Hypothyroidism, Malnutrition, Hypothermia. Cerebrovascular Disease, Lung Disease Or Cor Pulmonale. Pregnancy, Lactation, Glaucoma, Mitral Valve Prolapse, Cardiac Tamponade, Syncope. Gradual Withdrawal In Patients Who Have Received Prolonged High Dose Infusions. Avoid Prolonged Excessive Hypotension. Nitrate-Free Interval Is Recommended In Patients On Continuous Treatment With Nitrates To Reduce Risk Of Tolerance.

#### INTERACTIONS:

Enhances Bioavailability Of Dihydroergotamine. Glyceryl Trinitrate Infusion May Prolong Pancuronium-Induced Neuromuscular Blockade. May Reduce The Efficacy Of Heparin, Alteplase And Noradrenaline When Used Together. Efficacy Of Buccal And Sublingual Preparations May Be Reduced By Drugs That Can Cause Dry Mouth Due To Decreased Dissolution. Aspirin And Other NSAIDs May Reduce The Therapeutic Response To Glyceryl Trinitrate.

## ADVERSE EFFECTS:

- Flushing
- · Dizziness or lightheadedness
- Headaches
- Nausea
- Blurred vision
- Vomiting
- Fainting
- Difficulty breathing or swallowing
- Worsening of chest pain

#### 127. GLYCOPYRRONIUM CAP 50 MCG

#### SALIENT ACTIONS:

Glycopyrronium belongs to the group of medicines known as antimuscarinic bronchodilators. It is given to improve the air flow to your lungs. It works by opening up the air passages in your lungs so that air can flow into your lungs more freely. The inhaler should be used regularly every day.

#### INDICATIONS: Chronic obstructive pulmonary disease (COPD)

Glycopyrronium belongs to the group of medicines known as antimuscarinic bronchodilators. It is given to improve the air flow to your lungs. It works by opening up the air passages in your lungs so that air can flow into your lungs more freely. The inhaler should be used regularly every day.

# DOSAGE REGIMENS:

1 capsule once daily inhalation

## CONTRAINDICATIONS:

Hypersensitivity to glycopyrronium or to any of the excipients

# PRECAUTIONS:

Capsule may cause excessive drowsiness and calmness with alcohol.

#### INTERACTIONS:

Capsule may cause excessive drowsiness and calmness with alcohol.

## ADVERSE EFFECTS:

Visual disturbance, Reduced sweating, Irregular heartbeats, Dry mouth, Nausea, Vomiting, Dry skin, Photophobia, Flushing, Giddiness, Difficulty in urination, Confusion

# 128. GRANISETRON(TAB)

#### SALIENT ACTIONS:

Selective 5-HT<sub>3</sub> receptor antagonist.

### INDICATIONS:

Prevention of nausea and vomiting associated with chemotherapy (including high-dose cisplatin). Prevention and treatment of post-op nausea and vomiting.

# DOSAGE REGIMENS:

2 mg once daily or 1 mg twice daily.

Prevention and Treatment

# CONTRAINDICATIONS:

Concomitant apomorphine.

#### PRECAUTIONS:

Abdominal surgery. May mask progressive ileus and/or gastric distention. Pre-existing arrhythmias or cardiac conduction disorders. Cardiac disease, concomitant cardio-toxic chemotherapy or electrolyte abnormalities: increased risk of QT prolongation. Pregnancy (Cat.B). Nursing mothers.

# INTERACTIONS:

Caution with drugs that affect CYP450 or prolong the QT interval.

# ADVERSE EFFECTS:

Headache, asthenia, diarrhea, constipation; QT prolongation.

# 129. GRISEOFULVIN 250MG TAB

# SALIENT ACTIONS:

Griseofulvin belongs to a class of drugs called antifungal agents. A class of drugs is a group of medications that work in a similar way. These drugs are often used to treat similar conditions.

This drug works by binding to a part of the fungus causing the infection in your body. This stops the fungus from multiplying. This drug also prevents fungus from spreading to new cells. These actions cause the infection to die off.

# INDICATIONS:

Ringworm infections of the skin, hair, and nails.

## DOSAGE REGIMENS:

Adult:

500mg daily; max 1g daily.

Children:

30-50lbs: 125-250mg daily. Over 50lbs: 250-500mg daily.

# CONTRAINDICATIONS:

Porphyria. Hepatocellular failure. Pregnancy.

# PRECAUTIONS:

Don't take this drug again if you've ever had an allergic reaction to it

# INTERACTIONS:

When certain drugs are used with griseofulvin, these other drugs may not work as well. This is because the amount of these drugs in your body may be decreased.

- Warfarin
- Birth control pills
- Cyclosporine.
- Salicylates such as aspirin and magnesium salicylate

## ADVERSE EFFECTS:

- rash
- numbness or tingling in your hands or feet
- yeast infections in your mouth
- stomach pain
- diarrhea
- heartburn
- nausea
- vomiting
- dizziness
- headache

- trouble sleeping
- confusion

Severe skin allergic reaction

Liver damage

#### 130. HALOPERIDOL 5MG TABLET

#### **SALIENT ACTIONS:**

Haloperidol is a psychiatric medication (antipsychotic-type) that works by helping to restore the balance of certain natural substances in the brain(neurotransmitters).

#### INDICATIONS:

Haloperidol is used to treat certain mental/mood disorders (e.g., schizophrenia, schizoaffective disorders). Haloperidol can also be used to treat uncontrolled movements and outbursts of words/sounds related to Tourette's disorder. In children, Haldol may be used for severe behavior problems including hyperactivity or aggression.

#### DOSAGE REGIMENS:

Adults:

Moderate symptomology: 0.5 to 2 mg orally 2 to 3 times a day Severe symptomology: 3 to 5 mg orally 2 to 3 times a day

**Pediatrics:** 

3 to 12 years and 15 to 40 kg:

Initial dose: 0.5 mg/day orally in 2 to 3 divided doses

#### CONTRAINDICATIONS:

Breast cancer, Thyrotoxicosis Crisis, Untreated Decreased Level of Thyroid Hormones, low amount of magnesium in the blood, low amount of potassium in the blood, Deficiency of Granulocytes a Type of White Blood Cell, Decreased White Blood Cells, Decreased Neutrophils a Type of White Blood Cell, Parkinson Symptoms

#### PRECAUTIONS:

increased mortality in elderly patients with dementia-related psychosis

#### INTERACTIONS:

- Anticholinergic medications, such as scopolamine (Transderm-Scop) and lithium(Eskalith)
- Drugs for Parkinson's disease
- Heart rhythm drugs
- Antidepressants
- Sleep medication
- Anti-anxiety medication
- Muscle relaxants
- Psychiatric medications
- Narcotic pain relievers
- Epinephrine (Auvi-Q)
- Amphetamine
- Certain antibiotics

#### ADVERSE EFFECTS:

- · dizziness, fainting, fast or pounding heartbeat;
- · restless muscle movements in your eyes, tongue, jaw, or neck;
- tremor (uncontrolled shaking);
- seizure (convulsions);
- pale skin, easy bruising or bleeding, flu symptoms;
- very stiff (rigid) muscles, high fever, sweating, confusion, fast or uneven heartbeats, tremors, feeling like you might pass out;
- stabbing chest pain, feeling short of breath, cough with yellow or green mucus;
- sudden mood changes, agitation, hallucinations, unusual thoughts or behavior; or
- jaundice

# 131. HYDROXYCHLOROQUINE SULPHATE Tab 200 mg

#### SALIENT ACTIONS:

Hydroxychloroquine is a 4-aminoquinoline antimalarial with actions similar to those of chloroquine It interferes

with digestive vacuole function within susceptible malarial parasites by increasing pH and interrupting with lysosomal degradation of Hb thus impeding normal cell function of sensitive parasites.

# INDICATIONS & DOSAGE REGIMENS:

Should be taken with food.

Rheumatoid arthritis, Systemic lupus erythematosus: Adult: Initially, 400 mg daily. Maintenance: 200-400 mg/day. Max: 6.5 mg/kg/day or 400 mg/day. Child: Up to 6.5 mg/kg/day or 400 mg/day.

**Prophylaxis of malaria:** Adult: 400 mg every 7 days. Begin 2 week before exposure; continue for 4-6 week after leaving the endemic area. Child: 6.5 mg/kg once wkly. Max: 400 mg/dose.

Acute malaria: Adult: Initially, 800 mg followed by 400 mg 6-8 hr later, then a further 400 mg on each of the succeeding 2 days. Child: 13 mg/kg; followed by 6.5 mg/kg 6 hr later and repeat dose on the 2nd and 3rd days. CONTRAINDICATIONS:

Retinal or visual field changes, known hypersensitivity. Long-term use in children.

## PRECAUTIONS:

Pregnancy Category (US FDA) – C, Special precaution: Impaired liver or renal function, severe GI disorders, porphyria, psoriasis, neurological disorders especially a history of epilepsy, myasthenia gravis, G6PD deficiency, pregnancy, lactation. Monitor CBC in patients receiving prolonged therapy. Perform baseline and periodic 6-mth eye exams, test periodically for muscle weakness.

#### INTERACTIONS

Cimetidine increase serum levels of hydroxychloroquine. Absorption decreased by kaolin or Mg trisilicate. Increased risk of ventricular arrhythmias when used with halofantrine. Concurrent use with mefloquine may increase the risk of convulsions.

#### ADVERSE EFFECTS

Retinopathy, hair loss, photosensitivity, tinnitus, myopathy, Psychosis, seizures, leucopenia and rarely aplastic anaemia, hepatitis, GI upsets, dizziness, hypokalaemia, headache, pruritus, urticaria, difficulty in visual accommodation, bleaching of hair pigment, bluish-black pigmentation of the mucous membranes and skin, photosensitivity, tinnitus, reduced hearing, nerve deafness, neuromyopathy, and myopathy, including cardiomyopathy.

# 132. HYDROCHLOROTHIAZIDE 12.5MG TAB

#### SALIENT ACTIONS:

Hydrochlorothiazide belongs to a class of drugs called thiazide diuretics. A class of drugs refers to medications that work similarly. They have a similar chemical structure and are often used to treat similar conditions. It isn't known exactly how hydrochlorothiazide works. It's thought that it works to remove excess salt and water from your body. This keeps your heart from working as hard to pump blood. This lowers high blood pressure levels and reduces swelling.

#### INDICATIONS:

Hydrochlorothiazide is used to treat high blood pressure. It's also used to treat swelling that's caused by heart failure, liver damage (cirrhosis), and taking certain medications (corticosteroids or estrogens). It may also help treat swelling that's caused by kidney problems.

#### DOSAGE REGIMENS:

# Dosage for high blood pressure

## Adult dosage

The starting dosage is 25 mg taken by mouth once per day.

# Child dosage (ages 6 months-2 years)

The usual dosage is 0.5-1 mg per pound per day, taken in a single dose or two divided doses.

## Dosage for edema

# Adult dosage

The usual dosage is 25-100 mg each day, taken by mouth as a single or divided dose.

## Child dosage (ages 6 months-2 years)

The usual dosage is 0.5-1 mg per pound per day, taken in a single dose or two divided doses.

#### CONTRAINDICATIONS:

- are allergic to hydrochlorothiazide, sulfonamide medications (e.g., sulfamethoxazole), or any of the ingredients of the medication
- · have kidney disease that is worsening and reduced urine production while taking this medication
- · are unable to urinate

#### PRECAUTIONS:

This drug may decrease your potassium levels. consume foods high in potassium (such as bananas, orange juice) or use a salt substitute containing potassium

#### INTERACTIONS:

- Lithium/Eskalith (Lithobid)
- Digoxin/Lanoxin
- Cholestyramine/Prevalite
- Cholestyramine (Questran)
- Colestipol/Colestid
- Phenobarbital (Luminal)
- Secobarbital (Seconal)

#### ADVERSE EFFECTS:

- severe skin reactions such as Stevens-Johnson syndrome and exfoliative dermatitis
- hypotension
- blurred vision

#### 133. HYDROXYZINE Tab 10 mg

#### SALIENT ACTIONS:

Hydroxyzine blocks histamine H1-receptors on effector cells of the GI tract, blood vessels and respiratory tract; a sedating anihistamine with antimuscarinic and significant sedative properties. It also possesses skeletal muscle relaxing, bronchodilator, antiemetic and analgesic properties.

#### INDICATIONS & DOSAGE REGIMENS:

Short-term management of anxiety: Adult: 50-100 mg 4 times daily.

Pruritus in acute and chronic urticaria and dermatosis: Adult: 25 mg at night increased up to 25 mg 3-4 times daily. Child: 6 mth-6 yr: 5-15 mg daily, increased to 50 mg/day in divided doses; >6 yr: Initially, 15-25 mg/day, increased up to 50-100 mg/day.

Adjunct to pre- or post-operative sedation: Adult: 50-100 mg.

Reduce dose by 50 %( Renal impairment) & 33 %( Hepatic impairment)

#### **CONTRAINDICATIONS:**

Porphyria, neonates, pregnancy, lactation.

#### PRECAUTIONS:

Pregnancy Category (US FDA) – C.Special precaution: Renal and hepatic impairment; narrow-angle glaucoma; epilepsy; prostatic hypertrophy; bladder neck obstruction; asthma; COPD. Impair ability to drive or operate machinery.

#### INTERACTIONS:

Masks ototoxicity of aminoglycoside antibiotics. Potentially Fatal: Potentiates CNS depression by barbiturates, hypnotics, opioid analgesics, sedatives and neuroleptics. MAOIs, atropine, and TCAs potentiate antimuscarinic effects.

#### ADVERSE EFFECTS:

CNS depression, paradoxical CNS stimulation, dry mouth, thickened respiratory secretions, constipation, blurring of vision, tachycardia, GI disturbances, headache, hypotension and tinnitus.

## 134. HYOSCINE BUTYLBROMIDE Tab 10 mg

#### SALIENT ACTIONS:

Hyoscine competitively blocks muscarinic receptors and has central and peripheral actions. It relaxes smooth muscle and reduces gastric and intestinal motility.

# INDICATIONS & DOSAGE REGIMENS:

- 1. Gastrointestinal tract spasm, genitourinary spasm: Adult: 20 mg 4 times daily. Child: 6-12 yr: 10 mg tid.
- 2. Prophylaxis of motion sickness: Adult: 300 mcg 30 min before a journey, 300 mcg every 6 hr if required. Max: 3 doses in 24 hr. Child: 3-4 yr: 75 mcg 20 min before a journey. Max dose: 150 mcg in 24 hr. 4-10 yr: 75-150 mcg, >10 yr: 150-300 mcg. Max Dosage: 3 doses in 24 hrs.

#### **CONTRAINDICATIONS:**

Narrow-angle glaucoma, acute haemorrhage, paralytic ileus, tachycardia due to cardiac insufficiency, myasthenia gravis.

## PRECAUTIONS:

Pregnancy Category (US FDA)- C.Special precaution - Hepatic/renal disease, pyloric stenosis, urinary retention,

prostatic hyperplasia, psychosis, seizure disorders, ulcerative colitis, coronary artery disease, tachyarrhythmias, heart failure, hypertension, pregnancy, lactation.

## INTERACTIONS:

Increased sedative effects with alcohol or other CNS depressants.Reduced effects with acetylcholinesterase inhibitors (donepezil, galantamine, rivastigmine, tacrine).Potentially Fatal: Effect increased by other anticholinergic drugs and TCAs

#### ADVERSE EFFECTS:

Flushing, postural hypotension, tachycardia, fibrillation, Dizziness, drowsiness, fatigue, headache, memory loss, Dry skin, erythema, increased sensitivity to light, constipation, dry throat, dysphagia, nausea, vomiting, xerostomia. Dysuria, urinary retention. Tremor, weakness. Impaired accommodation, blurred vision, cycloplegia, dryness, narrow-angle glaucoma, increased intraocular pain, itching, photophobia, pupil dilation dry nose, Decreased diaphoresis, heat intolerance. Rarely psychotic reactions.

# 135. IBANDRONIC ACID 150MG TABLET SALIENT ACTIONS:

Ibandronic acid is a highly potent bisphosphonate belonging to the nitrogen-containing group of bisphosphonates, which act selectively on bone tissue and specifically inhibit osteoclast activity without directly affecting bone formation. It does not interfere with osteoclast recruitment. Ibandronic acid leads to progressive net gains in bone mass and a decreased incidence of fractures through the reduction of elevated bone turnover towards premenopausal levels in postmenopausal women.

# INDICATIONS:

Treatment of osteoporosis in postmenopausal women at increased risk of fracture

# DOSAGE REGIMENS:

The recommended dose is one 150 mg film-coated tablet once a month. The tablet should preferably be taken on the same date each month.

# CONTRAINDICATIONS:

- Hypersensitivity to ibandronic acid or to any of the excipients.
- Hypocalcaemia
- Abnormalities of the oesophagus which delay oesophageal emptying such as stricture or achalasia
- Inability to stand or sit upright for at least 60 minutes

# PRECAUTIONS:

Hypocalcaemia

Existing hypocalcaemia must be corrected before starting Ibandronic acid therapy. Other disturbances of bone and mineral metabolism should also be effectively treated. Adequate intake of calcium and vitamin D is important in all patients.

Gastrointestinal irritation

Orally administered bisphosphonates may cause local irritation of the upper gastrointestinal mucosa. Because of these possible irritant effects and a potential for worsening of the underlying disease, caution should be used when ibandronic acid is given to patients with active upper gastrointestinal problems (e.g. known Barrett's oesophagus, dysphagia, other oesophageal diseases, gastritis, duodenitis or ulcers).

Adverse experiences such as oesophagitis, oesophageal ulcers and oesophageal erosions, in some cases severe and requiring hospitalisation, rarely with bleeding or followed by oesophageal stricture or perforation, have been reported in patients receiving treatment with oral bisphosphonates. The risk of severe oesophageal adverse experiences appears to be greater in patients who do not comply with the dosing instruction and/or who continue to take oral bisphosphonates after developing symptoms suggestive of oesophageal irritation.

#### INTERACTIONS:

N/A

# ADVERSE EFFECTS:

- Oesophagitis,
- Gastritis, Gastro oesophageal reflux disease,
- Dyspepsia,
- o Diarrhoea,
- Abdominal pain,
- Nausea
- Arthralgia,
- Myalgia,

- Musculoskeletal pain,
- Muscle cramp,
- Musculoskeletal stiffness

# 136. IBUPROFEN Tab 400 mg

#### SALIENT ACTIONS:

Ibuprofen (NSAID) exhibits anti-inflammatory, analgesic and antipyretic activities. Its analgesic effect is independent of anti-inflammatory activity and has both central and peripheral effects. It potently inhibits the enzyme cyclooxygenase resulting in the blockage of prostaglandin synthesis. It also prevents formation of thromboxane A2 by platelet aggregation.

## INDICATIONS & DOSAGE REGIMENS:

1.Pain and inflammation: Adult: 1.2-1.8 g/day in divided doses. Maintenance: 0.6-1.2 g daily. Max: 2.4 g per day.2.Juvenile idiopathic arthritis: Child: ≥3 month: 30-40 mg/kg/day in 3-4 divided doses. Max: 2.4 g/day. 3.Fever: Adult: 200-400 mg every 4-6 hr. Max: 1.2 g/day. Child: 1-6 mth: 5 mg/kg 3-4 times daily, Max: 40 mg/kg/day.

#### CONTRAINDICATIONS:

Active peptic ulcer; hypersensitivity. Neonates with congenital heart disease.

### PRECAUTIONS:

Decreased peak serum levels if taken with food.Pregnancy Category (US FDA) - B, In 3rd trimester or near delivery- D.Special precaution: Asthma; renal or hepatic disorders; bleeding disorders; CV disease. Pregnancy, lactation.

# INTERACTIONS:

Reduces effects of antihypertensive. Enhanced effect with moclobemide. Increased risk of GI bleeding with warfarin. Potentially Fatal: Reduces antiplatelet effect of aspirin. Increases risk of methotrexate and lithium toxicity.

#### ADVERSE EFFECTS:

Overdose Symptoms: Apnoea, metabolic acidosis, coma, nystagmus, seizures, leukocytosis and renal failure. Dyspepsia, vomitting, abdominal pain, heart burn, nausea, diarrhoea, epigastric pain, edema, fluid retention, dizziness, rash, tinnitus. *Potentially Fatal:* Severe CV thrombotic events. Severe GI bleeding, ulceration and perforation.

#### 137. IMIPRAMINE Tab 25 mg

#### SALIENT ACTIONS:

Imipramine inhibits noradrenalin re-uptake and, to a lesser extent, that of serotonin.

# INDICATIONS & DOSAGE REGIMENS:

1. **Depression:**Adult: 75 mg daily to 150-200 mg daily. Elderly: 10 mg at night gradually increased to 30-50 mg daily.

2. Nocturnal enuresis: Child. Dose to be taken OD before bedtime for up to 3 mth.

6-7 yr	8-11 yr	>11 yr		
(20-25 kg): 25 mg	(25-35 kg): 25-50 mg	(35-54 kg): 50-75 mg		

## **CONTRAINDICATIONS:**

Post MI, heart block/arrhythmias; mania; porphyria; severe hepatic impairment

#### PRECAUTIONS:

Pregnancy Category (US FDA)- C.Special precaution: Epilepsy; children, elderly, pregnancy and lactation; cardiac disease; DM; prostatic hyperplasia; angle-closure glaucoma; phaeochromocytoma. Monitor for increased suicidality during early treatment. Withdraw gradually

#### INTERACTIONS:

Increased plasma levels and effects with quinidine, cimetidine, SSRIs, propafenone, flecainide.Reduced plasma levels with barbiturates, phenytoin.Increase effects of anticholinergic drugs. Severe orthostatic hypotension with altretamine, drowsiness and impaired performance in combination with alcohol.Potentially Fatal: Severe hypertension with adrenaline, noradrenaline and methylphenidate. Reduces hypotensive effects of guanethidine, bethanidine, debrisoquine, bretylium, methyldopa and clonidine.Possible serotonin syndrome with MAOIs.

#### ADVERSE EFFECTS:

Sinus tachycardia, AV/bundle-branch block, postural hypotension, dry mouth, wt loss/gain, constipation, urinary hesitancy/retention, impotence; blurring of vision, exacerbation of glaucoma, liver dysfunction, tremors, agranulocytosis.

# 138. INDOMETHACIN CAP SALIENT ACTIONS:

Indomethacin is a nonsteroidal anti-inflammatory drug (NSAID). It works by blocking an enzyme in your body that leads to inflammation. Blocking the enzyme helps to reduce inflammation and pain.

#### INDICATIONS:

Indomethacin is used to treat inflammation, pain, and fever. It's most commonly used to treat:

- moderate to severe rheumatoid arthritis
- · moderate to severe ankylosing spondylitis
- · moderate to severe osteoarthritis
- · acute painful shoulder (bursitis or tendinitis)
- · acute gouty arthritis (immediate-release only)

## DOSAGE REGIMENS:

- Immediate-release capsule: Indomethacin is usually dosed 2 to 3 times per day and starts at a dose of 25 mg.
   Your doctor may increase your dose by 25 or 50 mg per day. The maximum dose is 200 mg per day.
- Extended-release capsule: The dose is 75 mg once or twice per day. The maximum dose is 150 mg per day.

## CONTRAINDICATIONS:

- Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to indomethacin or any components of the drug product
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients
- In the setting of coronary artery bypass graft (CABG) surgery

#### PRECAUTIONS:

Gastrointestinal Bleeding, Ulceration, And Perforation

NSAIDs, including indomethacin, cause serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation of the esophagus, stomach, small intestine, orlarge intestine, which can be fatal.

## INTERACTIONS:

NSAIDs reduced the natriuretic effect of loop diuretics (e.g., furosemide) and thiazide diuretics. The concomitant use of INDOMETHACIN with digoxin has been reported to increase the serum concentration and prolong the half-life of digoxin.

#### ADVERSE EFFECTS:

- Cardiovascular Thrombotic Events
- GI Bleeding, Ulceration and Perforation
- Hepatotoxicity
- Hypertension
- Heart Failure and Edema
- Renal Toxicity and Hyperkalemia
- Anaphylactic Reactions
- Serious Skin Reactions
- Hematologic Toxicity

# 139. ISONIAZID 300 MG TABLET

#### SALIENT ACTIONS:

Isoniazid is a prodrug and must be activated by a bacterial catalase-peroxidase enzyme in Mycobacterium tuberculosis called KatG. [31] KatG catalyzes the formation of the isonicotinic acyl radical, which spontaneously couples with NADH to form the nicotinoyl-NAD adduct. This complex binds tightly to the enoyl-acyl carrier protein reductase known as InhA, thereby blocking the natural enoyl-AcpM substrate and the action of fatty acid synthase. This process inhibits the synthesis of mycolic acids, which are required components of the mycobacterial cell wall. A range of radicals are produced by KatG activation of isoniazid, including nitric oxide,

#### INDICATIONS:

TB

#### DOSAGE REGIMENS:

Adult: PO/IM 5 mg/kg up to 300 mg/day as a single dose or 15 mg/kg up to 900 mg/day, 2 or 3 times wkly CONTRAINDICATIONS

Hypersensitivity. Patient w/ acute liver disease or a history of isoniazid-associated hepatic injury.

#### PRECAUTIONS:

Patient w/ convulsive disorders, history of psychosis. Patient at risk of neuropathy (e.g. diabetics, alcoholics, malnourished, uraemic, infected w/ HIV) or pyridoxine deficiency. Hepatic and severe renal impairment. Pregnancy and lactation. Monitoring Parameters Monitor baseline and periodic LFTs (ALT and AST), sputum cultures mthly until 2 consecutive negative cultures reported and prodromal signs of hepatitis. INTERACTIONS:

Inhibit the hepatic metabolism of antiepileptics (e.g. carbamazepine, ethosuximide, primidone, phenytoin), benzodiazepines (e.g. diazepam, triazolam), chlorzoxazone, theophylline, disulfiram, sometimes leading to increased toxicity. Increased metabolism of enflurane, resulting in potentially nephrotoxic levels of fluoride. Increased concentrations and enhanced effects or toxicity of clofazimine, cycloserine and warfarin. Reduced absorption w/ Al-containing antacids. Increased risk of peripheral neuropathy w/ zalcitabine and stayudine.

#### ADVERSE EFFECTS:

Peripheral neuritis, psychotic reactions, convulsions, optic neuritis, transient increases in liver enzymes; haematological effects (e.g. anaemias, agranulocytosis, thrombocytopenia, eosinophilia); hypersensitivity reactions include skin eruptions (including erythema multiforme), fever, vasculitis; nausea, vomiting, dry mouth, constipation, pellagra, purpura, hyperglycaemia, lupus-like syndrome, vertigo, hyperreflexia, urinary retention, gynaecomastia.

Potentially Fatal: Hepatitis.

# 140. ISOSORBIDE DINITRATE Tab 5 mg / 10 mg

#### SALIENT ACTIONS:

Isosorbide dinitrate relaxes vascular smooth muscles by stimulating cyclic-GMP. It decreases left ventricular pressure (preload) and arterial resistance (afterload).

### INDICATIONS & DOSAGE REGIMENS:

- 1. Management of angina: Adult: 20-120 mg daily in divided doses. Max dose: 240 mg daily.
- 2. Heart failure: Adult: 30-160 mg daily in divided doses. Max dose: 240 mg daily.

#### CONTRAINDICATIONS:

Severe hypotension or anaemia, hypovolaemia, heart failure due to obstruction, or raised intracranial pressure due to head trauma or cerebral hemorrhage.

#### PRECAUTIONS:

Pregnancy Category (US FDA) – C.Special precaution: Raised intracranial pressure, hypotension, hypovolaemia. Mitral valve prolapse, arterial hypoxaemia, glaucoma, elderly, hypothyroidism, malnutrition, pregnancy, lactation.

### INTERACTIONS:

Increased hypotensive effects with alcohol or vasodilators. Marked orthostatic hypotension may occur when used with calcium channel blockers. Vasodilatory effect may be reduced with dihydroergotamine. Ergotamine effects may be enhanced. *Potentially Fatal:* Significant hypotension may occur with phosphodiesterase-5 inhibitors.

## ADVERSE EFFECTS:

Hypotension, tachycardia, flushing, headache, dizziness, palpitation, syncope, confusion. Nausea, vomiting, abdominal pain. Apprehension, restlessness, weakness and vertigo. *Potentially Fatal:* Severe hypotension, circulatory collapse.

# 141. ISOSORBIDE MONONITRATE 10 mg/20 mg

#### SALIENT ACTIONS:

Isosorbide mononitrate, Anti-Anginal Drug, relaxes vascular smooth muscles by stimulating cyclic-GMP. It decreases left ventricular pressure (preload) and arterial resistance (afterload).

#### INDICATIONS & DOSAGE REGIMENS:

Management of angina, Heart failure: Adult: 20 mg 2-3 times daily. Dose may range from 20-120 mg daily. Should be taken on an empty stomach.

#### CONTRAINDICATIONS:

Severe hypotension or anaemia, hypovolaemia, heart failure due to obstruction, or raised intracranial pressure due to head trauma or cerebral hemorrhage.

#### PRECAUTIONS:

Pregnancy Category (US FDA) - C.Special precaution: Severe renal or severe hepatic impairment,

hypothyroidism, malnutrition, or hypothermia, hypotensive. May aggravate angina caused by hypertrophic cardiomyopathy. Tolerance may develop after long-term treatment. Lactation.

## INTERACTIONS:

Hypotensive effects may be increased when used with alcohol or vasodilators. Concurrent use with calcium channel blockers may lead to marked orthostatic hypotension. Potentially Fatal: Significant hypotension may occur when used with phosphodiesterase-5 inhibitors.

#### ADVERSE EFFECTS:

Hypotension, tachycardia, flushing, headache, dizziness, palpitation, syncope, confusion. Nausea, vomiting, abdominal pain. Restlessness, weakness and vertigo. Dry mouth, chest pain, back pain, oedema, fatigue, abdominal pain, constipation, diarrhoea, dyspepsia and flatulence. *Potentially Fatal:* Severe hypotension and cardiac failure.

# 142. ISOTRETINOIN BP 20MG CAP.

### SALIENT ACTIONS:

It belongs to a class of drugs known as retinoids. It works by decreasing facial oil (sebum) production. High amounts of sebum can lead to severe acne.

## INDICATIONS:

This medication is used to treat severe cystic acne (also known as nodular acne) that has not responded to other treatment (e.g., benzoyl peroxide or clindamycin applied to the skin or tetracycline or minocycline taken by mouth)

#### DOSAGE REGIMENS:

The recommended dosage range for isotretinoin is 0.5 to 1.0 mg/kg/day given in two divided doses with food for 15 to 20 weeks.

# CONTRAINDICATIONS:

isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for short periods of time.

#### PRECAUTIONS:

Do not donate blood while you are taking isotretinoin and for at least 1 month after you stop taking it. This medication may make you more sensitive to the sun. Limit your time in the sun. Avoid tanning booths and sunlamps. Use sunscreen and wear protective clothing when outdoors.

# Isotretinoin can affect your night vision. Do not drive

#### INTERACTIONS:

tetracyclines (e.g., minocycline, tetracycline), vitamin A-type drugs (e.g., acitretin, bexarotene), vitamin A, drugs that cause bone loss (e.g., anti-seizure drugs such as phenytoin, corticosteroids such as prednisone).

#### ADVERSE EFFECTS:

mental/mood changes (e.g., depression, aggressive or violent behavior, and in rare cases, thoughts of suicide), tingling feeling in the skin, back/joint/muscle pain, signs of infection (e.g., fever, persistent sore throat), painful swallowing, peeling skin on palms/soles.

severe headache, vision changes, ringing in the ears, hearing loss, chest pain, yellowing eyes/skin, dark urine, severe diarrhea, rectal bleeding.

# 143. ISOXSUPRINE HCL(DUVADILAN 10 MG TAB)

## SALIENT ACTIONS:

It is β-Adrenergic receptor stimulant.

#### INDICATIONS:

1. For the relief of symptoms associated with cerebral vascular insufficiency

2. In Peripheral vascular disease of arteriosclerosis obliterans, thromboangitis obliterans (Buerger's Disease) and Raynaud's disease.

3. As a tocolytic

# DOSAGE REGIMENS:

Oral: 10 to 20 mg three or four times daily

## CONTRAINDICATIONS:

current abnormal bleeding, recent childbirth.

#### PRECAUTIONS:

N/A

#### INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

hypotension, tachycardia, chest pain, nausea, vomiting, dizziness, abdominal distress, and severe rash. If rash appears, the drug should be discontinued.

# 144. ITOPRIDE Tab 50 mg

#### SALIENT ACTIONS:

Itopride increases acetylcholine concentrations by inhibiting dopamine D2 receptors and acetylcholinesterase. Higher acetylcholine increases GI peristalsis, increases the lower esophageal sphincter pressure, stimulates gastric motility, accelerates gastric emptying, and improves gastro-duodenal coordination.

# INDICATIONS & DOSAGE REGIMENS:

Should be taken on an empty stomach (i.e. At least one hour before food or two hours after food). (Take before meals.)

Antiemetic, Prokinetic agent: Feeling of gastric fullness, upper abdominal pain, anorexia, heartburn, nausea and vomiting; non-ulcer dyspepsia or chronic gastritis. Adult: 50 mg tid.

#### CONTRAINDICATIONS:

Hypersensitivity; lactation. GI hemorrhage, obstruction or perforation. Pregnancy, elderly.

#### PRECAUTIONS:

Itopride is contraindicated in hypersensitivity to itopride or benzamides; lactation, GI hemorrhages obstruction or perforation. Itopride may not be indicated for those suffering from Parkinson's disease or other conditions involving dopamine regulation issues.

#### INTERACTIONS:

Anticholinergic agents reduce the action of itopride.

#### ADVERSE EFFECTS:

Rash, diarrhoea, constipation, abdominal pain, headache, sleeping disorders, dizziness, galactorrhea, gynecomastia. *Potentially Fatal:* Leucocytopenia.

#### ITRACONAZOLE CAP

SALIENT ACTIONS: Antifungal

# INDICATIONS & DOSAGE REGIMENS:

Tinea corporis; Tinea cruris As cap: 100 mg/day for 15 days or 200 mg/day for 7 days. Nail fungal infections As cap: 200 mg/day for 3 mth. Systemic fungal infections As cap: 100-200 mg once daily, increased to 200 mg bid for invasive or disseminated infections. For life-threatening infections: Loading dose: 200 mg tid for 3 days. Prophylaxis of infections in neutropenic or AIDS patients As cap: 200 mg/day, increased to 200 mg bid. Tinea manuum; Tinea pedis As cap: 100 mg/day for 30 days or 200 mg bid for 7 days. IV

# CONTRAINDICATIONS:

Hypersensitivity. Severe renal impairment (IV). Co-admin w/ astemizole, bepridil, cisapride, dofetilide, levacetylmethadol (levomethadyl), mizolastine, pimozide, quinidine, sertindole, terfenadine, atorvastatin, lovastatin, simvastatin, triazolam, oral midazolam, ergot alkaloids (e.g. ergotamine, dihydroergotamine, ergometrine, methylergometrine), eletriptan, nisoldipine, felodipine, disopyramide, methadone, ranolazine, eplerenone, dronedarone, halofantrine, irinotecan, lurasidone, and in patients w/ renal and hepatic impairment, colchicine.

## PRECAUTIONS:

Patient w/ risk factors for CHF (e.g. ischaemic and valvular disease, COPD, renal failure, oedematous disorders). Renal and hepatic impairment. Pregnancy and lactation. Patient Counselling May impair ability to drive or operate machinery. Monitoring Parameters Monitor liver function, serum concentrations, renal function, signs and symptoms of CHF.

## INTERACTIONS:

May increase the plasma concentrations of oral anticoagulants, digoxin, cilostazol, alprazolam, midazolam (IV), repaglinide, corticosteroids (e.g. budesonide, dexamethasone, fluticasone, methylprednisolone). May increase plasma concentration w/ HIV protease inhibitors

#### ADVERSE EFFECTS:

Nausea, vomiting, diarrhoea, abdominal pain, anorexia, constipation, dyspepsis, dysphagia, flatulence, gastritis, taste perversion, ulcerative stomatitis, gingivitis, gastroenteritis, increased appetite, rash, pruritus, urticaria, angioedema, alopecia, toxic epidermal necrolysis, headache, dizziness, somnolence, decreased libido, insomnia, depression, tremor, anxiety, fatigue, malaise, asthenia, vertigo, HTN, hypokalaemia, peripheral oedema, mild

transient increase in liver enzyme values, hepatitis, adrenal insufficiency, gynaecomastia, male breast pain, albuminuria, impotence, UTI, cystitis, abnormal renal function

## 145. IVERMECTIN 12MG TAB

#### SALIENT ACTIONS:

Ivermectin binds selectively and with high affinity to glutamate-gated chloride ion channels in invertebrate muscle and nerve cells of the microfilaria. This binding causes an increase in the permeability of the cell membrane to chloride ions and results in hyperpolarization of the cell, leading to paralysis and death of the parasite.

## INDICATIONS & DOSAGE REGIMENS:

Adult: PO Onchocerciasis ≥15 kg: 150 mcg/kg as a single dose 6-12 mthly until adult worms die. Strongyloidiasis 200 mcg/kg as a single dose for 1-2 days. Filariasis Mansonella streptocerca Single dose of 150 mcg/kg; Mansonella ozzardi Single dose of 200 mcg/kg. Ascariasis Ascaris lumbricoidesSingle dose of 150-200 mcg/kg. Gnathostomiasis Gnathostoma spinigerum: 200 mcg/kg once daily for 2 days. Scabies Sarcoptes scabiei 200 mcg/kg as a single dose, repeat dose in 2 wk.

#### CONTRAINDICATIONS:

Hypersensitivity.Pregnancy and lactation.Childn <15 kg body weight.

# PRECAUTIONS:

Concurrent Loa loa infection, impaired blood-brain barrier function due to infection.

#### INTERACTIONS:

Bioavailability may be increased by alcohol, levamisole.

#### ADVERSE EFFECTS:

Diarrhoea, nausea, vomiting, dizziness, pruritus, urticaria, rash, arthralgia, fever, myalgia, asthenia, postural hypotension, tachycardia, oedema, lymphadenopathy, sore throat, cough, headache, somnolence, transient eosinophilia, raised liver enzyme values.

#### 146. LABETALOL 100 MG TAB

SALIENT ACTIONS: Beta-Blockers

#### INDICATIONS & DOSAGE REGIMENS:

**Adult:** PO **HTN** Initial: 100 mg bid, may increase gradually according to patients response to 200-400 mg bid. Max: 2.4 g/day in 2-4 divided doses.

#### **CONTRAINDICATIONS:**

Obstructive airway disease (e.g. bronchial asthma), 2nd and 3rd degree heart block, cardiogenic shock, conditions w/ severe or prolonged hypotension, uncompensated heart failure, severe bradycardia.

## PRECAUTIONS:

Patients w/ phaeochromocytoma, inadequate cardiac function and well-compensated heart failure, DM, nonallergic bronchospasm.Patients undergoing major surgery involving general anaesth.May mask symptoms of hypoglycaemia. Avoid abrupt withdrawal as it may exacerbate angina. Hepatic impairment.Elderly, pregnancy and lactation. Monitoring Parameters Monitor LFT periodically and BP.

#### INTERACTIONS:

Synergistic hypotensive effect w/ halothane.Increased absolute bioavailability w/ cimetidine.Decreased absolute bioavailability w/ glutethimide.Additive hypotensive effect w/ nitroglycerin.Increased incidence of tremor w/ TCAs.Increased risk of bradycardia and heart block w/ Ca channel blocker (e.g. verapamil, diltiazem).

## ADVERSE EFFECTS:

Intraoperative floppy iris syndrome, orthostatic hypotension, bradycardia, syncope, paraesthesia, dizziness, dyspnoea, fatigue, vertigo, headache, nasal stuffiness, diarrhoea, abdominal pain, male sexual dysfunction, dyspepsia, nausea, vomiting, flatulence, constipation, taste disturbances, scalp tingling, tremor, muscle weakness, urinary retention, hepatitis, jaundice, rash, increased transaminases, nightmares, claudication. **Potentially Fatal:** Hepatic injury.

# 147. LACTIC ACID BACILLUS(TABLET)

#### SALIENT ACTIONS:

lactic acid producing organisms, combinations; Belongs to the class of antidiarrheal microorganisms. INDICATIONS:

Constipation, Diarrhea, Antibiotic associated diarrhea, Gastrointestinal disorders, Gastro-intestinal disorders, Pseudomembranous colitis

#### DOSAGE REGIMENS:

N/A

#### CONTRAINDICATIONS:

N/A

#### PRECAUTIONS:

N/A

#### INTERACTIONS:

- Alcohol
- Antibiotic drugs
- Azathioprine
- Barbiturates
- Basiliximab
- Cyclosporine
- Diphenylhydantoin
- Methotrexate
- Nitrofurantoin

#### ADVERSE EFFECTS:

- Gas
- Bloating
- Gastro-intestenal Infection

# 148. LAMIVUDINE Tab 150 mg

#### SALIENT ACTIONS:

Lamivudine, a nucleoside analogue, is phosphorylated in the body to the active triphosphate form. In the active form, it inhibits hepatitis B virus polymerase and HIV reverse transcriptase enzymes.

#### INDICATIONS & DOSAGE REGIMENS:

- 1. HIV infection: Adult: 150 mg bid or 300 mg once daily. Child: 3 mth-12 yr: 4 mg/kg bid. Max: 300 mg/day.
- 2. Chronic hepatitis B: Adult: 100 mg once daily. For patients with concomitant HIV infection: 300 mg ODor in 2 divided doses. Child: >2 yr: 3 mg/kg once daily. Max: 100 mg/day...

Reduce dose in patients with renal impairment.

May be taken with or without food.

#### CONTRAINDICATIONS:

Hypersensitivity, Lactation.

#### PRECAUTIONS:

Pregnancy Category (US FDA) – C.Discontinue use if there is rapid increase in aminotransferase levels. progressive hepatomegaly, or metabolic or lactic acidosis of unknown origin, pancreatitis. Monitor hepatic function in chronic hepatitis B patients. Exclude HIV infection prior to hepatitis B therapy. Renal impairment.

#### INTERACTIONS:

Renal excretion may be inhibited by high doses of trimethoprim. Antagonise the antiviral action of zalcitabine.

## ADVERSE EFFECTS:

Abdominal pain, nausea, vomiting, diarrhoea, insomnia, cough, nasal symptoms, arthralgia, muscle pain, headache, fever, rash, alopecia, malaise, increased creatinine phosphokinase and alanine aminotransferase, peripheral neuropathy. Rarely rhabdomyolysis, pancreatitis, hepatitis, thrombocytopenia, increases in LFTs, paronychia, Angioedema, urticaria, and anaphylactoid reaction. Potentially Fatal: Lactic acidosis associated with severe hepatomegaly and hepatic steatosis.

#### 149. LAMOTRIGINE TABLET

#### INDICATIONS & DOSAGE REGIMENS:

Adult: PO Epilepsy Monotherapy or adjunctive therapy w/o valproate and enzyme-inducing antiepileptics: Initial: 25 mg once daily for 2 wk, then 50 mg once daily for 2 wk. Thereafter, increase by max of 50-100 mg/day every 1-2 wk (immediate-release), or increase by 50 mg/day at wkly interval for 3 wk then increase by 100 mg/day at wkly interval thereafter (extended-release tab). Maintenance: 100-200 mg/day (immediaterelease); 300-400 mg/day (extended-release). Adjunctive therapy w/ enzyme-inducing antiepileptics w/o valproate: Initial: 50 mg once daily for 2 wk, then 50 mg bid for 2 wk. Thereafter, increase by max of 100 mg/day every 1-2 wk (immediate-release), or increase by 100 mg/day at wkly interval (extended-release). Maintenance: 200-400 mg/day (immediate-release); 400-600 mg/day (extended-release). Adjunctive therapy w/ valproate: Initial: 25 mg every other day for 2 wk, then 25 mg once daily for 2 wk. Thereafter, increase by max of 25-50 mg/day every 1 to 2 wk (immediate-release), or double the daily dose at wkly interval for 2 wk then increase by 50 mg/day at wkly interval thereafter (extended-release). Maintenance dose: 100-200 mg/day (immediate-release); 200-250 mg/day (extended-release). **Bipolar disorder** Monotherapy or adjunctive therapy w/o valproate and enzyme inducing antiepileptics: Initial: 25 mg once daily for 2 wk, then 50 mg/day for 2 wk, then 100 mg/day for 1 wk, then increase to a target dose of 200 mg/day. Adjunctive therapy w/ enzyme-inducing antiepileptics w/o valproate: Initial: 50 mg once daily for 2 wk, then 50 mg bid for 2 wk, then 100 mg bid for 1 wk, then increase to a target dose of 400 mg/day. Adjunctive therapy w/ valproate: 25 mg every other day for 2 wk, then 25 mg once daily for 2 wk, then 50 mg/day for 1 wk, then increase to a target dose of 100 mg/day. Max: 200 mg/day.

## CONTRAINDICATIONS:

Hypersensitivity.

## PRECAUTIONS:

Renal and moderate to severe hepatic impairment. Childn. Pregnancy and lactation. Avoid abrupt dose reduction and withdrawal. Patient Counselling This drug may cause dizziness and drowsiness, if affected do not drive or operate machinery. Monitoring Parameters Monitor for clinical worsening and suicidality, hypersensitivity reactions (e.g. rash), seizure frequency and duration, signs and symptoms of aseptic meningitis. Monitor hepatic and renal function.

# INTERACTIONS:

Increased plasma concentration and risk of severe skin reactions w/ valproate. Decreased plasma concentration w/ carbamazepine, phenytoin, phenobarbital, primidone, rifampicin, lopinavir/ritonavir, atazanavir/ritonavir, hormonal contraceptives.

#### ADVERSE EFFECTS.

Significant: Rash, aseptic meningitis, blood dyscrasias, CNS depression, suicidal ideation and behaviour.Nervous: Dizziness, drowsiness, headache, ataxia, tremor, fatigue, weakness, flu-like symptoms, coordination abnormality, anxiety, insomnia, aggression, irritability. CV: Lymphadenopathy. GI: Nausea, vomiting, diarrhoea, abdominal pain, dyspepsia, dry mouth. Resp: Bronchitis, rhinitis, chest pain.Endocrine: Wt decrease, dysmenorrhoea. Haematologic: Leucopenia, neutropenia, thrombocytopenia, agranulocytosis. Musculoskeletal: Arthralgia. Ophthalmologic: Diplopia,

nystagmus. Dermatologic:Photophobia. Immunologic: Hypersensitivity reactions, infection. Others: Fever, pain. **Potentially Fatal:** Serious skin rashes, Stevens-Johnson syndrome, toxic epidermal necrolysis. Rarely, multiorgan hypersensitivity reactions.

#### 150. LANSOPRAZOLE 30MG TAB

#### SALIENT ACTIONS:

Belongs to the class of proton pump inhibitors

#### INDICATIONS & DOSAGE REGIMENS:

Adult: PO Acid-related dyspepsia 15-30 mg once in the morning for 2-4 wk. GERD 15-30 mg once in the morning for 4-8 wk. Maintenance: 15-30 mg once daily. Erosive oesophagitis 30 mg once in the morning for up to 8 wk. Maintenance: 15 mg once daily. Peptic ulcer 30 mg once in the morning for up to 4 wk (duodenal ulcer) or up to 8 wk (gastric ulcer). H.pylori infection 30 mg bid, usually w/ clarithromycin and amoxicillin or metronidazole. NSAID-associated ulceration 30 mg once in the morning for 4-8 wk. Prophylaxis of NSAID-induced ulcers 15-30 mg once in the morning. Zollinger-Ellison syndromeInitial: 60 mg once in the morning. Daily doses >120 mg should be given in 2 divided doses. IV Erosive oesophagitis 30 mg over 30 min for up to 7 days.

# CONTRAINDICATIONS:

Concomitant use w/ rilpivirine and atazanavir.

#### PRECAUTIONS:

Gastric malignancy should be ruled out. Hepatic impairment.Pregnancy and lactation. Monitoring Parameters Monitor Mg levels prior to initiation and periodically during prolonged use.

## **INTERACTIONS:**

Increased risk of hypomagnesaemia w/ diuretics and digoxin. May decrease plasma concentration of erlotinib, dasatinib and lapatinib. May decrease the bioavailability of itraconazole and ketoconazole. May increase plasma concentration of cilostazol and methotrexate. Reduced bioavailability w/ antacids and sucralfate.

Potentially Fatal: May decrease serum levels and pharmacological effects of rilpivirine and atazanavir.

#### ADVERSE EFFECTS:

Increased risk of Clostridium difficile-associated diarrhoea (CDAD) and osteoporosis-related fractures. Diarrhoea, abdominal pain, nausea, vomiting, flatulence, constipation, headache, dry mouth, peripheral oedema, dizziness, sleep disturbances, fatigue, paraesthesia, arthralgia, myalgia, rash, pruritus, pancreatitis, glossitis, tremor, anorexia, restlessness, impotence, petechiae, purpura. Rare or very rarely, taste disturbance, stomatitis, hepatitis, jaundice, hypersensitivity reactions (e.g. bronchospasm), fever, depression, hallucinations, confusion, gynaecomastia, interstitial nephritis, hyponatraemia, hypomagnesaemia, blood disorders (e.g. leucopenia, leucocytosis, pancytopenia, thrombocytopenia), visual disturbances, sweating, photosensitivity, alopecia; colitis, increased serum cholesterol or triglycerides.

Potentially Fatal: Anaphylaxis, Stevens-Johnson syndrome and toxic epidermal necrolysis.

#### 151. LECITHIN CAPSULE

#### SALIENT ACTIONS:

Lecithin is a fat that is essential in the cells of the body. It can be found in many foods, including soybeans and egg yolks. Lecithin is converted into acetylcholine, a substance that transmits nerve impulses.

#### INDICATIONS:

Lecithin is used for treating memory disorders such as dementia and Alzheimer's disease. It is also used for treating gallbladder disease, liver disease, certain types of depression, high cholesterol, anxiety, and a skin disease called eczema.

#### DOSAGE REGIMENS:

lecithin in cognitive impairment have used a wide variety of doses, from 1 to 35 g daily.

# CONTRAINDICATIONS:

N/A

#### PRECAUTIONS:

N/A

#### INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

anorexia, nausea, increased salivation, other GI effects, and hepatitis.

# 152. LETROZOLE CAP

# SALIENT ACTIONS:

LetrozoleBelongs to the class of aromatase enzyme inhibitors.

INDICATIONS & DOSAGE REGIMENS: Adult: PO Advanced or locally advanced breast cancer; Adjuvant treatment in early breast cancerIn hormone receptor +ve postmenopausal women: 2.5 mg once daily.

#### CONTRAINDICATIONS:

Premenopausal status. Pregnancy and lactation.

#### PRECAUTIONS:

Patient w/ history of osteoporosis and/or fracture. Severe hepatic impairment (Child-Pugh score C) or cirrhosis. Patient Counselling This drug may cause somnolence and dizziness, if affected, do not drive or operate machinery. Monitoring Parameters Monitor LH and FSH level prior to therapy. Monitor BP, CBC, thyroid function test, BMD level, serum electrolytes, cholesterol, transaminases, and creatinine periodically INTERACTIONS:

Tamoxifen, anti-oestrogen agent, oestrogen-containing drugs may diminish the pharmacological action of letrozole. Decreased plasma concentration w/ strong CYP3A4 inducers (e.g. rifampicin).

#### ADVERSE EFFECTS:

Significant: Decreased BMD, CNS depression, hypercholesterolaemia. Nervous: Dizziness, insomnia, somnolence, fatigue, headache, hypertension. CV: Peripheral oedema, HTN, MI. GI: Nausea, anorexia, increased appetite, dyspepsia, constipation, abdominal pain, diarrhoea, vomiting. Resp: Dyspnoea, cough. Hepatic: Increased liver enzymes. Genitourinary: Vag bleeding. Endocrine: Hot flushes, wt gain. Haematologic: Thrombocytopenia. Musculoskeletal: Osteoporosis, bone fracture, arthralgia, myalgia. Dermatologic: Sweating, alopecia; erythematous, psoriaform, maculopapular or vesicular rash, dry skin.

# 153. LEUCOVORIN CALCIUM TABLET 15 MG SALIENT ACTIONS:

Leucovorin as the calcium salt of N-[4-[[(2-amino-5-formyl-1, 4, 5, 6, 7, 8-hexahydro-4-oxo-6-pteridinyl)methyl]amino]benzoyl]-L-glutamic acid. Leucovorin is a water soluble form of reduced folate in the folate group; it is useful as an antidote to drugs which act as folic acid antagonists. These tablets are intended for oral administration only

#### INDICATIONS:

Indicated to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosages of folic acidantagonists.

# DOSAGE REGIMENS:

oral administration of doses greater than 25 mg is not recommended.

# Impaired Methotrexate Elimination or Inadvertent Overdosage

Leucovorin rescue should begin as soon as possible after an inadvertent overdosage and within 24 hours of methotrexate administration when there is delayed excretion. Leucovorin 15 mg (10 mg/m²) should be administered IM, IV, or PO every 6 hours until serum methotrexate level is less than 10 -8 M. In the presence of gastrointestinal toxicity, nausea, or vomiting, leucovorin should be administered parenterally. The recommended dose of leucovorin to counteract hematologic toxicity from folic acid antagonists with less affinity for mammalian dihydrofolate reductase than methotrexate (i.e., trimethoprim, pyrimethamine) is substantially less and 5 to 15 mg of leucovorin per day has been recommended .

# CONTRAINDICATIONS:

Leucovorin is improper therapy for pernicious anemia and other megaloblastic anemias secondary to the lack of vitamin B<sub>12</sub>. A hematologic remission may occur while neurological manifestations continue to progress.

## PRECAUTIONS:

General

Parenteral administration is preferable to oral dosing if there is a possibility that the patient may vomit or not absorb the leucovorin. Leucovorin has no effect on other established toxicities of methotrexate, such as the nephrotoxicity resulting from drug and/or metabolite precipitation in the kidney. Pregnancy

# Teratogenic Effects

Pregnancy Category C.

Leucovorin should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when leucovorin is administered to a nursing mother.

#### INTERACTIONS:

Folic acid in large amounts may counteract the antiepileptic effect of phenobarbital, phenytoin and primidone, and increase the frequency of seizures in susceptible children.

Preliminary animal and human studies have shown that small quantities of systemically administered leucovorin enter CSF primarily as 5-methyltetrahydrofolate and, in humans, remain 1 to 3 orders of magnitude lower than usual methotrexate concentrations following intrathecal administration. However, high doses of leucovorin may reduce the efficacy of intrathecally administered methotrexate.

Leucovorin may enhance the toxicity of fluorouracil.

# ADVERSE REACTIONS:

Allergic sensitization, including anaphylactoid reactions and urticaria, has been reported following the administration of both oral and parenteral leucovorin.

# 154. LEVETIRACETAM 250 TABLET

## SALIENT ACTIONS:

The exact mechanism by which levetiracetam acts to treat epilepsy is unknown. However, the drug binds to a synaptic vesicle glycoprotein, SV2A, [26] and inhibits presynaptic calcium channels [27] reducing neurotransmitter release and acting as a neuromodulator. This is believed to impede impulse conduction across synapses.

#### INDICATIONS:

Epilepsy

Seizures

# DOSAGE REGIMENS:

Dosage in adults and adolescents (12 to 17 years) weighing 50 kg or more:

between 1,000 mg (4 tablets) and 3,000 mg (12 tablets) each day. •Levetiracetam must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

Dosage in infants (6 to 23 months), children (2 to 11 years) and adolescents (12 to 17 years) weighing less than 50 kg:

between 20 mg/kg and 60 mg/kg each day.

Infants (1 month to less than 6 months):

Dosage in infan between 14 mg/kg and 42 mg/kg each day

#### CONTRAINDICATIONS:

Levetiracetam tablets are contraindicated in patients with a hypersensitivity to Levetiracetam. Reactions have included anaphylaxis and angioedema.

#### PRECAUTIONS and Adverse effects:

#### Warnings for special population

## Pregnancy

This medicine is not recommended for use in pregnant women. Use only if clearly needed under the supervision of the doctor.

#### **Breast-feeding**

This medicine is known to excreted through human breast milk. It is not recommended for breastfeeding women.

#### General warnings

# Suicidal tendency

Use of Levipil 250 MG Tablet may increase the risk of suicidal thoughts. It should be used with caution and prescription size should be limited if you are suffering from depression or suicidal tendencies.

#### Blood cells count

Levipil 250 MG Tablet may cause a decrease in the blood cells count. Frequent monitoring of blood tests is to be performed and discontinue taking the medicine if Levitiracetram is suspected to be the cause.

#### Somnolence and Fatigue

Levipil 250 MG Tablet may cause sleepiness and tiredness. Avoid activities that need mental alertness like driving or operating machinery.

# **Dermatological reactions**

Levipil 250 MG Tablet may cause serious skin reactions. These reactions may occur after 14 to 17 days of initiation of therapy. Any symptoms of skin reactions should be informed to the doctor. Discontinue taking the medicine if it's suspected to cause the reaction,

#### Impaired kidney function

Levipil 250 MG Tablet is used with caution if you have kidney disease. Suitable dose adjustments are to be made based on the CrCl or GFR.

#### Impaired liver function

Levipil 250 MG Tablet is used with caution if you have liver disease due to the reduced clearance of the medicine from the body.

# INTERACTIONS:

# Interaction with Alcohol

Use of this medicine with alcohol will cause depression of the central nervous system and respiratory system. Consumption of alcohol with this medicine is not recommended as it can result in dizziness and difficulty in concentration. Avoid activities that need mental alertness like driving or operating machinery.

#### 155. LEVOCARNITINE 500MG TABLET

#### SALIENT ACTIONS:

Levocarnitine is a naturally occurring substance in the body, which is involved in protein, fat, and carbohydrate metabolism. It is an essential component of energy production.

#### INDICATIONS:

#### Primary systemic carnitine deficiency

Carnisure 500 mg Tablet is used in the treatment of Primary systemic carnitine deficiency, a condition characterized by muscle weakness, abdominal pain, vomiting, chest pain, and low blood glucose levels.

#### Secondary carnitine deficiency

Carnisure 500 mg Tablet is used in the treatment of secondary carnitine deficiency, a condition in which carnitine is not available in an appropriate amount for fat metabolism due to metabolic disorders.

Valproate toxicity

Heart condition that affects infants and children

#### PRECAUTIONS:

This product may contain inactive ingredients (such as peanut/soy), which can cause allergic reactions or other problems.

### ADVERSE EFFECTS:

Burning

Tingling sensation

Drug-related body odor

Headache

Nausea

Bone pain

# 156. LEVOFLOXACIN Tab 250 mg / 500 mg SALIENT ACTIONS:

Levofloxacin exerts antibacterial action by inhibiting bacterial topoisomerase IV and DNA gyrase, the enzymes required for DNA replication, transcription repair and recombination. It has in vitro activity against a wide range of gram-negative and gram-positive microorganisms.

# INDICATIONS & DOSAGE REGIMENS:

- 1. Acute bacterial sinusitis, Community-acquired pneumonia: Adult: 500 mg OD for 10-14 days or 750 mg OD for 5 days.
- Acute bacterial exacerbation of chronic bronchitis: Adult: 500 mg OD for 7 days.
- 3. Nosocomial pneumonia, complicated skin and skin structure infections: Adult: 750 mg OD for 7-14 days.Renal impairment: Haemodialysis/CAPD: Initially, 750 mg daily, then 500 mg every 48 hr.
- 4. Uncomplicated skin and skin structure infections: Adult: 500 mg OD for 7-10 days.
- 5. Uncomplicated urinary tract infections: Adult: 250 mg OD for 3 days.
- 6. Complicated urinary tract infections, Acute pyelonephritis: Adult: 250 mg OD for 10 days.
- 7. Chronic bacterial prostatitis: Adult: 500 mg OD for 28 days.
- 8. Treatment and post exposure prophylaxis of inhalation anthrax: Adult: 500 mg OD for 60 days. Renal impairment: Haemodialysis/CAPD: Initially, 500 mg daily, then 250 mg every 48 hr.

#### PRECAUTIONS:

Pregnancy Category (US FDA) -C.Known or suspected CNS disorders that predispose to seizures.H/O Wide QT interval, uncorrected electrolyte disturbances. DM. Periodically monitor renal, hepatic and haematopoietic functions during treatment. Pregnancy and lactation. Elderly. Avoid unnecessary exposure to sunlight or artificial UV light.

# INTERACTIONS:

Increased concentration of ciclosporin or tacrolimus. Reduced absorption with didanosine, ferrous sulfate or dietary supplements containing zinc, calcium, magnesium or iron. Increase plasma levels of theophylline. Increased risk of tendon rupture with corticosteroids. Reduced absorption with sucralfate and antacids containing magnesium and aluminium; administer at least 2 hr before or 2 hr after antacids. Increased half-life and decreased clearance of procainamide. Altered glucose levels with antidiabetic agents (e.g. insulin, glyburide). Potentially Fatal: Increased risks of ventricular arrhythmias with QT prolonging drugs e.g. class IA (quinidine, procainamide) or class III (amiodarone, sotalol) antiarrhythmics, fluoxetine, imipramine. Increased risk of CNS stimulation and seizures with NSAIDs. Increased prothrombin time with warfarin.

### ADVERSE EFFECTS:

Nausea, diarrhoea, constipation, headache, insomnia. Potentially Fatal: Anaphylaxis.

## 157. LEVONORGESTREL 1.5MG TAB

SALIENT ACTIONS: Is a progestin-only emergency contraceptive indicated for prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure. To obtain optimal efficacy, the tablet should be taken as soon as possible within 72 hours of intercourse. an agonist of the progesterone receptor (PR), the main biological target of the progestogen sex hormone progesterone. [23] It is also a weak agonist of the androgen receptor (AR), the main biological target of the androgen sex hormone testosterone

To prevent fertilization by inhibition of ovulation and thickening of cervical mucus

INDICATIONS & DOSAGE REGIMENS:

Birth control pills

At low doses, levonorgestrel is used in <u>monophasic</u> and <u>triphasic</u> formulations of <u>combined oral contraceptive</u> <u>pills</u>, with available monophasic doses ranging from 100–250  $\mu$ g, and triphasic doses of 50  $\mu$ g/75  $\mu$ g/125  $\mu$ g. It is combined with the estrogen ethinylestradiol in these formulations.

At very low daily dose of 30 µg, levonorgestrel is used in some progestogen only pill formulations.

## Emergency birth control[edit]

Levonorgestrel is used in emergency contraceptive pills (ECPs), both in a combined <u>Yuzpe regimen</u> which includes estrogen, and as a levonorgestrel-only method. The levonorgestrel-only method uses levonorgestrel 1.5 mg (as a single dose or as two 0.75 mg doses 12 hours apart) taken within 3 days of unprotected sex, with one study indicating that beginning as late as 120 hours (5 days) after intercourse could be effective.

#### INTERACTIONS:

If taken together with drugs that <u>induce</u> the <u>CYP3A4</u> <u>cytochrome P450</u> <u>liver</u> <u>enzyme</u>, levonorgestrel may be <u>metabolized</u> faster and may have lower effectiveness.

#### ADVERSE EFFECTS:

The most commonly reported adverse effects are alterations of menstrual bleeding patterns, nausea, abdominal/pelvic pain, headache/migraine, dizziness, fatigue, amenorrhea, ovarian cysts, genital discharge, acne/seborrhea, breast tenderness, and vulvovaginitis. Irregular menstrual bleeding. Abdominal or stomach pain, dizziness, headache, Nausea, tenderness of the breasts, unusual tiredness or weakness, vomiting

#### CONTRAINDICATIONS:

Pregnancy, undiagnosed vaginal bleeding, severe arterial disease; liver adenoma, porphyria; after recent evacuation of hydatidiform mole; history of breast cancer; hepatic impairment.

#### PRECAUTIONS:

Pregnancy Category (US FDA) – X. Sex-steroid dependent cancer, past ectopic pregnancy, malabsorption syndromes, functional ovarian cysts, active liver disease, recurrent cholestatic jaundice, history of jaundice in pregnancy, cardiovascular or renal impairment, DM, asthma, epilepsy, migraine, conditions aggravated by fluid retention, depression and thromboembolism; lactation.

# 158. LEVONORGESTREL 0.15 mg + ETHINYLOESTRADIOL 0.03 mg Tab SALIENT ACTIONS:

Combination of hormonal contraceptives inhibits ovulation by modulating pituitary secretion of gonadotrophins, luteinising hormone and follicle stimulating hormone through a negative feedback system. They reduce sperm penetration if ovulation does occur by altering the cervical mucus; cause changes in the endometrium which reduce the risk of nidation and may change the tubal transport of the ova through the fallopian tubes.

#### INDICATIONS & DOSAGE REGIMENS:

Contraception: Adult: Monophasic combined oral contraceptive (COC): levonorgestrel 150-250 mcg + ethinylestradiol 30 mcg once daily.

Triphasic COC: levonorgestrel 50-125 mcg + ethinylestradiol 30-40 mcg once daily.

## CONTRAINDICATIONS:

Pregnancy, undiagnosed vaginal bleeding, severe arterial disease; liver adenoma, porphyria; after recent evacuation of hydatidiform mole; history of breast cancer; hepatic impairment.

#### PRECAUTIONS:

Pregnancy Category (US FDA) – X. Sex-steroid dependent cancer, past ectopic pregnancy, malabsorption syndromes, functional ovarian cysts, active liver disease, recurrent cholestatic jaundice, history of jaundice in pregnancy, cardiovascular or renal impairment, DM, asthma, epilepsy, migraine, conditions aggravated by fluid retention, depression and thromboembolism; lactation.

#### INTERACTIONS:

CYP3A4 inducers may decrease levels/effects eg aminoglutethimide, carbamazepine, nafcillin, nevirapine, atazanavir, nelfinavir, phenobarbital, phenytoin, lamotrigine, rifamycins, griseofulvin and ritonavir; ampicillin, tetracycline and other antibiotics may reduce efficacy; oestrogens may antagonise anticoagulant effect of coumarins; may inhibit metabolism of prednisolone and ciclosporin; may reduce clearance of alprazolam, chlordiazepoxide, diazepam; may increase clearance of lorazepam, oxazepam, temazepam

# ADVERSE EFFECTS:

Menstrual irregularities; headache, dizziness; breast discomfort; depression; disturbance of appetite; wt changes; fluid retention; oedema; changes in libido; hair loss or hirsutism; GI disturbances (nausea and vomiting); genitourinary changes; haematologic disorders; endocrine and metabolic disorders; cholestatic jaundice; local skin reactions; chorea; contact lens intolerance; steeping of corneal curvature; pulmonary thromboembolism; carbohydrate and/or glucose intolerance; depression; chloasma; BP increase, liver impairment; reduced

menstrual loss, 'spotting' in early cycles, absence of withdrawal bleeding; rarely photosensitivity; increased risk in breast cancer; elevation of plasma bound iodine, cortisol and thyroid binding, erythrocyte sedimentation may be accelerated; increases in plasma copper, iron and alkaline phosphatase; may affect serum triglyceride and lipoprotein levels; retinal vascular thrombosis.

# 159. LINEZOLID Tab 600 mg

## SALIENT ACTIONS:

Linezolid is a bacteriostatic oxazolidinone, inhibiting ribosomal protein synthesis. It is active against gram-positive bacteria including vancomycin-resistant enterococci and MRSA. It has limited in-vitro activity against gram-negative bacteria.

#### INDICATIONS & DOSAGE REGIMENS:

Uncomplicated / Complicated skin and skin structure infections: Adult: 400 mg every 12 hr for 10-14 days. Child: 10 mg/kg every 12 hr for 10-14 days; 12-18 yr: 600 mg every 12 hr for 10-14 days.

#### CONTRAINDICATIONS:

Hypersensitivity.

#### PRECAUTIONS:

Pregnancy Category (US FDA) – C. Preexisting myelosuppression, renal impairment (CrCl < 30ml/min), uncontrolled hypertension, phaeochromocytoma, carcinoid syndrome, untreated hyperthyroidism, chronic infection, history of seizures, psychotic disturbances.

## INTERACTIONS:

Use cautiously with serotonergic, vasopressor or dopaminergic agents to reduce the incidence of serotonin syndrome. Precipitate hypertension with Adrenergic drugs Eg. Dopamine, epinephrine, phenylpropanolamine and pseudoephedrine. Concurrent use with tramadol may increase risk of seizures. *Potentially Fatal:* MAOI; avoid concurrent use or use within 2 wk of stopping another MAOI to reduce risk of hypertensive crisis.

#### ADVERSE EFFECTS:

Diarrhoea, headache, nausea, vomiting, constipation, abnormal liver function tests, fever, vaginal and oral candidiasis, skin rash, pruritus, dizziness, insomnia, anaemia, tongue discoloration, taste disturbance, lactic acidosis, optic and peripheral neuropathy (particularly if used ≥ 28 days). *Potentially Fatal:* Reversible myelosuppression including anaemia, leukopenia, pancytopenia and thrombocytopenia (particularly if using > 10-14 days), transient ischemic attacks, renal failure, Stevens-Johnson syndrome.

### 160. LITHIUM CARBONATE TABLET

#### SALIENT ACTIONS:

Also known as lithium salts, are primarily used as a psychiatric medication.

# Mechanism of action

Oxidative metabolism

Dopamine and G-protein coupling

Glutamate and NMDA receptors

GABA receptors

Cyclic AMP secondary messengers

Inositol depletion hypothesis

Intracellular calcium

#### INDICATIONS&DOSAGE REGIMENS:

the recommended starting dose in adults is:

Tablets: 300 mg three times daily

# Dosage for Acute Treatment of Manic Episodes in Bipolar I Disorder

Titrate to serum lithium concentrations between 0.8 and 1.2 mEq/L, which may be achieved in adults with:

Tablets: 600 mg, two to three times daily

Obtain serum lithium concentrations regularly until the serum concentration and clinical condition of the patient has stabilized. Adjust daily dosage based on serum lithium concentration and clinical response.

# Dosage for Maintenance Treatment of Bipolar I Disorder

Titrate to serum lithium concentrations between 0.8 and 1 mEg/L, which may be achieved in adults with:

Tablets: 300 mg to 600 mg, two to three times daily

Monitor the patient's clinical state and serum lithium concentrations regularly

#### CONTRAINDICATIONS:

Lithium is contraindicated in patients with known hypersensitivity to any inactive ingredient in the lithium

carbonate tablet or capsule or lithium citrate products

#### PRECAUTIONS:

### **Pre-treatment Screening**

Before initiating treatment with lithium, renal function, vital signs, serum electrolytes, and thyroid function should be evaluated. Concurrent medications should be assessed, and if the patient is a woman of childbearing potential, pregnancy status and potential should be considered.

# Serum Lithium Monitoring

Blood samples for serum lithium determination should be drawn immediately prior to the next dose when lithium concentrations are relatively stable (i.e., 12 hours after the previous dose). Total reliance must not be placed on serum concentrations alone. Accurate patient evaluation requires both clinical and laboratory analysis. In addition to regular monitoring of serum lithium concentrations for patients on maintenance treatment, serum lithium concentrations should be monitored after any change in dosage, concurrent medication (e.g., diuretics, non-steroidal anti- inflammatory drugs, renin-angiotensin system antagonists, or metronidazole), marked increase or decrease in routinely performed strenuous physical activity (such as an exercise program) and in the event of a concomitant disease

Patients abnormally sensitive to lithium may exhibit toxic signs at serum concentrations that are within what is considered the therapeutic range. Geriatric patients often respond to reduced dosage, and may exhibit signs of toxicity at serum concentrations ordinarily tolerated by other patients

# Dosage Adjustments during Pregnancy and the Postpartum Period

If the decision is made to continue lithium treatment during pregnancy, monitor serum lithium concentrations and adjust the dosage as needed in a pregnant woman because renal lithium clearance increases during pregnancy. Avoid sodium restriction or diuretic administration. To decrease the risk of postpartum lithium intoxication, decrease or discontinue lithium therapy two to three days before the expected delivery date to reduce neonatal concentrations and reduce the risk of maternal lithium intoxication due to the change in vascular volume which occurs during delivery. At delivery, vascular volume rapidly decreases and the renal clearance of lithium may decrease to pre-pregnancy concentrations. Restart treatment at the preconception dose when the patient is medically stable after delivery with careful monitoring of serum lithium concentrations

# Dosage Adjustments for Patients with Renal Impairment

Start patients with mild to moderately impaired renal function (creatinine clearance 30 to 89 mL/min evaluated by Cockcroft-Gault) with dosages less than those for patients with normal renal function [see Dosage and Administration (2.2)]. Titrate slowly while frequently monitoring serum lithium concentrations and monitoring for signs of lithium toxicity. Lithium is not recommended for use in patients with severe renal impairment (creatinine clearance less than 30 mL/min evaluated by Cockcroft-Gault

## ADVERSE DRUG REACTIONS:

#### **Acute Lithium Toxicity**

The toxic concentrations for lithium (≥1.5 mEq/L) are close to the therapeutic range (0.8 to 1.2mEq/L). Some patients abnormally sensitive to lithium may exhibit toxic signs at serum concentrations that are considered within the therapeutic range .Lithium may take up to 24 hours to distribute into brain tissue, so occurrence of acute toxicity symptoms may be delayed.

Diarrhea, vomiting, drowsiness, muscular weakness and lack of coordination may be early signs of lithium toxicity, and can occur at lithium concentrations below 2.0 mEq/L. At higher concentrations, giddiness, ataxia, blurred vision, tinnitus and a large output of dilute urine may be seen. Serum lithium concentrations above 3.0 mEq/L may produce a complex clinical picture involving multiple organs and organ systems, coma, and eventually death. Serum lithium concentrations should not be permitted to exceed 2.0 mEq/L.

Neurological signs of lithium toxicity range from mild neurological adverse reactions such as fine tremor, lightheadedness, and weakness; to moderate manifestations like apathy, drowsiness, hyperreflexia, muscle twitching, and slurred speech; and severe manifestations such as clonus, confusion, seizure, coma and death. Cardiac manifestations involve electrocardiographic changes, such as prolonged QT interval, ST and T-wave changes and myocarditis. Renal manifestations include urine concentrating defect, nephrogenic diabetes insipidus, and renal failure. Respiratory manifestations include dyspnea, aspiration pneumonia, and respiratory failure. Gastrointestinal manifestations include nausea, vomiting, and bloating. No specific antidote for lithium poisoning is known. Early symptoms of lithium toxicity can usually be treated by reduction or cessation of lithium, before restarting treatment at a lower dose 24 to 48 hours later [see Overdosage (10)].

The risk of acute toxicity is increased with a recent onset of concurrent illness or with the concomitant administration of drugs which increase lithium serum concentrations by pharmacokinetic interactions [see Drug Interactions (7)]. Additional risk factors for acute lithium toxicity include acute ingestion, age-related decline in

renal function, volume depletion and/or changes in electrolyte concentrations, especially sodium and potassium. Dose requirements during the acute manic phase are higher to maintain therapeutic serum concentrations and decrease when manic symptoms subside. The risk of lithium toxicity is very high in patients with significant renal or cardiovascular disease, severe debilitation or dehydration, or sodium depletion, and for patients receiving prescribed medications that may affect kidney function, such as angiotensin converting enzyme inhibitors (ACE inhibitors), diuretics (loops and thiazides) and NSAIDs. For these patients, consider starting with lower doses and titrating slowly while frequently monitoring serum lithium concentrations and signs of lithium toxicity.

To reduce the risk of acute lithium toxicity during treatment initiation, facilities for prompt and accurate serum lithium determinations should be available before initiating treatment [see Boxed Warning, Dosage and Administration (2.6)]. Advise patients and caregivers to watch for signs of early toxicity and to discontinue lithium and immediately inform their health care provider if they occur.

Lithium-Induced Polyuria

Chronic lithium treatment may be associated with diminution of renal concentrating ability, occasionally presenting as nephrogenic diabetes insipidus, with polyuria and polydipsia. The concentrating defect and natriuretic effect characteristic of this condition may develop within weeks of lithium initiation. Lithium can also cause renal tubular acidosis, resulting in hyperchloremic metabolic acidosis. Such patients should be carefully managed to avoid dehydration with resulting lithium retention and toxicity. This condition is usually reversible when lithium is discontinued, although for patients treated with long-term lithium, nephrogenic diabetes insipidus may be only partly reversible upon discontinuation of lithium. Amiloride may be considered as a therapeutic agent for lithium-induced nephrogenic diabetes insipidus.

Hyponatremia

Lithium can cause hyponatremia by decreasing sodium reabsorption by the renal tubules, leading to sodium depletion. Therefore, it is essential for patients receiving lithium treatment to maintain a normal diet, including salt, and an adequate fluid intake (2500 to 3000 mL) at least during the initial stabilization period. Decreased tolerance to lithium has also been reported to ensue from protracted sweating or diarrhea and, if such occur, supplemental fluid and salt should be administered under careful medical supervision and lithium intake reduced or suspended until the condition is resolved. In addition, concomitant infection with elevated temperatures may also necessitate a temporary reduction or cessation of medication.

Symptoms are also more severe with faster-onset hyponatremia. Mild hyponatremia (i.e., serum Na > 120 mEq/L) can be asymptomatic. Below this threshold, clinical signs are usually present, consisting mainly of changes in mental status, such as altered personality, lethargy, and confusion. For more severe hyponatremia (serum Na < 115 mEq/L), stupor, neuromuscular hyperexcitability, hyperreflexia, seizures, coma, and death can result. During treatment of hyponatremia, serum sodium should not be elevated by more than 10 to 12 meq/L in 24 hours, or 18 meq/L in 48 hours. In the case of severe hyponatremia where severe neurologic symptoms are present, a faster infusion rate to correct serum sodium concentration may be needed. Patients rapidly treated or with serum sodium <120mEq/L are more at risk of developing osmotic demyelination syndrome (previously called central pontine myelinolysis). Occurrence is more common among patients with alcoholism, undernutrition, or other chronic debilitating illness. Common signs include flaccid paralysis, dysarthria. In severe cases with extended lesions patients may develop a locked-in syndrome (generalized motor paralysis). Damage often is permanent. If neurologic symptoms start to develop during treatment of hyponatremia, serum sodium correction should be suspended to mitigate the development of permanent neurologic damage.

Lithium-Induced Chronic Kidney Disease

The predominant form of chronic renal disease associated with long-term lithium treatment is a chronic tubulointerstitial nephropathy (CTIN). The biopsy findings in patients with lithium induced CTIN include tubular atrophy, interstitial fibrosis, sclerotic glomeruli, tubular dilation, and nephron atrophy with cyst formation. The relationship between renal function and morphologic changes and their association with lithium treatment has not been established. CTIN patients might present with nephrotic proteinuria (>3.0g/dL), worsening renal insufficiency and/or nephrogenic diabetes insipidus. Postmarketing cases consistent with nephrotic syndrome in patients with or without CTIN have also been reported. The biopsy findings in patients with nephrotic syndrome include minimal change disease and focal segmental glomerulosclerosis. The discontinuation of lithium in patients with nephrotic syndrome has resulted in remission of nephrotic syndrome. Kidney function should be assessed prior to and during lithium treatment. Routine urinalysis and other tests may be used to evaluate tubular function (e.g., urine specific gravity or osmolality following a period of water deprivation, or 24-hour urine volume) and glomerular function (e.g., serum creatinine, creatinine clearance, or

proteinuria). During lithium treatment, progressive or sudden changes in renal function, even within the normal range, indicate the need for re evaluation of treatment.

## Encephalopathic Syndrome

An encephalopathic syndrome, characterized by weakness, lethargy, fever, tremulousness and confusion, extrapyramidal symptoms, leukocytosis, elevated serum enzymes, BUN and fasting blood glucose, has occurred in patients treated with lithium and an antipsychotic. In some instances, the syndrome was followed by irreversible brain damage. Because of a possible causal relationship between these events and the concomitant administration of lithium and antipsychotics, patients receiving such combined treatment should be monitored closely for early evidence of neurological toxicity and treatment discontinued promptly if such signs appear. This encephalopathic syndrome may be similar to or the same as neuroleptic malignant syndrome (NMS).

#### Serotonin Syndrome

Lithium can precipitate serotonin syndrome, a potentially life-threatening condition. The risk is increased with concomitant use of other serotonergic drugs (including selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, triptans, tricyclic antidepressants, fentanyl, tramadol, tryptophan, buspirone, and St. John's Wort) and with drugs that impair metabolism of serotonin, i.e., MAOIs [see Drug Interactions (7.1)].

Serotonin syndrome signs and symptoms may include mental status changes (e.g., agitation, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, and gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Monitor all patients taking lithium for the emergence of serotonin syndrome. Discontinue treatment with lithium and any concomitant serotonergic agents immediately if the above symptoms occur, and initiate supportive symptomatic treatment. If concomitant use of lithium with other serotonergic drugs is clinically warranted, inform patients of the increased risk for serotonin syndrome and monitor for symptoms.

## Hypothyroidism or Hyperthyroidism

Lithium is concentrated within the thyroid and can inhibit thyroid synthesis and release which can lead to hypothyroidism. Where hypothyroidism exists, careful monitoring of thyroid function during lithium stabilization and maintenance allows for correction of changing thyroid parameters, if any. Where hypothyroidism occurs during lithium stabilization and maintenance supplemental thyroid treatment may be used. Paradoxically, some cases of hyperthyroidism have been reported including Grave's disease, toxic multinodular goiter and silent thyroiditis.

Monitor thyroid function before the initiation of treatment, at three months and every six to twelve months while treatment is ongoing. If serum thyroid tests warrant concern, monitoring should occur more frequently.

# Hypercalcemia and Hyperparathyroidism

Long-term lithium treatment is associated with persistent hyperparathyroidism and hypercalcemia. When clinical manifestations of hypercalcemia are present, lithium withdrawal and change to another mood stabilizer may be necessary. Hypercalcemia may not resolve upon discontinuation of lithium, and may require surgical intervention. Lithium-induced cases of hyperparathyroidism are more often multiglandular compared to standard cases. False hypercalcemia due to plasma volume depletion resulting from nephrogenic diabetes insipidus should be excluded in individuals with mildly increased serum calcium. Monitor serum calcium concentrations regularly.

#### Unmasking of Brugada Syndrome

There have been postmarketing reports of a possible association between treatment with lithium and the unmasking of Brugada Syndrome. Brugada Syndrome is a disorder characterized by abnormal electrocardiographic (ECG) findings and a risk of sudden death. Lithium should be avoided in patients with Brugada Syndrome or those suspected of having Brugada Syndrome. Consultation with a cardiologist is recommended if: (1) treatment with lithium is under consideration for patients suspected of having Brugada Syndrome or patients who have risk factors for Brugada Syndrome, e.g., unexplained syncope, a family history of Brugada Syndrome, or a family history of sudden unexplained death before the age of 45 years, (2) patients who develop unexplained syncope or palpitations after starting lithium treatment.

#### Pseudotumor Cerebri

Cases of pseudotumor cerebri (increased intracranial pressure and papilledema) have been reported with lithium use. If undetected, this condition may result in enlargement of the blind spot, constriction of visual fields and eventual blindness due to optic atrophy. Consider discontinuing lithium if this syndrome occurs.

#### INTERACTIONS:

Lithium concentrations are known to be increased with concurrent use of diuretics — especially loop diuretics (such as furosemide) and thiazides — and non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen.[23] Lithium concentrations can also be increased with concurrent use of ACE inhibitors such as captopril, enalapril, and lisinopril.

Lithium is mainly removed from the body through glomerular function, but some is then reabsorbed together with sodium through the proximal tubule. Its levels are therefore sensitive to water and electrolyte balance.] Diuretics act by lowering water and sodium levels; this causes more reabsorption of lithium in the proximal tubules so that the removal of lithium from the body is less, leading to increased levels of lithium.[58][59] ACE inhibitors have also been shown in a retrospective case-control study to increase lithium concentrations. This is likely due to constriction of the afferent arteriole of the glomerulus, resulting in decreased glomerular filtration rate and clearance. Another possible mechanism is that ACE inhibitors can lead to a decrease in sodium and water. This will increase lithium reabsorption and its concentrations in the body. There are also drugs that can increase the clearance of lithium from the body, which can result in decreased lithium levels in the blood. These drugs include theophylline, caffeine, and acetazolamide. Additionally, increasing dietary sodium intake may also reduce lithium levels by prompting the kidneys to excrete more lithium.

Lithium is also known to be a potential precipitant of serotonin syndrome in people concurrently on serotonergic medications such as antidepressants, buspirone and certain opioids such

as pethidine (meperidine), tramadol, oxycodone, fentanyl and others Lithium co-treatment is also a risk factor for neuroleptic malignant syndrome in people on antipsychotics and other antidopaminergic medications. High doses of haloperidol, fluphenazine, or flupenthixol may be hazardous when used with lithium; irreversible toxic encephalopathy has been reported. Indeed, these and other antipsychotics have been associated with increased risk of lithium neurotoxicity, even with low therapeutic lithium doses

# 161. LOPERAMIDE HCL 2MG CAPS SALIENT ACTIONS:

Loperamide is an opioid-receptor agonist and acts on the  $\mu$ -opioid receptors in the myenteric plexus of the large intestine. Loperamide works like morphine, decreasing the activity of the myenteric plexus, which decreases the tone of the longitudinal and circular smooth muscles of the intestinal wall. This increases the time material stays in the intestine, allowing more water to be absorbed from the fecal matter. Loperamide also decreases colonic mass movements and suppresses the gastrocolic reflex.

# INDICATIONS & DOSAGE REGIMENS:

Indicated for the control and symptomatic relief of acute nonspecific diarrhea and of chronic diarrhea associated with inflammatory bowel disease.. Also indicated for reducing the volume of discharge from ileostomies.

#### Acute Diarrhea

Adults: The recommended initial dose is 4mg (two capsules) followed by 2 mg (one capsule) after each unformed stool. Daily dose should not exceed 16mg (eight capsules). Clinical improvement is usually observed within 48 hours.

Children: In children 2 to 5 years of age (20 kg or less), the non-prescription liquid formulation (IMODIUM® (loperamide hcl) A-D 1 mg/5 mL) should be used; for ages 6 to 12, either IMODIUM® (loperamide hcl) Capsules or IMODIUM® (loperamide hcl) A-D Liquid may be used. For children 2 to 12 years of age, the following schedule for capsules or liquid will usually fulfill initial dosage requirements:

# Recommended First Day Dosage Schedule

Two to five years: 1 mg t.i.d. (3mg daily dose) (13 to 20 kg) Six to eight years: 2 mg b.i.d. (4mg daily dose) (20 to 30 kg) Eight to twelve years: 2mg t.i.d. (6mg daily dose) (greater than 30 kg)

# Recommended Subsequent Daily Dosage

Following the first treatment day, it is recommended that subsequent IMODIUM® (loperamide hcl) doses (1 mg/10 kg body weight) be administered only after a loose stool. Total daily dosage should not exceed recommended dosages for the first day.

## Chronic Diarrhea

Children: Although IMODIUM® (loperamide hcl) has been studied in a limited number of children with chronic diarrhea; the therapeutic dose for the treatment of chronic diarrhea in a pediatric population has not been established.

Adults: The recommended initial dose is 4 mg (two capsules) followed by 2 mg (one capsule) after each unformed stool until diarrhea is controlled, after which the dosage of IMODIUM® (loperamide hcl) should be

red used to meet individual requirements. When the optimal daily dosage has been established, this amount may the nobe administered as a single dose or in divided doses.

The average daily maintenance dosage in clinical trials was 4 to 8 mg (two to four capsules). A dosage of 16 mg (eight capsules) was rarely exceeded. If clinical improvement is not observed after treatment with 16 mg per day for at least 10 days, symptoms are unlikely to be controlled by further administration. IMODIUM® (loperamide hcl) administration may be continued if diarrhea cannot be adequately controlled with diet or specific treatment.

#### Children under 2 Years

The use of IMODIUM (loperamide hcl) in children under 2 years is not recommended. There have been rare reports of paralytic ileus associated with abdominal distention. Most of these reports occurred in the setting of acute dysentery, overdose, and with very young children less than two years of age.

# CONTRAINDICATIONS:

- 1) hypersensitivity to loperamide hydrochloride or to any of the excipients.
- 2)a bdominal pain in the absence of diarrhea.
- 3)notrecommended in infants below 24 months of age.
- 4) should not be used as the primary therapy:
- in patients with acute dysentery, which is characterized by blood in stools and high fever,
- in patients with acute ulcerative colitis,
- in patients with bacterial enterocolitis caused by invasive organisms including Salmonella, Shigella, and Campylobacter,
- in patients with pseudomembranous colitis associated with the use of broad- spectrum antibiotics.

## INTERACTIONS:

Loperamide is a substrate of P-glycoprotein; therefore, the concentration of loperamide will increase when given with a P-glycoprotein inhibitor. Common P-glycoprotein inhibitors include quinidine, ritonavir, and ketoconazole, among others. Loperamide is capable of decreasing the absorption of some other drugs. As an example, when saquinavir concentrations can decrease by half when given with loperamide Loperamide is an anti-diarrheal agent which decreases intestinal movement. As such, when combined with other antimotility drugs, there is an increased risk of constipation. These drugs include other opioids, antihistamines, antipsychotics, and anticholinergics

# 162. LORAZEPAM Tab 1 mg/2 mg SALIENT ACTIONS:

Lorazepam binds to an allosteric site on GABA-A receptors, which are pentameric ionotropic receptors in the CNS. Binding potentiates the effects of the inhibitory neurotransmitter GABA, which upon binding opens the chloride channel in the receptor, allowing chloride influx and causing hyperpolerization of the neuron.

# INDICATIONS & DOSAGE REGIMENS:

Anxiety- 1-6 mg/day in 2 or 3 divided doses, up to 10 mg/day.

Insomnia associated w/ anxiety - 1-4 mg/day at bedtime.

Prophylaxis of nausea and vomiting associated with cytotoxic therapy for moderately emetogenic chemotherapy: 1-2 mg to the antiemetic therapy.

Premedication in surgery 2-3 mg the night before operation, then a smaller dose in the morning if needed. **CONTRAINDICATIONS**:

Severe hepatic impairment; respiratory depression; acute narrow-angle glaucoma; pregnancy and lactation **PRECAUTIONS**:

Pregnancy Category (US FDA) – D. Hepatic and renal dysfunction; pulmonary insufficiency; myasthenia gravis; may impair ability to drive or operate machinery; elderly or debilitated patients.

#### INTERACTIONS

Potentiates CNS depression produced by alcohol; general anaesthetics; narcotic analgesics; TCAs; MAOIs; phenothiazines; antipsychotics; barbiturates; scopolamine.

## ADVERSE EFFECTS:

Drowsiness, headache, dizziness, confusion; blurred vision; nausea; weakness; unsteadiness. *Potentially Fatal:* Respiratory depression.

# 163. LOSARTAN POTASSIUM Tab 25 mg SALIENT ACTIONS:

Losartan is an angiotensin II receptor antagonist. The drug and its active metabolite selectively block the vasocon strictor and aldosterone-secreting effects of angiotensin II by selectively antagonising its binding to AT1

receptors.

# INDICATIONS & DOSAGE REGIMENS:

Hypertension: Adult: 50 mg once daily, increased to 100 mg daily as a single dose or in 2 divided doses if needed. Child: ≥6 yr: Initially 700 mcg/kg increased to a maximum of 50 mg ODif needed. Elderly: >75 yr: Initally, 25 mg once daily.

Diabetic nephropathy in Type 2 diabetes mellitus: Adult: 50 mg once daily, increased to 100 mg daily as a single dose or in 2 divided doses if needed. Elderly: >75: Initially 25 mg once daily.

Renal impairment: CrCl <20 ml/min & Hepatic impairment: Initially 25 mg once daily.

# CONTRAINDICATIONS:

Pregnancy, lactation; children with CrCl <30 ml/min/1.73m2.

#### PRECAUTIONS:

Pregnancy Category (US FDA) - C, In 2nd & 3rd trimesters.- D. Volume-depleted patients including patients on diuretics and salt restriction; renal artery stenosis; elderly; renal or hepatic impairment. Monitor serumpotassium concentration

#### INTERACTIONS:

Hypotensive effect of losartan increased by diuretics and other antihypertensives. Risk of hyperkalemia increases with concomitant ACE inhibitors, ciclosporin, potassium-sparing diuretics and K supplements. Hypotensive effect may be antagonised and increased risk of renal impairment when used with NSAIDs.

Potentially Fatal: Risk of lithium toxicity with losartan use.

# ADVERSE EFFECTS:

Headache, dizziness, back pain, myalgia, respiratory tract disorders, asthenia/fatigue, first dose hypotension, rash, angioedema, neutropenia, GI disturbances, transient elevation of liver enzymes, impaired renal function, taste disturbances and hyperkalemia.

# 164. LOSARTAN POTASIUM 50 mg + HYDROCHLOROTHIAZIDE 12.5 mg Tab SALIENT ACTIONS:

Hydrochlorothiazide increases renal excretion of sodium and chloride and reduces cardiac load. Losartan is an angiotensin II receptor (type AT1) antagonist antihypertensive which acts by blocking the actions of angiotensin II of renin-angiotensin-aldosterone system. The drug and its active metabolite selectively block the vasoconstrictor and aldosterone secreting effects of angiotensin II.

The two drugs exert additive effects in hypertension.

# INDICATIONS & DOSAGE REGIMENS:

Hypertension: Adult: Per tablet contains losartan 50 mg and hydrochlorothiazide 12.5 mg. monotherapy: 1 tab OD. May increase to 2 tabs OD 2-4 wk later if needed. Max: 2 tabs/day.

### CONTRAINDICATIONS:

Pregnancy, lactation; intravascular volume depletion.

#### PRECAUTIONS:

Pregnancy Category (US FDA) - C, in 2nd & 3rd trimesters-D. Special precaution: Existing electrolyte disturbances; hepatic cirrhosis; severe hepatic failure; oedema; elderly (>75 yr); renal impairment; hepatic impairment; diabetes, gout, hyperlipidaemia; hyperuricaemia; ECG: LVH and/or ventricular ectopics extrasystoles); volume depleted patients; patients on diuretics and salt restriction; renal artery stenosis; aortic and mitral stenosis. Monitor potassium concentration. Discontinue before performing tests for parathyroid function

# INTERACTIONS:

Increased hypotensive effect with: ACE inhibitors, alcohol, adrenergic neurone blockers, aldesleukin, αblockers, alprostadil, general anaesthetics, antipsychotics, anxiolytics and hypnotics, baclofen, β-blockers, calcium-channel blockers, clonidine, diazoxide, epoetin, hydralazine, levodopa, MAOIs, methyldopa, minoxidil, monoxidine, nitrates, NSAIDs, oestrogens, sodium nitroprusside, tizanidine, phenothiazines. Increased risk of renal impairment with aspirin, NSAIDs. Hypotensive effect antagonised by aspirin, corticosteroids, indomethacin, ketorolac.increased risk of hyperkalaemia with potassium-sparing and aldosterone antagonists, drospirenone (monitor serum potassium during 1st cycle), epoetin, heparin, ketorolac, potassium salts. Increased risk of hypersensitivity with allopurinol (especially in renal impairment). May antagonise hypoglycaemic effects of antidiabetics. Increased risk of hypercalcaemia with calcium salts and vitamin D. Increased risk of hyponatraemia with chlorpropamide. Increased risk of hypermagnesaemia with ciclosporin. Absorption may be reduced by colestipol and colestyramine (take at least 2 hr apart). Potentially Fatal:

Increased risk of nephrotoxicity and ototoxicity with platinum compounds, aminoglycosides. Hypokalaemia caused by diuretics may cause cardiac toxicity with amiodarone (interaction may occur for several weeks or months due to long half life of amiodarone). Increased risk of nephrotoxicity and hyperkalaemia with ciclosporin. Reduced excretion of lithium (risk of lithium toxicity with diuretics).

#### ADVERSE EFFECTS:

Volume depletion and electrolyte imbalance (especially hyperkalaemia); dry mouth, thirst; lethargy, drowsiness; muscle pain and cramps; rashes, photosensitivity, thrombocytopenia, jaundice, pancreatitis; fatigue, weakness; may precipitate an attack of gout; impotence; hyperglycemia; anorexia, nausea, vomiting, constipation, diarrhoea; sialdenitis; raised urinary calcium concentration; headache, dizziness; back pain, myalgia; first-dose hypotension; angiodema; neutropenia; GI disturbances; transient elevation of liver enzymes; taste disturbances, cough; exacerbation or activation of systemic lupus erythematous; palpitations; xanthopsia; leucopenia, agranulocytosis, aplastic anaemia; necrotising angiitis; glucosuria; renal dysfunction, interstitial nephritis, renal failure; migraine; hyponatraemia; UTI; chest pain; gastritis, wt gain, dyspepsia, abdominal pain; bronchitis, upper respiratory infection, nasal congestion, sinusitis; rise in cholesterol and/or triglycerides. *Potentially Fatal:* Hypersensitivity reactions; hemolytic anaemia; toxic epidermal necrolysis.

#### 165. MEBEVERINE TABLET

#### SALIENT ACTIONS:

**Mebeverine** is a drug used to alleviate some of the symptoms of irritable bowel syndrome. It works by relaxing the muscles in and around the gut.

Mebeverine is an anticholinergic but its mechanism of action is not known; it appears to work directly on smooth muscle within the gastrointestinal tract and may have an anesthetic effect, may affect calcium channels, and may affect muscarinic receptors.

It is metabolized mostly by esterases, and almost completely. The metabolites are excreted in urine.

#### INDICATIONS:

Mebeverine is used to alleviate some of the symptoms of irritable bowel syndrome (IBS) and related conditions these conditions; specifically stomach pain and cramps, persistent diarrhea, and flatulence.

#### DOSAGE REGIMENS:

Adults and the elderly: • Take 1 tablet 3 times a day • The number of tablets you take can be lowered if your symptoms improve • Do not take more than 3 tablets per day. Do not give tablets to children or adolescents younger than 18 years.

#### CONTRAINDICATIONS:

None except hypersensitivity

#### ADVERSE EFFECTS:

Adverse effects include hypersensitivity reactions and allergic reactions, immune system disorders, skin disorders including hives, edema and widespread rashes.

Additionally, the following adverse effects have been reported: heartburn, indigestion, constipation, loss of appetite, general malaise, dizziness, insomnia, headache, and decreased pulse rate. It does not have systemic anticholinergic side effects.

# 166. MECOBALAMIN Tab 500 mcg

## SALIENT ACTIONS:

Mecobalamin is the neurologically active form of vitamin B12 and occurs as a water-soluble vitamin in the body. It is a cofactor in the enzyme methionine synthase, which functions to transfer methyl groups for the regeneration of methionine from homocysteine. In anaemia, it increases erythrocyte production by promoting nucleic acid synthesis in the bone marrow and by promoting maturation and division of erythrocytes.

#### INDICATIONS & DOSAGE REGIMENS:

Peripheral neuropathies: Adult: 1500 mcg/day in 3 divided doses.

#### CONTRAINDICATIONS:

No

# PRECAUTIONS:

May interfere with precise diagnosis in patients with folate deficiency.

## INTERACTIONS:

Decreased GI tract absorption with neomycin, aminosalicylic acid, H2-blockers and colchicine.Reduced serum concentrations with oral contraceptives. Reduced effects in anaemia with parenteral chloramphenicol.

#### ADVERSE EFFECTS:

Oral: Anorexia, nausea, vomiting and diarrhea. Potentially Fatal: Anaphylactoid reactions (parenteral).

# 167. MECOBALAMIN 1500 mcg + ALPHA LIPOIC ACID 100 mg+ THIAMINE MONOMITRATE 10 mg + PYRIDOXINE Tab

# SALIENT ACTIONS:

Mecobalamin is the neurologically active form of vitamin B12 and occurs as a water-soluble vitamin in the body. It is a cofactor in the enzyme methionine synthase, which functions to transfer methyl groups for the regeneration of methionine from homocysteine. In anaemia, it increases erythrocyte production by promoting nucleic acid synthesis in the bone marrow and by promoting maturation and division of erythrocytes.

# INDICATIONS & DOSAGE REGIMENS:

Peripheral neuropathies: as per physician

## CONTRAINDICATIONS:

No

#### PRECAUTIONS:

May interfere with precise diagnosis in patients with folate deficiency.

#### INTERACTIONS:

Decreased GI tract absorption with neomycin, aminosalicylic acid, H2-blockers and colchicine. Reduced serum concentrations with oral contraceptives. Reduced effects in anaemia with parenteral chloramphenicol. INH therapy therapy increase pyridoxine excretion. Hydrallazine, cycloserine, penicillamine interfere with pyridoxine utilization

## ADVERSE EFFECTS:

Anorexia, nausea, vomiting and diarrhoea.

# 168. MEDROXYPROGESTERONE ACETATE IP 10MG TABLET

#### SALIENT ACTIONS:

Is a hormonal medication of the progestin type

# INDICATIONS & DOSAGE REGIMENS:

Adult: PO Menorrhagia 2.5-10 mg/day for 5-10 days on days 16-21 of the menstrual cycle. Repeat for 2 cycles. Mild to moderate endometriosis 10 mg 3 times/day. As progestogen component in menopausal HRT Dosage depends on oestrogen component of therapy, several regimens are used: 1.5 mg, 2.5 mg or 5 mg/day; 5 or 10 mg/day for 12-14 days of a 28-day cycle; 20 mg/day for 14 days of a 91-day cycle. Breast cancer 0.4-1.5 g/day. Max: 2 g/day. Palliation of endometrial and renal carcinoma200-600 mg/day. Palliation of prostatic carcinoma 100-600 mg/day. Secondary amenorrhoea 2.5-10 mg/day for 5-10 days. Repeat for 3 cycles. IM Endometriosis 50 mg/wk. Contraception 150 mg 12 wkly. Breast cancer 0.5-1 g/day for 1st 4 wk. Maintenance 0.5 g twice wkly. Palliation of endometrial and renal carcinoma Initial: 0.4-1 g/wk. Reduce if needed, maintenance may be as low as 0.4 g/mth. Palliation of prostatic carcinoma 0.5 g twice wkly for 1st 3 mth. Maintenance: 0.5 g/wk. SCContraception; Endometriosis 104 mg 12-14 wkly.

#### INTERACTIONS:

Aminoglutethimide and enzyme-inducing drugs (e.g. carbamazepine, griseofulvin, phenobarbital, rifampicin, phenytoin) may reduce plasma concentrations leading to reduced efficacy. Additional measures required when medroxyprogesterone is used for contraception during coadministration with these drugs.

#### PRECAUTIONS:

Patients with depression, DM, epilepsy, asthma, migraine, hypertension, renal or cardiac dysfunction. Monitor patient closely for loss of vision, proptosis, diplopia and thromboembolic disorders. Lactation

#### CONTRAINDICATIONS:

Thromboembolic disorders; cerebral apoplexy; severe hepatic dysfunction; undiagnosed vaginal bleeding, incomplete abortion, hormone-dependent carcinoma; pregnancy.

## ADVERSE EFFECTS:

Depression, fluid retention. Fatigue, insomnia, dizziness, headache, nausea; breast tenderness; wt gain/loss, anorexia; cholestatic jaundice; pain at Inj site.

Potentially Fatal: Thrombophlebitis and pulmonary embolism.

## 169. MEFENAMIC ACID TABLET

#### SALIENT ACTIONS:

Mefenamic acid is a member of the anthranilic acid derivatives (or fenamate) class of NSAID drugs.

Like other members of the anthranilic acid derivatives (or fenamate) class of <u>NSAID</u> drugs, it inhibits both isoforms of <u>COX</u> and prevents formation of <u>prostaglandins</u>.

#### INDICATIONS & DOSAGE REGIMENS:

# Usual Adult Dose for Pain

Initial dose: 500 mg orally once

Following initial dose: 250 mg orally every 6 hours as needed

Duration of therapy: Usually not to exceed 1 week

Use: For the relief of acute pain
Usual Adult Dose for Dysmenorrhea

Initial dose: 500 mg orally once

Following initial dose: 250 mg orally every 6 hours as needed

Duration of therapy: 2 to 3 days

#### Comments:

-Treatment should begin at the onset of bleeding and associated symptoms.

Use: For the treatment of primary dysmenorrhea

## **Usual Pediatric Dose for Pain**

# 14 years or older:

-Initial dose: 500 mg orally once

-Following initial dose: 250 mg orally every 6 hours as needed

-Duration of therapy: Usually not to exceed 1 week

Use: For the relief of acute pain

## Usual Pediatric Dose for Dysmenorrhea

## 14 years or older:

-Initial dose: 500 mg orally once

-Following initial dose: 250 mg orally every 6 hours as needed

-Duration of therapy: 2 to 3 days

#### Comments:

-Treatment should begin at the onset of bleeding and associated symptoms.

Use: For the treatment of primary dysmenorrhea

#### INTERACTIONS:

Some products that may interact with this drug include: <u>aliskiren</u>, <u>ACE inhibitors</u>(such as <u>captopril</u>, <u>lisinopril</u>), angiotensin II receptor blockers (such as <u>valsartan</u>, <u>losartan</u>), <u>cidofovir</u>, corticosteroids

(e.g., prednisone), fluconazole, ketorolac, lithium, methotrexate, "water pills" (diuretics such as furosemide). This medication may increase the risk of bleeding when taken with other drugs that also may cause bleeding. Examples include anti-platelet drugs such as clopidogrel, "blood thinners" such as dabigatran/enoxaparin/warfarin, among others.

#### PRECAUTIONS:

Mefenamic acid can cause a severe allergic reaction. Symptoms may include:

trouble breathing

swelling of your face or throat

hives

Don't take this drug again if you've ever had an allergic reaction to it. Taking it again could be fatal.

Don't take this medication if you're allergic to aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs).

These include ibuprofen, naproxen, diclofenac, and meloxicam.

## Alcohol interaction

Combining alcohol with mefenamic acid increases your risk of stomach bleeding or ulcer.

#### ADVERSE EFFECTS:

Mefenamic acid is recommended to be taken with food. [7]

Known mild <u>side effects</u> of mefenamic acid include <u>headaches</u>, nervousness, and <u>vomiting</u>. Serious side effects may include <u>diarrhea</u>, <u>hematemesis</u> (vomiting blood), <u>hematuria</u> (blood in urine), blurred vision, skin rash, itching and swelling, sore throat and <u>fever</u>. [4]:334 It has been associated with acute liver damage.

#### 170. MELATONIN 3MG TAB

# SALIENT ACTIONS:

Melatonin, also known as N-acetyl-5-methoxy tryptamine, is a hormone that is produced by the pineal gland in animals and regulates sleep and wakefulness

# INDICATIONS & DOSAGE REGIMENS:

Melatonin Dosage For Adults

Melatonin dose for Sleep or Insomnia: Adults may take doses of 0.3 to 3 milligrams at least 1 hours prior to bedtime. If 3mg does not produce desired effect after 3 days, increase dose to 5 or 6 mg.

Melatonin dosage for Jet Lag: Adults may take nightly doses between 0.5 to 5mg at least 1 hour prior to bedtime after arriving at the final destination. An alternative method involves taking doses 1 to 5mg at least one hour prior to bedtime for up to 2 days before departure and for 2 to 3 days after arriving at the final destination.

Disrupted Sleep-Wake Cycle: Between 2 to 12 mg taken at bedtime for a maximum of 4 weeks.

Long-term Difficulty Sleeping: 2 to 3 mg taken before bedtime for up to 29 weeks has been used in clinical trials. It is recommended to consult with a doctor if taking this supplement for a duration of longer than 4 weeks. Regulating Blood Pressure: Melatonin has been recommended at a nightly dose of 2 to 3 mg in a controlled-release form for up to 4 weeks. Consult with a doctor before taking this supplement for this purpose. Melatonin dosage for children

Melatonin is sometimes given to children or infants to address sleep disturbances or as an adjunct therapy in the treatment of ADHD (Attention-Deficit Hyperactivity Disorder) or autism disorder. Do not give melatonin to a baby, toddler or child without first consulting with a doctor.

Dosages used in children are much lower than those given to adults. Doses between 1 and 5mg may be dangerous to young kids, potentially causing seizures.

## PRECAUTIONS:

Melatonin is LIKELY SAFE for most adults when taken by mouth or injected into the body in the short-term, or when applied to the skin.

Melatonin is **POSSIBLY SAFE** when used by mouth appropriately, long-term. Melatonin has been used safely for up to 2 years in some people. However, it can cause some side effects including headache, short-term feelings of depression, daytime sleepiness, dizziness, stomach cramps, and irritability. Do not drive or use machinery for four to five hours after taking melatonin.

Pregnancy and breast-feeding: Melatonin is POSSIBLY UNSAFE when taken by mouth or injected into the body during pregnancy. Do not use it. Melatonin might also interfere with ovulation, making it more difficult to become pregnant.

Children: Melatonin is POSSIBLY SAFE when taken by mouth as a single dose. It is POSSIBLY UNSAFE when taken by mouth or injected into the body in multiple doses in the short-term. Because of its effects on other hormones, melatonin might interfere with development during adolescence. Bleeding disorders: Melatonin might make bleeding worse in people with bleeding disorders.

Depression: Melatonin can make symptoms of depression worse.

Diabetes: Melatonin might increase blood sugar in people with diabetes. Monitor your blood sugar carefully, if you have diabetes and take melatonin.

**High blood pressure**: Melatonin can raise blood pressure in people who are taking certain medications to control blood pressure. Avoid using it.

Seizure disorders: Using melatonin might increase the risk of having a seizure.

Transplant recipients: Melatonin can increase immune function and might interfere with immunosuppressive therapy used by people receiving transplants.

## ADVERSE EFFECTS:

Melatonin can cause <u>nausea</u>, next-day <u>grogginess</u>, and irritability. In the elderly, it can cause reduced blood flow and <u>hypothermia</u>. In <u>autoimmune disorders</u>, evidence is conflicting whether melatonin supplementation may ameliorate or exacerbate symptoms due to <u>immunomodulation</u>

#### INTERACTIONS:

Melatonin can lower follicle-stimulating hormone levels.

Anticoagulants and other substances are known to interact with melatonin.

# 171. MESALAMINE 400MG TABLET

#### SALIENT ACTIONS:

Mesalazine is the active <u>moiety</u> of <u>sulfasalazine</u>, which is metabolized to <u>sulfapyridine</u> and mesalazine. It is also the active component of the prodrug <u>balsalazide</u> along with the inert carrier molecule 4-aminobenzoyl-beta-alanine.

# INDICATIONS& DOSAGE REGIMENS:

Adult: PO Ulcerative colitis Dose is dependent on product used. Asacol 400 mg tab, Ipocol tab Acute attack: Initial: 2.4 g/day in divided doses. Maintenance of remission: 1.2-2.4 g/day in divided doses. Asacol 800 mg

tab Mild acute exacerbations: 2.4 g/day in divided doses. Moderate acute exacerbations: 4.8 g/day in divided doses. Maintenance of remission: Up to 2.4 g/day in divided doses. Mezavant Acute attack: Initial: 2.4-4.8 g once daily. Maintenance of remission: 2.4 g once daily. Pentasa tab Acute attack: Initial: Up to 4 g/day in 2 or 3 divided doses. Maintenance of remission: Initial: 2 g once daily, then adjusted individually. Pentasa granule Acute attack: Initial: Up to 4 g/day in 2-4 divided doses. Maintenance of remission: 2 g once daily. Salofalk Acute attack: As tab: Initial: 1.5-3 g/day in 3 divided doses. As granule: Initial: 1.5-3 g once daily or in 3 divided doses. Maintenance of remission: 1.5 g/day in 3 divided doses. Rectal Ulcerative proctitis Dose is dependent on preparation and brand used. Asacol supp 0.75-1.5 g/day in divided doses. Asacol foam enema Rectosigmoid region: 1 g/day for 4-6 wk. Descending colon: 2 g/day for 4-6 wk. Pentasa supp or susp enema Acute treatment: 1 g/day for 2-4 wk. Maintenance: 1 g/day. Salofalk supp 0.5-1 g given 2 or 3 times/day. Salofalk foam/susp enema 2 g/day at bedtime.

## PRECAUTIONS:

Patient w/ conditions predisposing to myocarditis or pericarditis, active peptic ulceration, history of sulfasalazine hypersensitivity. Mild to moderate renal or hepatic impairment. Pregnancy and lactation. *Patient Counselling* This drug may cause nausea, if affected, do not drive or operate machinery. *Monitoring Parameters* Monitor renal and hepatic function (i.e. ALT, CBC).

#### CONTRAINDICATIONS:

Hypersensitivity to salicylates. Severe hepatic or renal (GFR <20 mL/min) impairment.

## INTERACTIONS:

Drugs that lower colonic pH (e.g. lactulose) may prevent the release of mesalazine. Increased risk of haematologic toxicity w/ azathioprine or mercaptopurine. Increased risk of nephrotoxicity w/ nephrotoxic drugs (e.g. NSAIDs, azathioprine). May decrease GI absorption of digoxin.

#### ADVERSE EFFECTS:

Headache, dizziness, GI disturbances (e.g. diarrhoea, nausea, vomiting, abdominal pain, flatulence), Rarely, blood dyscrasia (e.g. agranulocytosis, aplastic anaemia, leucopenia, methaemoglobinaemia, neutropenia, thrombocytopenia), myocarditis, pericarditis, pancreatitis, interstitial nephritis, nephritic syndrome, allergic lung reaction, increased liver enzyme values, hepatitis, lupus-like syndrome, skin reactions, alopecia, peripheral neuropathy, arthralgia, myalgia, hypersensitivity reactions, exacerbation of symptoms of colitis.

Potentially Fatal: Induced pericarditis.

# 172. METFORMIN Tab 500 mg

#### SALIENT ACTIONS:

The exact mechanism of action of metformin is unclear but it appears to reduce glucose absorption from the GI tract, reduce gluconeogenesis and enhance insulin sensitivity by increasing peripheral glucose uptake and utilisation.

# INDICATIONS & DOSAGE REGIMENS:

Type 2 diabetes mellitus: Adult: Initially 500 mg bid-tid or 850 mg 1-2 times daily, may increase doses in steps of 500 mg at intervals of at least 1 wk. Max: 2.25 g daily. Child: ≥10 yr: Initially 500 or 850 mg once daily, increase doses either wkly by 500 mg daily or every 2 wk by 850 mg daily to a maintenance dose of 1500 - 2000 mg daily in 2 or 3 divided doses. Max dose 2000 mg daily. Elderly: Doses may need to be reduced by around a third in elderly patients.

Polycystic ovarian syndrome: Adult: Initially 500 mg daily in the morning for 1 wk, then 500 mg bid for 1 wk, then 1.5-1.7 g daily in 2-3 divided doses.

#### CONTRAINDICATIONS:

Patients with renal impairment should not receive metformin, hepatic disease, a past history of lactic acidosis, cardiac failure requiring pharmacological therapy, or chronic hypoxic lung disease.

#### PRECAUTIONS:

Pregnancy Category (US FDA)- B. Adjust dose in patients with renal impairment: 150 mg/day orally or 25 mg for parenteral administration. Exclude malignancy before treating gastric ulcer. Renal and hepatic impairment. Infants, pregnancy and lactation

#### INTERACTIONS:

Additive effect with sulphonylureas. Glycaemic control affected by diuretics, corticosteroids, phenothiazines, thyroid products, oestrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blockers, chlorpromazine and isoniazid. Metformin effects may be increased by ACE inhibitors, disopyramide, MAOIs. Cimetidine increases the serum levels of metformin. Decrease the anticoagulant effect of

phenprocoumon, therefore routine anticoagulant monitoring is recommended. *Potentially Fatal:* Lactic acidosis with alcohol. Thrombocytopenia has been reported with ketotifen.

#### ADVERSE EFFECTS:

Anorexia, nausea, vomiting, diarrhoea, wt loss, flatulence, occasional metallic taste; weakness; hypoglycaemia; rash, malabsorption of vit B<sub>12</sub>. Chest discomfort, flushing, palpitation, chills, headache, lightheadedness, indigestion, abdominal discomfort.

# 173. METFORMIN HCL 500 mg + GLIMEPERIDE 1mg Tab SALIENT ACTIONS:

Glimepiride stimulates the insulin release from functioning pancreatic  $\beta$ -cells and inhibits gluconeogenesis at hepatic cells. It also increases insulin sensitivity at peripheral target sites. The exact mechanism of action of metformin is unclear but it appears to reduce glucose absorption from the GI tract, reduce gluconeogenesis and enhance insulin sensitivity by increasing peripheral glucose uptake and utilisation.

# INDICATIONS & DOSAGE REGIMENS:

Type 2 diabetes mellitus: Take as directed. Titrate according to response. (Take immediately before or during breakfast, or the 1st main meal of the day. Do not skip meals.)

#### CONTRAINDICATIONS:

Diabetic ketoacidosis with or without coma, renal impairment, hepatic disease, a past history of lactic acidosis, cardiac failure requiring pharmacological therapy, or chronic hypoxic lung disease.

PRECAUTIONS: Pregnancy, Adjust dose in patients with renal impairment, exclude malignancy before treating gastric ulcer, hepatic impairment, infants, lactation, SIADH in patients with CHF or hepatic cirrhosis. Monitor blood-glucose concentration.

#### INTERACTIONS:

NSAIDs, salicylates, sulphonamides, chloramphenicol, coumarin, probenecid, CYP2C9 inhibitors, fibric acid derivatives, TCAs, MAOIs and β-adrenergic blockers may potentiate the hypoglycaemic action of glimepiride. Thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, oestrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, rifampicin, CYP2C9 inducers and isoniazid may reduce hypoglycaemic effect of glimepiride. May increase the serum levels of ciclosporin. Serum levels may be increased by fluconazole. May cause disulfiram-like reaction and hypoglycemia when used with ethanol. Hypoglycemic risk when used with chromium, garlic. Additive effect with sulphonylureas. Glycaemic control affected by diuretics, corticosteroids, phenothiazines, thyroid products, oestrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blockers, chlorpromazine and isoniazid. Metformin effects may be increased by ACE inhibitors, disopyramide, MAOIs. Cimetidine increases the serum levels of metformin. Decrease the anticoagulant effect of phenprocoumon, therefore routine anticoagulant monitoring is recommended. *Potentially Fatal:* Lactic acidosis with alcohol. Thrombocytopenia has been reported with ketotifen.

## ADVERSE EFFECTS:

Vomiting, GI pain, diarrhoea; pruritus, erythema, urticaria, morbilliform, maculopapular eruptions; leukopenia, agranulocytosis, thrombocytopenia, hemolytic anaemia, aplastic anaemia and pancytopenia; hyponatremia; changes in accommodation, blurred vision, jaundice. Anorexia, nausea, flatulence, occasional metallic taste; weakness; hypoglycaemia; rash, malabsorption of vit B<sub>12</sub>. Chest discomfort, flushing, palpitation, chills, headache, lightheadedness, indigestion, abdominal discomfort.

# 174. METHOTREXATE Tab 5 mg

# SALIENT ACTIONS:

Methotrexate is a folic acid antagonist that inhibits DNA synthesis. It irreversibly binds to dihydrofolate reductase, inhibiting the formation of reduced folates, and thymidylate synthesase, resulting in inhibition of purine and thymidylic acid synthesis.

## INDICATIONS & DOSAGE:

- 8. Burkitt's lymphoma: Adult: 10-25 mg daily for 4-8 days, repeated after 7-10 days.
- 9. Acute lymphoblastic leukaemia: Adult: Maintenance: 15 mg/m2 once or twice wkly, with other agents.
- 10. Choriocarcinoma: Adult: 15-30 mg daily for 5 days, repeat after an interval of ≥1 wk for 3-5 courses.
- 11. Mycosis fungoides: Adult: 2.5-10 mg daily to induce remission.
- 12. Psoriasis: Adult: 10-25 mg wkly as a single dose, adjust subsequent doses based on response.
- 13. Rheumatoid arthritis: Adult: 7.5 mg once wkly, adjust by response. Not more than 20 mg/wk.
- 14. Crohn's disease: Adult: 12.5-22.5 mg once wkly for up to 1 yr.

Hepatic impairment: Bilirubin 3.1-5 mg/dl: Administer 75% of dose; Bilirubin >5 mg/dl: Avoid use. Should be taken on an empty stomach.(Avoid taking w/ milk-rich products.)

#### CONTRAINDICATIONS:

Severe renal or hepatic impairment, pre-existing profound bone marrow suppression in patients with psoriasis or rheumatoid arthritis, alcoholic liver disease, AIDS, pre-existing blood dyscrasias, pregnancy (in patients with psoriasis or rheumatoid arthritis), breast-feeding.

#### PRECAUTIONS:

Pregnancy Category (US FDA) – X.Special precaution: Hepatic or renal impairment, bone marrow depression, elderly, neonates, Ulcerative disorders of the GI tract. Monitor haematological, renal and hepatic function, and GI toxicity regularly.

#### INTERACTIONS:

Decreased effectiveness with folic acid and its derivatives. Increased toxicity with NSAIDs and salicylates; probenecid; some penicillins; aminoglycosides neomycin and paromomycin; sulfafurazole and sulfamethoxazole; co-trimoxazole or trimethoprim; cisplatin; ciclosporin; etretinate. Synergistic enhancement of effects with fluorouracil. Increased bioavailability of mercaptopurine. Reduces serum-valproate concentrations. Reduced serum concentrations with colestyramine. Increased serum concentrations with omeprazole.

#### ADVERSE EFFECTS:

Ulceration of the mouth and GI disturbances (stomatitis and diarrhoea), bone marrow depression, hepatotoxicity, renal failure, skin reactions, alopecia, ocular irritation, arachnoiditis in intrathecal use, megaloblastic anaemia, osteoporosis, precipitation of diabetes, arthralgias, necrosis of soft tissue and bone, anaphylaxis, impaired fertility. *Potentially Fatal:* interstitial lung disease; neurotoxicity.

# 175. METHYLERGOMETRINE MALEATE 0.125MG TAB

#### SALIENT ACTIONS:

Methylergometrine is an ergot alkaloid, which directly stimulates contractions of uterine and vascular smooth muscle.

#### INDICATIONS:

Is indicated for routine management of uterine atony, hemorrhage and subinvolution of the uterus following delivery of placenta and for control of uterine hemorrhage in the second stage of labor following delivery of the anterior shoulder.

#### Dosage:

One tablet, 0.2 mg, 3 or 4 times daily in the puerperium for a maximum of 1 week.

#### CONTRAINDICATIONS:

Hypertension, eclamptic or previously hypertensive patients, heart disease, venoatrial shunts, mitral valve stenosis, obliterative vascular disease. Do not use in cases of threatened spontaneous abortion. Pregnancy

# PRECAUTIONS:

Captivation of the placenta may occur if given during the 2nd or 3rd stage of labour prior to delivery of the placenta; use in this situation should only be done by a qualified personnel. Avoid prolonged use. Caution in patients with sepsis, hepatic or renal impairment. Lactation

#### INTERACTIONS:

Possible increase in serum levels and risk of severe vasoconstrictive effects with potent CYP3A4 inhibitors e.g. erythromycin, troleandomycin, clarithromycin, ritonavir, indinavir, nelfinavir, delavirdine, ketoconazole, itra conazole, voriconazole) and less potent CYP3A4 inhibitors (e.g.saquinavir, nefazodone, fluconazole, fluoxetine, fluvoxamine, zileuton

#### ADVERSE DRUG REACTIONS:

Headache, dizziness, hallucinations; tinnitus; nausea, vomiting, foul taste, diarrhoea; hypertension, temporary chest pain, palpitations, bradycardia; nasal congestion, dyspnoea; diaphoresis; thrombophlebitis; haematuria; water intoxication; leg cramps; allergic reactions.

### Potentially Fatal: Shock

# 176. METHYLPREDNISOLONE TABLET SALIENT ACTIONS:

This can help control a wide number of disease states, characterised by excessive inflammation. They include severe allergic reactions, inflammation of the lungs in asthma and inflammation of the joints in arthritis. Methylprednisolone also decreases the numbers of white blood cells circulating in the blood. This, along with the decrease in inflammatory chemicals, can prevent the rejection of organ transplants, as it prevents the body

from attacking foreign tissue. Methylprednisolone is used in much higher doses than the levels of corticosteroids produced naturally by the body, and as such, the usual actions of corticosteroids become exaggerated and can be observed as side effects of this medicine.

# Dosage and Administration

# Usual Adult Dose for Allergic Rhinitis

Acetate suspension:

80 to 120 mg IM

#### Comment:

-Symptom relief may occur within 6 hours and persist for several days to 3 weeks.

Use: For symptom relief of allergic rhinitis (hay fever).

# Usual Adult Dose for Alopecia

Dosing should be individualized based on disease and patient response

Systemic Effect:

Oral:

Initial dose: 4 to 48 mg orally once a day or in divided doses

-Adjust or maintain initial dose until a satisfactory response is obtained; then, gradually in small decrements at appropriate intervals decrease to the lowest dose that maintains an adequate clinical response

Alternatively, Methylprednisolone Dosepak(R):

Day 1: 24 mg orally (8 mg before breakfast; 4 mg after lunch; 4 mg after dinner; 8 mg at bedtime)

Day 2: 20 mg orally (4 mg before breakfast; 4 mg after lunch; 4 mg after dinner; 8 mg at bedtime)

Day 3: 16 mg orally (4 mg before breakfast; 4 mg after lunch; 4 mg after dinner; 4 mg at bedtime)

Day 4: 12 mg orally (4 mg before breakfast; 4 mg after lunch; 4 mg at bedtime)

Day 5: 8 mg orally (4 mg before breakfast; 4 mg at bedtime)

Day 6: 4 mg orally (4 mg before breakfast).

# CONTRAINDICATIONS:

Serious infections except septic shock or tuberculous meningitis; viral, fungal and tubercular skin lesions; admin of live virus vaccines. Preparations containing benzyl alcohol preservative are contraindicated in infants.

#### PRECAUTIONS:

including family history (glucose regulation altered), osteoporosis especially post-menopausal women (associated with increased bone loss and osteoporotic fractures), glaucoma including family history (risk of increased intraocular pressure), corneal perforation, severe affective disorders (particularly if history of steroidinduced psychosis), epilepsy, GI disease (perforation risk), thyroid disease (changes in thyroid status may necessitate dosage adjustments ), history of steroid myopathy. Pregnancy and lactation. Avoid abrupt withdrawal after a prolonged period of use. When applied topically to large areas, broken skin, or under occlusive dressings, may cause systemic effects.

#### INTERACTIONS:

Decreases effect of anticholinesterases in myasthenia gravis. May decrease the hypoglycaemic effects of antidiabetic agents. Decreases serum concentrations of salicylates. Increased hypokalemic effects of potassiumdepleting diuretics (thiazides or furosemide), amphotericin B, bronchodilator therapy with xanthines or β<sub>2</sub> agonists. Increase incidence of GI bleeding and ulceration with NSAIDs. May increase the anticoagulant effects of warfarin. Decreased levels/effects with CYP3A4 inducers viz.

nafcillin, nevirapine, phenobarbital, phenytoin, and rifamycins). Increased levels/effects with CYP3A4 inhibitors (azole antifungals, clarithromycin, diclofenac, oxycycline, erythromycin, imatinib, isoniazid, nefazodone, nicardipine, propofol, protease inhibitors, quinidine, telithromycin, and verapamil). May decrease the effects of vaccines (dead organism) or increase the risk of vaccinal infection (live organism). Antacids and bile sequestrants may decrease the absorption of corticosteroids. Increased hypokalemic effects of potassiumdepleting diuretics (thiazides or furosemide), amphotericin B, bronchodilator therapy with xanthines or β<sub>2</sub> agonists. Increase incidence of GI bleeding and ulceration with NSAIDs.

# ADVERSE DRUG REACTIONS:

Oedema, hypertension, arrhythmia; CNS, endocrine, metabolic and GI effects; hirsutism, acne, skin atrophy, bruising, hyperpigmentation; transient leukocytosis; arthralgia, muscle weakness, osteoporosis, fractures, cataracts, glaucoma; infections, hypersensitivity reactions, avascular necrosis, secondary malignancy, intractable hiccups.

## 177. METOCLOPRAMIDE Tab 10 mg

#### SALIENT ACTIONS:

Metoclopramide enhances the motility of the upper GI tract and increases gastric emptying without affecting gastric, biliary or pancreatic secretions. It increases duodenal peristalsis which decreases intestinal transit time, and increases lower oesophageal sphincter tone. It is also a potent central dopamine-receptor antagonist and may also have serotonin-receptor (5-HT3) antagonist properties.

#### INDICATIONS & DOSAGE REGIMENS:

- 1. **Diabetic gastric stasis:** Adult: 10 mg 4 times/day. To be given 30 minutes before meals and at bedtime. Usual treatment duration: 2-8 wk. Renal impairment: Moderate to severe: Reduce dose by at least 50%
- 2. Nausea and vomiting associated with cancer chemotherapy or radiotherapy: Adult: 2 mg/kg/dose, given 1 hr before start of treatment. Repeat dose 3 times at 2-hrly intervals. repeat 2 additional doses at 3-hrly intervals if needed. Max: 12 mg/kg/day.

1 mth-1 yr	1-3 yr	3-5 yr	5-9 yr	9-14 yr	15-19 yr	15-19 yr
10 kg	10-14kg	15-19 kg	20-29 kg	≥30 kg	30-59 kg	≥60 kg
100 mcg/kg max1 mg bd	1 mg bid- tid	2 mg bid-tid	2.5 mg tid	5 mg tid	5 mg tid	10 mg tid

Child: Neonate: 100 mcg/kg every 6-8 hr; Max: 500 mcg/kg.

- 3. Gastro-esophageal reflux disease: Adult: 10-15 mg up to 4 times/day, given 30 minutes before meals and at bedtime, depending on severity of symptoms. If symptoms are intermittent, may give single doses of 20 mg prior to the provoking situation. Max Dosage: 500 mcg/kg
- 4. **Prevent delayed emesis following chemotherapy:** *Adult:* 20-40 mg 2-4 times/day for 3-4 days.Renal impairment: Moderate to severe: Reduce dose by at least 50%.

#### **CONTRAINDICATIONS:**

GI hemorrhage, mechanical obstruction and perforation; phaeochromocytoma; history of seizures.

#### PRECAUTIONS:

Pregnancy Category (US FDA)- B.Special precaution: Adjust dose in patients with renal impairment: 150 mg/day orally or 25 mg for parenteral administration. Exclude malignancy before treating gastric ulcer. Renal and hepatic impairment. Infants, pregnancy and lactation

#### INTERACTIONS:

Increased sedative effects with CNS depressants.GI effects antagonised by antimuscarinics and opioids. Reduces absorption of digoxin.Increases absorption of ciclosporin, levodopa, aspirin, paracetamol.Interferes with hypoprolactinaemic effect of bromocriptine. Inhibits serum cholinesterase and prolongs neuromuscular blockade produced by suxamethonium and mivacurium.*Potentially Fatal:* Serotonin syndrome with sertraline (SSRI).

# ADVERSE EFFECTS:

Extrapyramidal symptoms, restlessness, drowsiness, anxiety, diarrhoea, hypotension, hypertension, headache, depression aganulocytosis, methaemoglobinaemia, hypersensitivity reactions (e.g. bronchospasm, rash), galactorrhoea or related disorders, transient increase in plasma aldosterone levels. *Potentially Fatal*: Neuroleptic malignant syndrome; cardiac conduction disorders may occur with IV dosage form.

#### 178. METOLAZONE TABLET

#### SALIENT ACTIONS:

**Description:** Metolazone is a thiazide-like diuretic. It inhibits reabsorption of sodium in the distal tubules resulting in increased excretion of sodium and water, as well as potassium and hydrogen ions.

Onset: Approx 60 min. Duration: ≤24 hr. Pharmacokinetics:

Absorption: Incompletely absorbed from the GI tract (oral).

Distribution: Crosses the placenta and enters breast milk. Protein-binding: 95%.

Metabolism: Not metabolised to a substantial extent.

Excretion: Via urine (80-95% unchanged); via bile and some undergo enterohepatic recycling; 6-20 hr (elimination half-life)..

# INDICATIONS & DOSAGE REGIMENS:

Adult: PO HTN Initial: 1.25 mg/day, adjusted after 3-4 wk. Usual range: 2.5-5 mg/day, either alone or w/ other antihypertensives. Maintenance: 5 mg on alternate days. Oedema 5-10 mg/day, up to 20 mg/day if needed. Max: 80 mg/24 hr.

Oral

Hypertension

**Adult:** Initially, 1.25 mg daily, adjusted after 3-4 wk according to response. Usual dose: 2.5-5 mg daily, either alone or with other antihypertensives. Maintenance dose: 5 mg on alternate days. Formulations with enhanced bioavailability: 0.5-1 mg daily.

Elderly: Initially, 2.5 mg/day or every other day.

Oral

Oedema

Adult: 5-10 mg daily, increased if necessary to 20 mg daily. Max: 80 mg in 24 hr.

Elderly: Initially, 2.5 mg/day or every other day. Should be taken with food. Take after breakfast.

CONTRAINDICATIONS:

Anuria; hepatic coma or pre-coma. Pregnancy.

PRECAUTIONS:

Pre-diabetes or DM; gout; SLE; hepatic and renal impairment; hypercholesterolaemia. Correct electrolyte disturbances prior to therapy. Risk of cross-sensitivity with sulfonamides, sulfonylureas, carbonic anhydrase inhibitors, thiazides and loop diuretics. Lactation.

INTERACTIONS:-

Hypotensive and nephrotoxic effects of ACE inhibitors may be enhanced. Absorption may be reduced with bile acid sequestrants. Hyperglycaemic effect may be enhanced with diazoxide. May increase serum concentration and QTc-prolonging effect of dofetilide. May reduce lithium excretion. Hypotensive effect may be increased with alcohol.

Potentially Fatal: Increased risk of nephrotoxicity with ciclosporin. Severe electrolyte disturbances may occur with furosemide.

Photosensitisation may occur with dong quai, St John's wort. Hypertension may be exacerbated with ephedra, yohimbe, ginseng. Antihypertensive effect may be increased with garlic. Avoid natural licorice.

ADVERSE EFFECTS:

Chest pain, palpitation, necrotising angiitis, orthostatic hypotension, syncope, venous thrombosis, vertigo, volume depletion; depression, dizziness, chills, drowsiness, fatigue, restlessness, headache, lightheadedness; petechiae, photosensitivity, hypersensitivity reactions; gout attacks, electrolyte disturbances; abdominal bloating, diarrhoea, abdominal pain, anorexia, constipation, epigastric distress, nausea, xerostomia, pancreatitis, vomiting; impotence; aplastic anaemia, thrombocytopenia, haemoconcentration, leukopenia; cholestatic jaundice, hepatitis; joint pain, muscle cramps, weakness, neuropathy, paraesthesia; blurred vision; increased BUN, glucosuria.

Potentially Fatal: Stevens-Johnson syndrome, toxic epidermal necrolysis.

## 179. METOPROLOL 25MG TAB

## SALIENT ACTIONS:

Selective  $\beta_1$  receptor blocker used in treatment of several diseases of the cardiovascular system, especially hypertension. The active substance metoprolol is employed either as *metoprolol succinate* or *metoprolol tartrate* (where 100 mg metoprolol tartrate corresponds to 95 mg metoprolol succinate). The tartrate is an immediate-release and the succinate is an extended-release formulation.

# INDICATIONS & DOSAGE REGIMENS:

Usual Adult Dose for Hypertension

Metoprolol Tartrate Immediate Release Tablets:

Initial dose: 100 mg orally per day in single or divided doses

Maintenance dose: 100 to 450 mg orally per day Metoprolol Succinate Extended Release Tablets: Initial dose: 25 to 100 mg orally once a day

Maintenance dose: 100 to 400 mg orally once a day Usual Adult Dose for Angina Pectoris

Initial dose

-Metoprolol tartrate immediate release tablets: 50 mg orally twice a day -Metoprolol succinate extended release tablets: 100 mg orally once a day

Maintenance dose: 100 to 400 mg per day Usual Adult Dose for Myocardial Infarction

Metoprolol Tartrate:

#### Early Treatment:

Initial dose: 5 mg IV every 2 minutes as tolerated for 3 doses

- -Patients tolerant of full IV dose (15 mg): 50 mg orally every 6 hours starting 15 minutes after the last IV dose and continued for 48 hours
- -Patients intolerant of full IV dose (15 mg): 25 or 50 mg orally every 6 hours depending on the degree of intolerance starting 15 minutes after the last IV dose or as soon as their clinical condition allows

#### Late Treatment:

Maintenance dose: 100 mg orally twice a day Usual Adult Dose for Congestive Heart Failure Metoprolol Succinate Extended Release Tablets:

25 mg orally once a day (12.5 mg orally once a day in patients with more severe heart failure); double dose every 2 weeks to highest tolerated dose or up to 200 mg orally once a day. Use: Treatment of stable, symptomatic New York Heart Association (NYHA) Class II or III heart failure of ischemic, hypertensive, or cardiomyopathic origin.

## Usual Pediatric Dose for Hypertension

**Metoprolol Succinate Extended Release Tablets:** 

#### 6 Years or Older:

Initial dose: 1 mg/kg orally once a day (not to exceed 50 mg orally once a day)

Maximum dose: 2 mg/kg (or 200 mg) orally once a day

#### CONTRAINDICATIONS:

2nd or 3rd degree AV block; sick sinus syndrome; decompensated heart failure; clinically relevant sinus bradycardia. Severe peripheral arterial circulatory disorders. Cardiogenic shock. Asthma. Phaeochromocytoma (without  $\alpha$ -blockade), systolic BP <100 mmHg. Metabolic acidosis. Pregnancy (2nd and 3rd trimesters

#### PRECAUTIONS:

Compensated heart failure, bronchospastic disease, hepatic impairment, AV conduction disorders, bradycardia, peripheral arterial circulatory disorders. An α-blocker should be given concurrently in patients with phaeochromocytoma. May mask signs of acute hypoglycaemia. May mask symptoms of hyperthyroidism. Caution when used in patients with history of cardiac failure or those with minimal cardiac reserve. Avoid using anaesthetic agents that may depress the myocardium. May impair ability to drive or operate machinery. Myasthenia gravis; history of psychiatric disorder. Lactation. Avoid abrupt drug withdrawal

#### INTERACTIONS:

Additive effect with catecholamine-depleting drugs e.g. reserpine and MAOIs. May antagonise β<sub>1</sub>-adrenergic stimulating effects of sympathomimetics. Additive negative effects on SA or AV nodal conduction with cardiac glycosides, nondihydropyridine calcium-channel blockers. Increased oral bioavailability with aluminium/magnesium-containing antacids. Paradoxical response to epinephrine may occur. Increased plasma concentrations with CYP2D6 inhibitors (e.g. bupropion, cimetidine,diphenhydramine, fluoxetine, hydroxycholoquine, paroxetine, propafenone,quinidine, ritonavir, terbinafine, thioridazine). Increased risk of hypotension and heart failure with myocardial depressant general anaesthetics (e.g. diethyl ether). Risk of pulmonary hypertension with vasodilators e.g. hydralazine in uraemic patients. Reduced plasma levels with rifampicin. May increase negative inotropic and negative dromotropic effect of anti-arrhythmic drugs e.g. quinidine and amiodarone. Propafenone may increase serum levels of metoprolol. Concurrent use with indomethacinmay reduce the antihypertensive efficacy of β-blocker. May reduce clearance of lidocaine. May increase effects of hypoglycaemics. Efficacy may be reduced by isoprenaline. Concurrent use with digoxin may lead to additive bradycardia.

Potentially Fatal: Additive or synergistic effects with verapamil; increased oral bioavailability with verapamil. Exacerbation of rebound hypertension during abrupt clonidine withdrawal.

## ADVERSE DRUG REACTIONS:

Bradycardia, hypotension, arterial insufficiency, chest pain, CHF, oedema, palpitation, syncope, gangrene; dizziness, fatigue depression, confusion, headache, insomnia, short-term memory loss, nightmares, somnolence; pruritus, rash, increased psoriasis, reversible alopecia; sexual dysfunction/impotence, Peyronie's disease; diarrhoea, constipation, flatulence, GI pain, heartburn, nausea, xerostomia; agranulocytosis (rare); musculoskeletal pain; blurred vision, dry eyes, oculomucocutaneous syndromtinnitus; dyspnoea, bronchospasm, wheezing, rhinitis; cold extremities.

# 180. METRONIDAZOLE Tab 400 mg SALIENT ACTIONS:

Metronidazole is converted to reduction products that interact with DNA to cause destruction of helical DNA structure and strand leading to a protein synthesis inhibition and cell death in susceptible organisms. It is effective against a wide range of organisms including E. histolytica, T. vaginalis, Giardia, anaerobes e.g. Bacterioides sp, Fusobacterium sp, Clostridium sp, Peptococcus sp and Peptostreptococcus sp, and moderately active against Gardnerella sp and Campylobacter sp.

# INDICATIONS & DOSAGE REGIMENS:

Elderly: Use lower end of adult dose recommendations. Do not admin as a single dose.

1. Amoebiasis, Balantidiasis, Blastocystis hominis infection: Adult: 400-800 mg tid for 5-10 days or 1.5-2.5 g as a OD for 2-3 days. Child: 35-50 mg/kg daily in divided doses.2. Trichomoniasis: Adult: 2 g OD, or 800 mg in the morning and 1.2 g in the evening for 2 days, or 0.6-1 g daily in 2-3 divided doses for 7 days. There should be an interval of 4-6 wk if treatment needs to be repeated. Child: 1-3 yr: 50 mg tid; 3-7 yr: 100 mg bid; 7-10 yr: 100 mg tid, for 7 days, OR 15 mg/kg daily for 7 days.3. Giardiasis: Adult: 2 g OD for 3 consecutive days, or 400 mg tid for 5 days, or 500 mg bid for 7-10 days. Child: 1-3 yr: 1/4 (AD) adult dose; 3-7 yr: 1/3 AD; 7-10 yr: 1/2 AD. Alternatively, 15 mg/kg daily in divided doses.4.Bacterial vaginosis:Adult: 2 g as a single dose, or 400-500 mg bid for 5-7 days.5. Acute necrotizing ulcerative gingivitis, Acute dental infections: Adult: 200 mg tid for 3 days. 6.Anaerobic bacterial infections: Adult: 800 mg followed by 400 mg 8 hly for 7 days. OR 500 mg 8 hrly or 7.5 mg/kg 6 hrly (max: 4 g in 24 hr). Child: 7.5 mg/kg 8 hrly. 7. Prophylaxis of postoperative anaerobic bacterial infections: Adult: 400 mg 8 hrly in the 24 hr prior to surgery followed postoperatively by IV or rectal admin until oral therapy is possible. Other sources recommend that oral doses be initiated only 2 hr prior to surgery and that number of doses for all admin routes be limited to a total of 4. 8. Eradication of H. pylori associated with peptic ulcer disease 9. Adult: In combination with another antibacterial (e.g. clarithromycin) + either a PPI (e.g. lansoprazole) or ranitidine bismuth citrate: 400 mg bid. In combination with omeprazole and amoxicillin: 400 mg tid for 1 wk. 10.Leg ulcers and pressure sores: Adult: 400 mg tid for 7 Days. .Antibioticassociated colitis: Adult: 250-500 mg bid-tid for 10-14 days. Child: 20 mg/kg/day 6 hrly. Max dose: 2 g/day.

# CONTRAINDICATIONS:

History of hypersensitivity to metronidazole or other nitroimidazole derivatives. Pregnancy (1st trimester) and lactation.

#### PRECAUTIONS:

Pregnancy Category (US FDA)- B.Patients with CNS diseases; discontinue IV therapy if abnormal neurologic symptoms occur. History of seizure disorder. Evidence or a history of blood dyscrasias; perform TLC & DLC before and after treatment. Severe hepatic impairment; monitor plasma levels. Prolonged use may result in fungal or bacterial superinfection.

# INTERACTIONS:-

Acute psychoses or confusion with disulfiram. Additive/synergistic effect with other antimicrobials. Effects reduced with phenobarbital or phenytoin. Potentially Fatal: Disulfiram-like reaction with alcohol. Increased risk of adverse effects of coumarin anticoagulants, phenytoin, lithium, ciclosporin, fluorouracil. Increased risk of neurological effects with cimetidine.

# ADVERSE EFFECTS:

GI disturbances e.g. nausea, unpleasant metallic taste, vomiting, diarrhoea or constipation. Furred tongue, glossitis, and stomatitis due to overgrowth of Candida. Rarely, antibiotic-associated colitis. Weakness, dizziness, ataxia, headache, drowsiness, insomnia, changes in mood or mental state. Numbness or tingling in the extremities, epileptiform seizures (high doses or prolonged treatment). Transient leucopenia and thrombocytopenia. Hypersensitivity reactions. Urethral discomfort and darkening of urine. Raised liver enzyme values, cholestatic hepatitis, jaundice. Potentially Fatal: Anaphylaxis.

# 181. MIRTAZAPINE IP 15MG TABLET

# SALIENT ACTIONS:

Mirtazapine, a piperazinoazepine tetracyclic antidepressant, enhances noradrenergic and serotonergic activity through blockade of central presynaptic adrenergic α2-receptors.

# INDICATIONS & DOSAGE REGIMENS

Oral

# Depression

Adult: Initially, 15 mg daily; may be increased gradually depending on clinical response. Change dose at intervals of at least 1-2 wk. Usual effective dose: 15-45 mg daily given as single dose, preferably at bedtime, or

#### in 2 divided doses.

#### PRECAUTIONS:

Epilepsy or history of seizures; avoid completely in unstable cases. Hepatic or renal impairment, cardiac disorders e.g. conduction disturbances, angina pectoris, recent MI. Hypotension, DM, psychoses, history of bipolar disorder. Stop treatment if jaundice develops. Micturition disturbances, angle-closure glaucoma, raised intraocular pressure. Monitor patient for signs of bone marrow depression. Monitor patient for suicidal tendency. Avoid abrupt withdrawal. May impair ability to drive or operate machinery. Pregnancy and lactation. Elderly.

#### INTERACTIONS:

Potentiation of sedative effects with alcohol or benzodiazepines. Increased plasma levels with potent CYP3A4 inhibitors (e.g. HIV-protease inhibitors, azole antifungals including ketoconazole, erythromycin, nefazodone). Reduced plasma levels with carbamazepine and other inducers of CYP3A4. Increased bioavailability with cimetidine.

**Potentially Fatal:** Do not use with or within 2 wk of stopping an MAOI; at least 1 wk should elapse between discontinuing mirtazapine and initiating any drug which may provoke a serious reaction (e.g. phenelzine).

# ADVERSE EFFECTS:

Increase in appetite and wt, oedema; drowsiness or sedation; dizziness, headache, increased liver enzyme levels; jaundice. Orthostatic hypotension, rash, nightmares, agitation, mania, hallucinations, paraesthesia, convulsions, tremor, myoclonus, akathisia, restless legs syndrome, arthralgia, myalgia, reversible agranulocytosis, leucopenia, granulocytopenia, hyponatraemia.

# 182. MISOPROSTOL Tab 200 mcg SALIENT ACTIONS:

Misoprostol, a synthetic prostaglandin E<sub>1</sub> analogue, exerts its antisecretory activity by directly acting on specific prostaglandin receptors found on the surface of gastric parietal cells. It exerts its protective effects on the mucosa by replacing the prostaglandins consumed during prostaglandin-inhibiting therapies e.g. NSAIDs.

# INDICATIONS & DOSAGE REGIMENS:

- 1. Benign gastric and duodenal ulceration: Adult: 800 mcg daily in 2-4 divided doses for at least 4 wk, up to 8 wk if needed.
- 2. **NSAID-associated ulceration:** Adult: 800 mcg daily in 2-4 divided doses for at least 4 wk, up to 8 wk if needed.
- 3. **Prophylaxis of NSAID-induced ulcers:** *Adult:* 200 mcg 2-4 times daily. Patient not tolerating high dose: Reduce dose to 100 mcg 2-4 times daily.
- 4. Cervical ripening before surgical termination of pregnancy in the 1st trimester: Adult: 400 mcg as a single dose 3-4 hr before surgery.
- 5. **Termination of pregnancy (49 days or less duration):** Adult: 400 mcg as a single dose 36-48 hr after mifepristone

# CONTRAINDICATIONS:

Pregnancy and lactation

# PRECAUTIONS:

Pregnancy Category (US FDA)- X. Conditions where hypotension might precipitate severe complications e.g. cerebrovascular or CV disease. Inflammatory bowel disease. Patients prone to dehydration. Elderly. Renal impairment

#### INTERACTIONS:

May increase effects of oxytocin. Increased risk of misoprostol-induced diarrhoea with magnesium-containing antacids.

#### ADVERS E EFFECTS:

Diarrhoea, abdominal pain, dyspepsia, constipation, flatulence, nausea and vomiting; abnormal vaginal bleeding, cramps, increased uterine contractility, headache

# 183. MIZOLASTINE 10MG TABLET

# SALIENT ACTIONS:

Mizolastine, a non-sedating antihistamine, blocks histamine  $H_1$ -receptors on effector cells of the GI tract, blood vessels and respiratory tract. It also has mast-cell stabilising properties.

# INDICATIONS & DOSAGE REGIMENS: :

Oral

Allergic conditions

Adult: 10 mg daily.

Child: ≥12 yr: 10 mg daily.

Elderly: 10 mg daily. PRECAUTIONS:

May impair ability to drive or operate machinery. Elderly. Pregnancy (avoid in 1st trimester) and lactation CONTRAINDICATIONS:

Significant cardiac or hepatic disease; electrolyte imbalance, particularly hypokalaemia; known or suspected QT prolongation. Clinically significant bradycardia.

# INTERACTIONS:

Antidepressants and anxiolytics may enhance sedative effect. Potent inhibitors of or substrates for the hepatic metabolism of mizolastine (e.g. cimetidine, ciclosporin, nifedipine) may alter its metabolism.

Potentially Fatal: Increased risk of cardiac arrhythmias with drugs known to prolong the QT interval e.g. class I and III antiarryhthmics. Increased plasma concentrations with macrolide antibiotics and imidazole antifungals.

# ADVERSE EFFECTS:

Dry mouth, diarrhoea, abdominal pain, nausea; transient drowsiness, headache, dizziness; anxiety and depression; raised liver enzymes: low neutrophil count; transient asthenia, increased appetite associated with wt gain; allergic reactions e.g. angioedema, generalised rash/urticaria, pruritus and hypotension; tachycardia, palpitations; vasovagal attack; arthralgia and myalgia.

Potentially Fatal: Anaphylaxis.

# 184. MONTELUKAST SODIUM CHEW TABLET

# SALIENT ACTIONS:

Montelukast is a selective leukotriene receptor antagonist that inhibits the effects of cysteinyl leukotrienes in the airways. Cysteinyl leukotrienes and leukotriene receptor occupation have been correlated w/ the pathophysiology of asthma, including airway oedema, smooth muscle contraction, and altered cellular activity associated w/ the inflammatory process, which contribute to the signs and symptoms of asthma.

# INDICATIONS & DOSAGE REGIMENS:

Oral

# Chronic asthma

Adult: As film-coated tab: 10 mg once daily in the evening.

Child: 6 mth to <2 yr As granules: 4 mg once daily; 2-5 yr As granules or chewable tab: 4 mg once daily; 6-14 yr As chewable tab: 5 mg once daily; ≥15 yr As film-coated tab: 10 mg once daily. All doses to be taken in the evening.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Mild to moderate: No dosage adjustment needed.

Oral

# Allergic rhinitis

Adult: 10 mg once daily.

Child: ≥15 yr 10 mg once daily.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Mild to moderate: No dosage adjustment needed.

Oral

# Prophylaxis of exercise-induced asthma

Adult: 10 mg at least 2 hr prior to exercise; do not take additional doses w/in 24 hr.

Child: 2-5 yr As granules or chewable tab: 4 mg once daily; 6-14 yr As chewable tab: 5 mg once daily; ≥15 yr As film-coated tab: 10 mg once daily. Doses are given at least 2 hr prior to exercise; do not take additional doses w/in 24 hr.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Mild to moderate: No dosage adjustment needed.

# PRECAUTIONS:

Not intended for the treatment of acute asthma attacks. Patient w/ aspirin-sensitive asthma should continue to avoid aspirin and other NSAIDs. Avoid abrupt substitution to oral or inhaled corticosteroids. Pregnancy and

lactation. Monitoring Parameters Monitor mood or behaviour changes, including suicidal thinking/behaviour.

#### INTERACTIONS:

Induced hepatic metabolism resulting to decreased plasma concentration w/ potent inducers of cytochrome P450 isoenzymes (e.g. phenobarbital, phenytoin, rifampicin).

# ADVERSE EFFECTS:

Churg-Strauss syndrome; headache, dizziness, asthenia/fatigue, dream abnormalities, hallucinations, agitation (e.g. aggressive behaviour, hostility), anxiousness, paraesthesia/hypoesthesia, seizures, drowsiness, insomnia, somnambulism, irritability, depression, suicidal thinking/behaviour, tremor, restlessness; abdominal pain, dyspepsia, gastroenteritis, dental pain or infection, diarrhoea, nausea, vomiting; increased serum ALT or AST, hepatocellular injury, cholestatic hepatitis or mixed-pattern liver injury; rash, eczema, dermatitis, urticaria, varicella, skin infection, hypersensitivity, angioedema, pruritus, erythema multiforme, erythema nodosum, Stevens-Johnson syndrome, toxic epidermal necrolysis; upper resp tract infection, influenza, pneumonia, acute bronchitis; fever, trauma, otitis, pyuria, conjunctivitis, leg pain, thirst, myopia, epistaxis, oedema, myalgia, arthralgia, palpitations, bruising, increased tendency for bleeding, thrombocytopenia, pulmonary eosinophilia. Rarely, pancreatitis, hepatic eosinophilic infiltration.

# 185. MOSAPRIDE CITRATE TABLET

# **SALIENT ACTIONS:**

Mosapride is a 5-HT<sub>4</sub> receptor agonist which increases the release of acetylcholine and stimulates GI motility. It also has 5-HT<sub>3</sub> antagonist properties.

# INDICATIONS & DOSAGE REGIMENS:

Oral

# Disorders associated with reduced gastrointestinal motility

Adult: As anhydrous citrate: 5 mg tid.

# PRECAUTIONS:

Continuous admin of this drug is not recommended if no improvement in GI symptoms is observed after 2 wk of admin. Elderly, renal impairment, hepatic impairment.

# DRUG INTERACTIONS:

Mosapride concentration increased by erythromycin. May increase risk of QT prolongation with QT prolonging drugs.

# ADVERSE DRUG REACTIONS:

Diarrhoea, abdominal pain; dizziness; constipation; headache; insomnia; nausea.

# 186. MYCOPHENOLATE MOFETIL 500MG TABLET

# SALIENT ACTION:

Mycophenolic acid acts by blocking purine synthesis of human lymphocytes through reversible inhibition of inosine monophosphate dehydrogenase. It also inhibits proliferation of both T- and B- lymphocytes.

# INDICATIONS & DOSAGE REGIMENS:

Oral

# Prophylaxis of acute renal graft rejection

**Adult:** As mycophenolate mofetil: 1 g bid starting within 72 hr of transplantation. Max: 2 g/day. As mycophenolic acid: 720 mg bid.

Child: As mycophenolate mofetil: 2-18 yr: 600 mg/m² bid. Max: 1 g bid. BSA 1.25-1.5 m²: 750 mg bid; >1.5 m²: 1 g bid. As mycophenolic acid: 5-16 yr: 400 mg/m² bid (max: 720 mg bid). BSA 1.19-1.58 m²: 540 mg bid (max: 1,080 mg); >1.58 m²: 720 mg bid (max: 1,440 mg).

Elderly: As mycophenolic acid: Max: 720 mg bid.

**Renal impairment:** Severe chronic renal impairment (GFR <25 ml/min/1.73 m<sup>2</sup>): Avoid >1 g bid of mycophenolate mofetil.

**Reconstitution:** Oral suspension: Add 47 ml of water to bottle and shake well for about 1 min. Add another 47 ml of water and shake for another min. Final concentration: 200 mg/ml mycophenolate mofetil.

Oral

# Prophylaxis of cardiac graft rejection

Adult: As mycophenolate mofetil: 1.5 g bid starting within 5 days after transplantation.

**Reconstitution:** Oral suspension: Add 47 ml of water to bottle and shake well for about 1 min. Add another 47 ml of water and shake for another min. Final concentration: 200 mg/ml mycophenolate mofetil.

# CONTRAINDICATIONS:

Pregnancy, lactation. Rare hereditary deficiency of hypoxanthine-guanine phosphoribosyltransferase (HGPRT), including Kelley-Seegmiller or Lesch-Nyhan syndrome.

#### PRECAUTIONS:

Teratogenic in animals; avoid inhalation or direct skin contact. Monitor patients for lymphoproliferative disorders; advise patient to limit exposure to sunlight/UV light. Active peptic ulcer disease. Severe renal impairment. Mycophenolate mofetil and mycophenolate sodium are not interchangeable. Perform CBCs; monitor for neutropenia.

# DRUG INTERACTIONS:

Increased plasma levels of both drugs when combined with aciclovir, valaciclovir, ganciclovir and valganciclovir. Reduced absorption with colestyramine, magnesium- and aluminium hydroxide-containing products, sevelamer and other calcium-free phosphate binders. Reduced plasma levels with ciclosporin, metronidazole, quinolones, rifamycins. May reduce plasma levels of progestins; may reduce efficacy of oral contraceptives. Increased plasma levels with probenecid. May reduce efficacy of live vaccines Food reduces MPA peak serum levels by 40% and 33% following mycophenolate mofetil and mycophenolate sodium admin, respectively. Extent of absorption is not affected. Avoid cat's claw and echinacea as they have immunostimulant effects.

# ADVERSE DRUG REACTIONS:

Diarrhoea, vomiting, GI haemorrhage and perforation; leucopenia; asthenia, pain, headache, anaemia, thrombocytopenia, renal tubular necrosis, haematuria, BP changes, hyperglycaemia, disturbances of electrolytes and blood lipids, peripheral oedema, dyspnoea, cough, acne, rash, alopecia, dizziness, insomnia, paraesthesia, tremor, hypersensitivity reactions, pancreatitis, hepatitis.

Potentially Fatal: Angioedema, anaphylaxis, fatal pulmonary fibrosis.

# 187. NAPROXEN Tab 250 mg

#### SALIENT ACTIONS:

Naproxen has anti-inflammatory, analgesic, antipyretic actions. It reduces prostaglandin synthesis by inhibiting the enzyme cyclooxygenase. It also inhibits platelet aggregation.

# INDICATIONS & DOSAGE REGIMENS:

- 1. **Rheumatic disorders:** Adult: 0.5-1 g as a single dose or in 2 divided doses, up to 1.5 g daily for patients who can tolerate lower doses, for up to 6 mth, if required. Child: ≥2 yr: 5-7.5 mg/kg bid. Max: 1 g/day.
- 2. Dysmenorrhoea, Acute musculoskeletal disorders: Adult: Initially, 500 mg followed by 250 mg every 6-8 hr. Max: 1.25 g on the 1st day and 1 g thereafter.
- 3. Acute gout: Adult: Initially, 750 mg followed by 250 mg every 8 hr.
- 4. Acute migraine attacks: Adult: 750 mg at the onset of attack, followed after at least ½ an hr by further doses of 250-500 mg daily. Max: 1250 mg daily.

# CONTRAINDICATIONS:

Hypersensitivity. Aspirin or NSAID allergy, Pregnancy (3rd trimester).

# PRECAUTIONS:

Pregnancy Category (US FDA)- C, In 3<sup>rd</sup> trimester – D.Special precaution: Pre-existing CV risk factors or disease e.g. fluid retention, CHF, hypertension. History of GI disease (bleeding or ulcers). Other forms of asthma. Hepatic impairment; closely monitor patients with any abnormal LFT. Renal impairment. Elderly. Lactation.

# INTERACTIONS:

Antihypertensive effects of hypotensive agents may be reduced. Increase cyclosporine levels. Increased risk of seizures with fluoroquinolones. Rreduce efficacy of diuretics. Diminish the cardioprotective effect of acetylated salicylates. Alcohol may enhance gastric mucosal irritation. Increased serum levels with probenecid. *Potentially Fatal*: Increased risk of GI ulceration with corticosteroids. May increase lithium levels/toxicity. Severe bone marrow suppression, aplastic anaemia and GI toxicity may occur with methotrexate. Increased risk of bleeding with anticoagulants (e.g. warfarin, heparin, LMWHs) and antiplatelet agents (e.g. ticlopidine, clopidogrel, aspirin, abciximab, dipyridamole, eptifibatide, tirofiban). Absorption may be reduced with colestyramine (and other bile acid sequestrants).

# ADVERSE EFFECTS:

Oedema, palpitation, dizziness, drowsiness, headache, light headedness, vertigo, pruritus, skin eruption, ecchymosis, purpura, rash, fluid retention, abdominal pain, constipation, nausea, heartburn, diarrhoea, dyspepsia, stomatitis, flatulence, gross bleeding/perforation, indigestion, ulcers, vomiting, abnormal renal

function, haemolysis, anaemia, increased bleeding time, elevated LFTs, visual disturbances, tinnitus, hearing disturbances, dyspnoea, diaphoresis, thirst. *Potentially Fatal:* Anaphylactic/anaphylactoid reactions. Exfoliative dermatitis, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis

#### 188. NICORANDIL 10MG TABLET

#### SALIENT ACTIONS:

Nicorandil dilates arterioles and large coronary arteries by opening the potassium channels, and stimulates guanylate cyclase causing venous vasodilatation. It therefore reduces preload and afterload, and improves coronary blood flow.

#### INDICATION&DOSAGES REGIMENS:

Oral

#### Angina pectoris

Adult: 10 mg bid, increase if necessary. Usual dose: 10-20 mg bid. May use 5 mg bid for patients prone to headache. Max dose: 30 mg bid.

Hepatic impairment: Dose reduction may be necessary.

#### **CONTRAINDICATIONS:**

Cardiogenic shock; hypotension; left ventricular failure with low filling pressure; lactation.

#### PRECAUTIONS:

Hypovolaemia, low systolic BP, acute pulmonary oedema, pregnancy. May impair ability to drive or operate machinery.

#### INTERACTIONS:

Hypotensive interaction may occur with alcohol, TCAs, antihypertensives and other vasodilators.

Potentially Fatal: Enhanced hypotensive effect with sildenafil and other phosphodiesterase type-5 inhibitors.

# ADVERSE DRUG REACTIONS:

Headache (usually transitory), flushing, dizziness, nausea, vomiting and weakness. Hypotension and reflex tachycardia at high doses.

# 189. NICOUMALONE 4 MG TAB

#### SALIENT ACTIONS:

Acenocoumarol, a coumarin derivative, is a vitamin K-epoxide-reductase complex 1 (VKORC1) antagonist, depleting functional vit K reserves, thus, reducing the synthesis of coagulation factors II (prothrombin), VII, IX, and X, as well as proteins C and S. It also reduces  $\gamma$ -carboxylation of certain glutamic acid molecules, important for blood clotting initiation.

#### INDICATION&DOSAGES REGIMENS:

Oral

#### Thromboembolic disorders

Adult: Initially: 2-4 mg daily for 2 days. Alternatively, 6 mg on the 1st day as loading dose, followed by 4 mg on the 2nd day. Subsequent dose adjusted according to response. Maintenance: 1-8 mg daily. Administer at the same time each day.

Elderly: Reduce dose if necessary.

Renal impairment: Severe: Contraindicated

#### CONTRAINDICATIONS:

Haemorrhagic diathesis and blood dyscrasia (e.g. haemophilia, thrombocytopenic purpura, leukaemia), peptic ulcer or haemorrhage of the GI tract, urogenital tract or resp system; cerebrovascular haemorrhage, acute pericarditis, pericardial effusion, infective endocarditis, severe HTN. Recent or potential surgery of the eyes/CNS. Recent surgery resulting in increased fibrinolytic activity (e.g. surgery of the lung, prostate, uterus). Uncooperative patient (e.g. unsupervised senile, alcoholic, psychotic, w/ dementia). Severe hepatic and renal impairment. Pregnancy.

# PRECAUTIONS:

Patient w/ severe heart failure, known or suspected protein C or S and vit K deficiency. Mild to moderate hepatic and renal impairment. Elderly. Lactation. *Monitoring Parameters* Determine prothrombin time (PT)/INR (daily or on alternate days in early days of treatment, then at longer intervals depending on response) Monitor CBC, hepatic and renal function.

#### INTERACTIONS:

Increased effect w/ antiarrhythmics (e.g. amiodarone, quinidine), antibiotics (e.g. broad spectrum antibiotics, tetracyclines, chloramphenicol), antifungal (e.g. metronidazole), SSRIs (e.g. citalopram, fluoxetine, sertraline, paroxetine), antigout (e.g. allopurinol), lipid-regulating drugs (e.g. atorvastatin, fluvastatin, simvastatin), and

inhibitors of CYP2C9 isoenzyme. Reduced anticoagulant effect w/ antineoplastics (e.g. azathioprine, 6-mercaptopurine), antivirals (e.g. ritonavir, nelfinavir), thiazide diuretics, oral contraceptives, and inducers of CYP2C9, CYP2C19, and CYP3A4 isoenzymes. May increase the serum hydantoin concentration of phenytoin. May potentiate the hypoglycaemic effect of sulphonylurea derivatives (e.g. glibenclamide, glimepiride).

Potentially Fatal: Increased risk of haemorrhage w/ other anticoagulants (e.g. warfarin, heparin, LMWH), antiplatelets (e.g. dipyridamole, clopidogrel, ticlopidine), antibiotics (e.g. clindamycin), analgesics (e.g. salicylates, pyrazolone derivatives, COX-2 inhibitors), high dose IV methylprednisolone.

Reversed anticoagulant effect w/ foods high in vit K (e.g. beef and pork liver, green tea, green leafy vegetables). Increased metabolism and reduced PT/INR w/ chronic alcohol consumption; conversely, acute ingestion reduces metabolism and increases PT/INR. Increased INR and may cause severe bleeding w/ cranberry juice. Reduced effect w/ St. John's wort.

# ADVERSE DRUG REACTIONS:

Rarely, urticaria, rash, dermatitis, purpura, skin necrosis; fever, decreased appetite, nausea, vomiting, diarrhoea; alopecia; hepatic dysfunction, jaundice, pancreatitis; purple toe syndrome.

Potentially Fatal: Haemorrhage.

# 190. NIFEDIPINE 5MG CAP

#### SALIENT ACTIONS:

Nifedipine prevents Ca ion from entering the slow channels of cardiac and smooth muscles during depolarisation, producing peripheral and coronary vasodilatation. It reduces afterload, peripheral resistance and BP; increases coronary blood flow and causes reflex tachycardia. It has little or no effect on cardiac conduction and rarely has negative inotropic activity.

# INDICATION&DOSAGES REGIMENS:

Oral

# Hypertension

Adult: Immediate-release: Initially, 5 mg tid. Maintenance: 10-20 mg tid. Extended-release: Initially, 10-40 mg bid. or 20-90 mg once daily.

Elderly: Dose reduction may be necessary.

Hepatic impairment: Dose reduction may be necessary.

Oral

# Angina pectoris

Adult: Immediate-release: Initially, 5 mg tid. Maintenance: 10-20 mg tid. Extended-release: 10-40 mg bid or 30-90 mg once daily.

Elderly: Dose reduction may be necessary.

Hepatic impairment: Dose reduction may be necessary.

Oral

# Raynaud's syndrome

Adult: Immediate-release: 5-20 mg tid. Elderly: Dose reduction may be necessary.

Hepatic impairment: Dose reduction may be necessary.

# CONTRAINDICATIONS:

Cardiogenic shock, acute unstable angina, use w/in 1 mth of MI. Treatment of angina attack in chronic stable angina or acute reduction of BP in adults. Concomitant use w/ strong CYP3A4 inducers.

#### PRECAUTIONS:

Patients w/ hypotension, poor cardiac reserve, heart failure, severe aortic stenosis, DM, underlying severe GI narrowing (extended-release tab). Avoid abrupt withdrawal as it may casue rebound angina. Hepatic impairment. Elderly. Pregnancy and lactation. *Patient Counselling* Discontinue if ischaemic pain follows after admin. *Monitoring Parameters* Monitor BP, heart rate.

# INTERACTIONS:

Enhanced antihypertensive effects w/ other antihypertensives, aldesleukin, and antipsychotics. Concomitant use w fentanyl during surgery caused severe hypotension. May modify insulin and glucose responses. Attenuation of tachycardic effect when used w/ benazerpril. Prothrombin time may be increased w/ coumarin anticoagulants. Increased serum levels w/ CYP3A4 inhibitors (e.g. azole antifungals, cimeridine, erythromycin, HIV-protense inhibitors, nefazodone, fluoxetine, quinupristin/dalfopristin).

Potentially Fatal: Decreased bioavailability and efficacy w/ strong CYP3A4 inducers (e.g. rifampicin, phenytoin, carbamazepine).

#### ADVERSE DRUG REACTIONS:

Dizziness, flushing, headache, hypotension, peripheral oedema, tachycardia, palpitations, nausea, constipation, other GI disturbances, increased micturition frequency, lethargy, eye pain, visual disturbances, syncope, vertigo, migraine, mood disturbances, rashes (including erythema multiforme), liver function abnormalities (including cholestasis), pruritus, gingival hyperplasia, myalgia, gynaecomastia, tremor, impotence, fever. Paradoxical increase in ischaemic chest pain during initiation of treatment. GI obstruction in some tablets covered in indigestible membrane.

#### 191. NIMODIPINE 30MG TABLET

#### SALIENT ACTIONS:

Nimodipine inhibits inflow of Ca ions into cells by blocking Ca channels or select voltage-sensitive areas resulting in relaxation of vascular smooth muscle and myocardium during depolarisation. Nimodipine has greater action on the cerebral vessels because of its high lipophilicity.

#### INDICATION&DOSAGES REGIMENS:

Oral

# Prophylaxis of neurological deficit following subarachnoid haemorrhage

Adult: 60 mg 4 hrly beginning w/in 4 days of onset of haemorrhage and continued for 21 consecutive days. Hepatic impairment: Initially, 30 mg 4 hrly.

#### CONTRAINDICATIONS:

Use w/in 1 mth of MI or an episode of unstable angina. Concomitant use w/ potent CYP3A4 inhibitors (e.g. clarithromycin, ritonavir, ketoconazole, nefazodone).

# PRECAUTIONS:

Patients w. cerebral oedema or severely raised intracranial pressure. Contents of oral capsules should be given only by mouth or through a feeding tube. It must never be administered IV or by any other parenteral route. Hepatic and renal impairment. Pregnancy and lactation. *Monitoring Parameters* Careful monitoring of BP and pulse rate.

#### INTERACTIONS:

Plasma concentration and efficacy may be significantly reduced when administered w/ strong CYP3A4 inducers (e.g. ritampicin, carbamazepine, phenobarbital, phenytoin). May increase serum levels and toxicity of phenytoin. Increased plasma concentrations w/ cimetidine or sodium valproate.

Potentially Fatal: Increased risk of significant hypotension w/ concomitant potent CYP3A4 inhibitors (e.g. clarithromycin, ritonavir, ketoconazole, nefazodone).

#### ADVERSE DRUG REACTIONS:

Hypotension, oedema, ECG abnormalities, palpitations, rebound vasospasm, flushing, fluid retention, lower abdominal discomfort or cramps, constipation, mental depression, headache, lightheadedness, dizziness, dyspnoea, muscle pain, thrombocytopenia, anaemia, rash, pruritus, haematoma, diaphoresis.

# 192. NITROFURANTOIN SUSTAINED RELEASE 100MG TAB

#### SALIENT ACTIONS:

Nitrofurantoin interferes with cell metabolism and cell wall synthesis by inhibiting several enzyme systems including acetyl coenzyme A. It is bactericidal to most gram-positive and gram-negative urinary tract pathogens.

# INDICATION&DOSAGES REGIMENS:

Oral

#### Acute uncomplicated urinary tract infections

Adult: 50-100 mg 4 times daily for 7 days. Dual-release preparation: 100 mg bid.

Child: 3 mm and older children: 3 mg/kg daily in 4 divided doses.

Oral

# Prophylaxis of uncomplicated urinary tract infections

Adult: 50-1" m\_ it bedtime.

Child: >3 min and older children: 1 mg/kg once daily.

#### CONTRAINDICATIONS:

Severe renal impairment (anuria, oliguria, significantly elevated serum creatinine, CrCl <60 ml/min). Hypersensitivity to nitrofurans, G6PD deficiency, infants <3 mth. Pregnancy at term, during labour and delivery, or when the onset of labour is imminent.

# PRECAUTIONS:

Elderly. Monitor hepatic and pulmonary function during prolonged therapy. Pre-existing pulmonary, hepatic, neurological, or allergic disorders, predisposition to peripheral neuropathy e.g. renal impairment, anaemia, DM, electrolyte imbalance, debility, vitamin B deficiency. Withdraw if signs of peripheral neuropathy occur. Lactation.

# INTERACTIONS:

Reduced excretion with probenecid or sulfinpyrazone. Absorption reduced by magnesium trisilicate. Antagonistic effects with quinolone antibacterials. Reduced effects with carbonic anhydrase inhibitors or urinary alkalinisers.

# ADVERSE DRUG REACTIONS:

Nausea, vomiting, anorexia, abdominal pain, diarrhoea; headache, drowsiness, vertigo, dizziness, nystagmus, benign intracranial hypertension; rash, urticaria, pruritus, fever, sialadenitis, angioedema, erythema multiforme, exfoliative dermatitis, pancreatitis, lupus-like syndrome, myalgia, arthralgia; acute pulmonary sensitivity reactions; megaloblastic anaemia, leucopenia, granulocytopenia or agranulocytosis, thrombocytopenia, aplastic anaemia, haemolytic anaemia (in G6PD-deficient patients); transient alopecia; brownish discolouration of urine. **Potentially Fatal:** Peripheral polyneuropathy, hepatotoxicity, anaphylaxis, Stevens-Johnson syndrome, interstitial pneumonitis, pulmonary fibrosis.

# 193. NITROGLYCERIN CONTROLLED RELEASE 2.6MG TAB SALIENT ACTIONS:

Glyceryl trinitrate forms free radical nitric oxide (NO), which stimulates guanylate cyclase in the vascular smooth muscle cells resulting in relaxation of smooth muscles. It reduces cardiac oxygen demand by decreasing preload and may modestly reduce afterload, dilates coronary arteries and improves collateral flow to ischaemic regions. It also decreases sphincter tone and intra-anal pressure when administered rectally.

# INDICATION&DOSAGES REGIMENS:

Oral

# Stable angina

Adult: As modified-release tab/cap: 2.5-6.5 mg 3-4 times daily, adjust according to response. Max: 26 mg 4 times daily.

Sublingual

# Acute angina

Adult: As tab: 300-600 mcg, repeat if necessary. Seek medical help if pain persists after a total of 3 doses w/in 15 min. As aerosol spray (400 mcg/spray): 1-2 sprays directed onto or under the tongue, close the mouth after spraying; 3 sprays may be used for acute attack.

Buccal

# Acute angina

Adult: 2 mg, placed between the gum and upper lip, increase to 3 mg if necessary. Severe angina: 5 mg may be given.

Buccal

# Heart failure

Adult: 5 mg, repeat until symptoms are controlled. Chronic heart failure: 5-10 mg tid.

Buccal

# Stable angina

Adult: 2-5 mg tid.

Buccal

# Unstable angina

Adult: Up to 5 mg.

# CONTRAINDICATIONS:

Uncorrected hypovolaemia, postural hypotension, hypotension, marked anaemia, hypertrophic obstructive cardiomyopathy, constrictive pericarditis or pericardial tamponade, aortic or mitral stenosis, raised intracranial pressure (e.g. cerebral haemorrhage, head trauma), migraine or recurrent headache, closed-angle glaucoma. Concomitant use w/ phosphodiesterase type 5 (PDE5) inhibitors, riociguat, other organic nitrates w/ nitric oxide (NO) donors, heparin.

# PRECAUTIONS:

Patient w/ hypothyroidism, hypothermia, malnutrition, recent MI, arterial hypoxaemia due to severe anaemia, hypoxaemia or ventilation/perfusion imbalance due to lung disease or ischaemic heart failure. Severe renal or

hepatic impairment. Pregnancy and lactation. *Patient Counselling* This drug may cause postural hypotension, dizziness, light-headedness, blurred vision, headache or tiredness, if affected, do not drive or operate machinery. *Monitoring Parameters* Monitor heart rate and BP.

#### INTERACTIONS:

Enhanced hypotensive effect w/ vasodilators and other hypotensive drugs. Reduced efficacy (oral/buccal preparations) w/ drugs that cause dry mouth (e.g. TCAs, other antimuscarinics). Increased vasodilatory effect w/ acetylcysteine. May reduce the thrombolytic activity of alteplase. May increase the bioavailability of dihydroergotamine which may lead to coronary vasoconstriction.

Potentially Fatal: Potentiation of hypotensive effect w/ PDE5 inhibitors (e.g. sildenafil, tadalafil, vardenafil), riociguat and other organic nitrates w/ nitric oxide (NO) donors. May reduce the anticoagulant effect of heparin.

# ADVERSE DRUG REACTIONS:

Orthostatic hypotension, peripheral oedema, bradycardia, tachycardia flushing, hypotension, syncope, dizziness, headache, light-headedness, nausea, vomiting, xerostomia, weakness, paraesthesia, diaphoresis, dyspnoea, rhinitis, pharyngitis.

# 194. NORETHINDRONE ACETATE TABLET

# SALIENT ACTIONS:

Norethisterone has typical effects of a progestogen and converts the endometrium from the proliferative to the secretory phase. It may also have some oestrogenic, anabolic and androgenic activities, but these may not be significant. Norethisterone delays onset of periods and controls abnormal uterine bleeding. It also has contraceptive effects due to negative feedback inhibition of pituitary gonadotropin thus preventing ovulation.

# INDICATION&DOSAGES REGIMENS:

Oral

# Menorrhagia

Adult: 10-15 mg daily in a cyclical regimen. Usual dose: 5 mg tid for 10 days as primary treatment, subsequently 5 mg bid on days 19-26 of cycle to prevent recurrence. As acetate: 2.5-10 mg daily in a cyclical regimen, beginning during the assumed latter half of the cycle.

#### Endometriosis

*Adult:* 10-25 mg daily continuously for 4-9 mth. As acetate: 5-15 mg daily, start at 5 mg daily and increase by 2.5 mg at 14 day intervals. Take continuously for 4-9 mth.

Oral

Oral

#### Contraception

**Adult:** 0.35 mg daily, or 0.5-1 mg daily when combined with oestrogen. As acetate: 0.6 mg daily, or 1-1.5 mg daily when combined with oestrogen.

# Oral

# Progestogen component of menopausal hormonal replacement therapy

Adult: 0.7 mg as a continuous daily dose. As acetate: 1 mg daily for 10-12 days of a 28-day cycle.

# Oral

# Premenstrual syndrome

Adult: 5 mg tid on days 16-25 of cycle.

Oral

#### Breast cancer

Adult: 40 mg daily increasing to 60 mg daily if no regression is noted.

Oral

#### Postponement of menstruation

Adult: 5 mg tid starting 3 days before expected onset of menstruation.

#### CONTRAINDICATIONS:

Severe hepatic dysfunction; undiagnosed vaginal bleeding; porphyria; pregnancy; previous idiopathic or current thromboembolism; thromboembolis disease; DVT.

#### PRECAUTIONS:

Hypertension; CVS disease; hepatic impairment; epilepsy; lactation; new onset of migraine-type headache; asthma; renal impairment; history of clinical depression.

# INTERACTIONS:

Concentration may be reduced by CYP450 inducers (e.g. phenobarbital, phenytoin, carbamazepine, rifampicin, rifabutin, nevirapine, efavirenz, tetracyclines, ampicillin, oxacillin, co-trimoxazole) and ritonavir, nelfinavir

(usually inhibitors of CYP450 but have inducing properties when used with steroid hormones). May cause additive fluid retention with NSAIDs, vasodilators. Adjustment in antidiabetic, thyroid hormone and anticoagulant therapy may be required.

Potentially Fatal: May increase ciclosporin concentration.

St John's wort may induce norethisterone metabolism, leading to decreased concentrations.

# ADVERSE DRUG REACTIONS:

Mental depression, cholestatic jaundice, porphyria, epilepsy, migraine, headache, breast discomfort, dizziness, nausea and vomiting, changes in libido, appetite and weight, breakthrough bleeding, changes in menstrual flow, amenorrhoea, oedema, rash, melasma or cholasma, acne, urticaria, abnormal LFTs, moodswings, insomnia, thrombotic and thromoembolic events, optic neuritis, altered lipid profile.

# 195. NORETHISTERONE Tab 5 mg SALIENT ACTIONS:

Norethisterone has typical effects of a progestogen and converts the endometrium from the proliferative to the secretory phase. It may also have some estrogenic, anabolic and androgenic activities, but these may not be significant. Norethisterone delays onset of periods and controls abnormal uterine bleeding. It also has contraceptive effects due to negative feedback inhibition of pituitary gonadotropin thus preventing ovulation.

# INDICATIONS & DOSAGES REGIMENS:

- 1. Menorrhagia: Adult: 10-15 mg daily in a cyclical regimen. Usual dose: 5 mg tid for 10 days as primary treatment, subsequently 5 mg bid on days 19-26 of cycle to prevent recurrence. As acetate: 2.5-10 mg daily in a cyclical regimen, beginning during the assumed latter half of the cycle.
- 2. Endometriosis: Adult: 10-25 mg daily continuously for 4-9 mth. As acetate: 5-15 mg daily, start at 5 mg daily and increase by 2.5 mg at 14 day intervals. Take continuously for 4-9 mth.
- 3. Contraception: Adult: 0.35 mg daily, or 0.5-1 mg daily when combined with oestrogen. As acetate: 0.6 mg daily, or 1-1.5 mg daily when combined with oestrogen. Progestogen component of menopausal hormonal replacement therapy Adult: 0.7 mg as a continuous daily dose. As acetate: 1 mg daily for 10-12 days of a 28-day cycle.
- 4. Premenstrual syndrome: Adult: 5 mg tid on days 16-25 of cycle.
- 5. Breast cancer: Adult: 40 mg daily increasing to 60 mg daily if no regression is noted.
- 6. Postponement of menstruation: Adult: 5 mg tid starting 3 days before expected onset of menstruation. CONTRAINDICATIONS:

Severe hepatic dysfunction; undiagnosed vaginal bleeding; porphyria; pregnancy; previous idiopathic or current thromboembolism; thromboembolic disease; DVT.

# PRECAUTIONS:

Pregnancy Category (US FDA): X.Hypertension; CVS disease; hepatic impairment; epilepsy; lactation; new onset of migraine-type headache; asthma; renal impairment; history of clinical depression.

# INTERACTION:

Decrease concentration by phenobarbital, phenytoin, carbamazepine, rifampicin, rifabutin, nevirapine, efavirenz, tetracyclines, ampicillin, oxacillin, co-trimoxazole and ritonavir, nelfinavir .Cause additive fluid retention with NSAIDs, vasodilators. Adjustment in antidiabetic, thyroid hormone and anticoagulant therapy may be required. Potentially Fatal: May increase ciclosporin concentration.

# ADVERS EFFECTS:

Mental depression, cholestatic jaundice, porphyria, epilepsy, migraine, headache, breast discomfort, dizziness, nausea and vomiting, changes in libido, appetite and weight, breakthrough bleeding, changes in menstrual flow, amenorrhoea, oedema, rash, melasma or cholasma, acne, urticaria, abnormal LFTs, moodswings, insomnia, thrombotic and thromoembolic events, optic neuritis, altered lipid profile.

# 196. NORFLOXACIN Tab 400 mg

# SALIENT ACTIONS:

Norfloxacin inhibits the action of DNA gyrase in DNA replication, transcription, repair, recombination and transposition.

# INDICATIONS & DOSAGE:

- 1. Uncomplicated gonorrhea: Adult: 800 mg as a single daily dose.
- 2. Chronic bacterial prostatitis: Adult: 400 mg bid for 28 days.
- 3. Complicated urinary tract infections: Adult: 400 mg bid for 10-21 days.

- 4. Chronic relapsing urinary tract infections: Adult: 400 mg bid for up to 12 wk, may be reduced to 400 mg OD if adequate suppression within first 4 wk.
- 5. Gastroenteritis: Adult: 400 mg bid for 3-5 days
- 6. Uncomplicated urinary tract infections: Adult: Infections caused by susceptible Escherichia coli, Klebsiella pneumoniae, roteus mirabilis species: 400 mg bid for 3 days. Infections caused by other susceptible bacteria: 400 mg bid for 7-10 days.

Should be taken on an empty stomach.

# CONTRAINDICATIONS:

Hypersensitivity to quinolones; children <18 yr. Lactation.

#### PRECAUTIONS:

Pregnancy Category (US FDA) – C. Special precaution: Renal impairment; history of CNS disorders; myasthaenia gravis. Pregnancy. QT prolongation; discontinue if signs of neuropathy occur.

#### INTERACTIONS:

Antacids reduce absorption from GI tract. Probenecid reduces urinary excretion of norfloxacin. Norfloxacin may increase concentration of clozapine, ropinirole, tacrine, tizanidine. Severe hypoglycaemia has occured rarely with glyburide. Increased risk of CNS stimulation and seizures with NSAIDs. *Potentially Fatal:* Raises theophylline and ciclosporin levels. Effects of warfarin increased. Risk of QT prolongation and torsades de pointes with class I and III antiarrythmics, cisapride, erythromycin, antipsychotics, TCAs.

# ADVERSE EFFECTS:

Nausea, vomiting, heartburn, constipation, diarrhoea, abdominal cramping, anorexia; headache, dizziness; depression, insomnia; phototoxicity; rash, fever, arthralgia; elevated liver enzymes, urea and creatinine. Eosinophilia, neutropenia, thrombocytopenia and anaemia; hyperhidris; tendon rupture; QT prolongation. *Potentially Fatal:* Anaphylaxis, acute renal failure, seizures.

# 197. NORFLOXACIN 200 mg + LACTIC ACID BACILLUS Tab

#### SALIENT ACTIONS:

Norfloxacin inhibits the action of DNA gyrase in DNA replication, transcription, repair, recombination and transposition.

# INDICATIONS & DOSAGE REGIMENS:

Diarhoea/ dysentry of bacterial origin

# CONTRAINDICATIONS:

Hypersensitivity to quinolones; children <18 yr. Lactation.

#### PRECAUTIONS:

Pregnancy Category (US FDA) – C. Special precaution: Renal impairment; history of CNS disorders; myasthaenia gravis. Pregnancy. QT prolongation; discontinue if signs of neuropathy occur.

#### INTERACTIONS:

Antacids reduce absorption from GI tract. Probenecid reduces urinary excretion of norfloxacin. Norfloxacin may increase concentration of clozapine, ropinirole, tacrine, tizanidine. Severe hypoglycaemia has occured rarely with glyburide. Increased risk of CNS stimulation and seizures with NSAIDs. *Potentially Fatal:* Raises theophylline and ciclosporin levels. Effects of warfarin increased. Risk of QT prolongation and torsades de pointes with class I and III antiarrythmics, cisapride, erythromycin, antipsychotics, TCAs.

# ADVERSE EFFECTS:

Nausea, vomiting, heartburn, constipation, diarrhoea, abdominal cramping, anorexia; headache, dizziness; depression, insomnia; phototoxicity; rash, fever, arthralgia; elevated liver enzymes, urea and creatinine. Eosinophilia, neutropenia, thrombocytopenia and anaemia; hyperhidris; tendon rupture; QT prolongation. *Potentially Fatal:* Anaphylaxis, acute renal failure, seizures.

# 198. OFLOXACIN Tab 200 mg

#### SALIENT ACTIONS

Ofloxacin is a fluoroquinolone which inhibits bacterial topoisomerase IV and DNA gyrase enzymes required for DNA replication, transcription, repair and recombination. It has activity against a wide range of gram-negative and gram-positive microorganisms.

# INDICATIONS & DOSAGE REGIMENS:

- 1. Leprosy: Adult: As part of a multidrug therapy: 400 mg daily or intermittently, depending on regimen.
- 2. Uncomplicated gonorrhea: Adult: 400 mg as a single dose.
- 3. Acute bacterial exacerbation of chronic bronchitis, Community-acquired pneumonia, Uncomplicated

skin infections: Adult: 400 mg bid for 10 days.

- 4. Non-gonococcal cervicitis/urethritis due to Chlamydia trachomatis, Mixed infection of the urethra and cervix due to C. trachomatis & Neisseria gonorrhoeae: Adult: 200-300 mg bid for 7 days.
- 5. Pelvic inflammatory disease: Adult: 400 mg bid for 14 days.
- 6. Uncomplicated cystitis: Adult: 200 mg bid for 3 days if due to E. Coli or Klebsiella pneumoniae; 7 days if due to other susceptible organisms.
- 7. Complicated urinary tract infections: Adult: 200 mg bid for 10 days.
- 8. Chronic bacterial prostatitis: Adult: 300 mg bid for 6 wk.
- 9. Traveller's diarrhoea: Adult: 300 mg bid for 1-3 days
- 10. Postexposure prophylaxis after suspected or confirmed exposure to inhalational anthrax: Adult: 400 mg bid for ≥60 days.
- 11. Legionnaire's disease: Adult: 400 mg bid for 2-3 wk.
- 12. Typhoid fever: Adult: 200-400 mg bid for 7-14 days.

# CONTRAINDICATIONS:

Hypersensitivity to quinolones; pregnancy and lactation; prolongation of the QT interval; uncorrected hypokalaemia.

# PRECAUTIONS:

Pregnancy Category (US FDA) – C.Epilepsy or other predisposition to seizures; known or suspected CNS disorders; renal, hepatic impairment; myasthaenia gravis; superinfection; children <18 yr; exposure to strong sunlight and UV light; ensure adequate hydration; elderly.

# INTERACTIONS:

Probenecid decreases elimination. Antacids reduce ofloxacin absorption, avoid for 2 hr either side of administration. Cimetidine increase ofloxacin concentrations. Monitor blood glucose in patients on antidiabetic medication. *Potentially Fatal:* Corticosteroids may increase risk of tendon rupture. Increases effects of oral anticoagulants, ciclosporin, theophylline. Increased risk of seizures with NSAIDs. Avoid in patients taking QT prolonging medication (e.g. class Ia or III antiarrythmics, astemizole, terfenadine, cisapride, erythromycin, pentamidine, phenothiazines and some TCA).

#### ADVERSE EFFECTS:

Nausea, vomiting, abdominal pain, diarrhoea; headache, dizziness, insomnia, hallucinations; leucopenia and eosinophilia; vaginitis; dysgeusia; tendon damage and rupture; anorexia; tremor; photosensitivity; hypersensitivity reactions. Discontinue if psychiatric, neurological or hypersensitivity reactions occur. Potentially Fatal: Anaphylaxis; rarely seizures.

# 199. OFLOXACIN 200 mg + ORNIDAZOLE 500 mg

#### SALIENT ACTIONS

This is a FDC of antibacterial Norfloxacin with antiamoebic ornidazole Ofloxacin is a fluoroquinolone which inhibits bacterial topoisomerase IV and DNA gyrase enzymes required for DNA replication, transcription, repair and recombination. It has activity against a wide range of gram-negative and gram-positive microorganisms.

# INDICATIONS & DOSAGE REGIMENS:

Diarrhoea / dysentery of bacterial, amoebic or mixed origin. 1 tablet twice a day for 5 days

#### CONTRAINDICATIONS:

Hypersensitivity to quinolones; children, pregnancy and lactation; prolongation of the QT interval; uncorrected hypokalaemia.

# PRECAUTIONS:

Pregnancy Category (US FDA) – C.Epilepsy or other predisposition to seizures; known or suspected CNS disorders; renal, hepatic impairment; myasthaenia gravis; superinfection; children <18 yr; exposure to strong sunlight and UV light; ensure adequate hydration; elderly.

#### INTERACTIONS:

Probenecid decreases elimination. Antacids reduce of loxacin absorption, avoid for 2 hr either side of administration. Cimetidine increase of loxacin concentrations. Monitor blood glucose in patients on antidiabetic medication. Potentially Fatal: Corticosteroids may increase risk of tendon rupture. Increases effects of oral anticoagulants, ciclosporin, the ophylline. Increased risk of seizures with NSAIDs. Avoid in patients taking QT prolonging medication (e.g. class Ia or III antiarrythmics, astemizole, terfenadine, cisapride, erythromycin, pentamidine, phenothiazines and some TCA).

# ADVERSE EFFECTS:

Nausea, vomiting, abdominal pain, diarrhoea; headache, dizziness, insomnia, hallucinations; leucopenia and

eosinophilia; vaginitis; dysgeusia; tendon damage and rupture; anorexia; tremor; photosensitivity; hypersensitivity reactions. Discontinue if psychiatric, neurological or hypersensitivity reactions occur. Potentially Fatal: Anaphylaxis; rarely seizures.

# 200. OLANZAPINE Tab 2.5 mg / 10 mg SALIENT ACTIONS:

Olanzapine is an atypical antipsychotic with affinity for serotonin 5-HT2A/2C, dopamine, muscarinic M1-M5, histamine H1 and adrenergic α1 receptors.

# INDICATIONS & DOSAGE REGIMENS:

- Schizophrenia: Adult: 5-10 mg daily adjusted in steps of 5 mg, Usual range: 5-20 mg daily. Doses > 10 mg should be given only after clinical reassessment. Max: 20 mg daily.
- Acute mixed or manic episodes in bipolar disorder: Adult: 10 or 15 mg daily as monotherapy or 10 mg daily when used as part of combination therapy. Adjust dose in steps of 5 mg; usual range: 5-20 mg daily. For prevention of recurrence: Start with 10 mg daily.

# CONTRAINDICATIONS:

Angle-closure glaucoma; lactation. IM: History of CVS disease, heart surgery.

#### PRECAUTIONS:

Pregnancy Category (US FDA)- C. Impaired renal, hepatic, cardiovascular function; prostatic hypertrophy; paralytic ileus; DM; parkinsonism; pregnancy. History of blood dyscrasias, myelosuppression, seizures; dementia; dyslipidaemia. IM: Hypotension, bradyarrhythmia, hypoventilation; monitor BP carefully. Caution when used in adolescents due to increased risk of weight gain and hyperlipidaemia. Efficacy and safety have not been established in paediatric patients <13 yr.

#### INTERACTIONS:

Olanzapine may antagonise the effects of levodopa and dopamine agonists. Drugs that induce CYP1A2 or glucuronyl transferase enzymes e.g. omeprazole and rifampicin, may increase olanzapine clearance. Inhibitors of CYP1A2 may potentially inhibit olanzapine elimination. Carbamazepine may increase the clearance of olanzapine. Concomitant admin of activated charcoal reduced the oral bioavailability of olanzapine by 50-60%. Caution should be taken when olanzapine is administered with centrally acting drugs and alcohol.

# ADVERSE EFFECTS:

Postural hypotension; constipation; dizziness; wt gain; agitation; insomnia; akathisia; tremor; personality disorders; edema; somnolence; increased appetite; antimuscarinic effects; speech difficulty; exacerbation of Parkinson's disease: hallucinations; asthenia; increased body temperature; bradycardia; hyperprolactinaemia; QT prolongation (uncommon); asymptomatic elevations of hepatic transaminases. Potentially Fatal: Exacerbation of preexisting diabetes sometimes leading to ketoacidosis. Neuroleptic malignant syndrome.

# 201. OMEGA 3 FATTY ACIDS 500MG CAPSULE

# **SALIENT ACTIONS:**

Omega-3 fatty acids—also called  $\omega$ -3 fatty acids or n-3 fatty acids —are polyunsaturated fatty acids(PUFAs).

The three types of omega-3 fatty acids involved in human physiology are α-linolenic acid (ALA)(found in plant oils), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)(both commonly found in marine oils)

# INDICATIONS:

- Lower blood pressure
- Reduce triglycerides
- Slow the development of plaque in the arteries
- Reduce the chance of abnormal heart rhythm
- Reduce the likelihood of heart attack and stroke
- Lessen the chance of sudden cardiac death in people with heart disease

# ADVERSE EFFECTS:

Side effects from omega-3 fish oil may include:

- A fishy taste in your mouth
- Fishy breath
- Stomach upset
- Loose stools
- Nausea

#### PRECAUTIONS:

Taking more than 3 grams of fish oil daily may increase the risk of bleeding.

# 202. OMEPRAZOLE Tab 20 mg

# SALIENT ACTIONS:

Omeprazole suppresses gastric acid secretion by specific inhibition of the enzyme system hydrogen/potassium adenosine triphosphatase (H+/K+ ATPase) present on the secretory surface of the gastric parietal cell.

# INDICATIONS & DOSAGE REGIMENS:

- 1. Peptic ulcer: Adult: 20 mg daily as a single dose or 40 mg daily in severe cases. Treatment duration: Duodenal ulcers: 4 wk; gastric ulcers: 8 wk. Maintenance: 10-20 mg once daily.
- 2. NSAID-associated ulceration: Adult: 20 mg daily. Same dose may also be used for prophylaxis of ulceration in patients who require continued NSAID therapy.
- 3. *H.pylori* infection: *Adult:* Dose varies with regimen. As triple therapy: 20 mg bid or 40 mg once daily; requires combination therapy with antibiotics. Therapy is given for 1 wk. Omeprazole may be continued for another 4-8 wk on its own.
- 4. Gastro-oesophageal reflux disease: Adult: 20 mg OD for 4 wk, may continue for another 4-8 wk if necessary. Maintenance: 10 mg daily. Child: Neonate, 1 mth-2 yr: 700 mcg/kg/day, may increase up to 3 mg/kg/day, or 20 mg daily. >2 yr: <20 kg: 10 mg once daily; ≥20 kg: 20 mg daily. Doses may be doubled if necessary.</p>
- 5. Zollinger-Ellison syndrome: Adult: Initially, 60 mg once daily, adjust according to response. Maintenance: 20-120 mg daily. Doses >80 mg are administered usually in 2 divided doses.
- 6. Prophylaxis of acid aspiration during general anaesthesia: Adult: Initially, 40 mg given the evening before surgery and another 40 mg 2-6 hr before the procedure.
- 7. Acid-related dyspepsia: Adult: 10 or 20 mg daily for 2-4 wk.
- 8. Erosive oesophagitis: Adult: 20 mg/day for 4-8 wk. Maintenance of healing: 20 mg/day for up to 12 mth of total therapy (including treatment period).
  Cap: Should be taken with food. (Take immediately before a meal.)

# CONTRAINDICATIONS:

No

# PRECAUTIONS:

Pregnancy Category (US FDA) – C.Exclude malignancy, prolonged use, and hepatic impairment. Pregnancy, lactation, children <1 yr. Elderly and Asians (increased bioavailability).

# INTERACTIONS:

Decreases absorption of itraconazole, ketoconazole, dasatinib, oral iron salts. Decreases levels of nelfinavir. Increases levels of benzodiazepines (e.g. diazepam, midazolam, triazolam), HMG-CoA reductase inhibitor, CYP2C19 substrates (e.g. citalopram, diazepam, methsuximide, phenytoin, propranolol, and sertraline), and CYP2C9 substrates (e.g. bosentan, dapsone, fluoxetine, glimepiride, glipizide, losartan, montelukast, nateglinide, paclitaxel, phenytoin, warfarin, and zafirlukast). Decreased effects with CYP2C19 inducers (e.g. aminoglutethimide, carbamazepine, phenytoin, and rifampin). Decreases excretion of methotrexate. Enhances the adverse/toxic effect of cilostazol. May alter the concentrations/effects of clozapine.

# ADVERSE EFFECTS

Diarrhoea, nausea, fatigue, constipation, vomiting, flatulence, acid regurgitation, taste perversion, arthralgia, myalgia, urticaria, dry mouth, dizziness, headache, paraesthesia, abdominal pain, skin rashes, weakness, back pain, upper respiratory infection, cough. *Potentially Fatal:* Anaphylaxis.

# 203. ONDANSETRON HCL IP EQ. TO ONDANSETRON 8MG TAB SALIENT ACTIONS:

Antiemetics / Supportive Care Therapy. Belongs to the class of serotonin (5HT3) antagonists. Used for the prevention of nausea and vomiting

# INDICATION & DOSAGE REGIMENS:

Oral

# Prophylaxis of postoperative nausea and vomiting

Adult: 16 mg taken 1 hr prior to anaesth; or 8 mg taken 1 hr prior to anaesth followed by 2 more doses of 8 mg 8 hrly.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Moderate or severe: Max: 8 mg/day.

Oral

Nausea and vomiting associated with cancer chemotherapy

Adult: 24 mg as a single dose, 30 min prior to the start of single-day chemotherapy.

Child: 4-11 yr 4 mg 30 min prior to chemotherapy; repeat dose at 4 and 8 hr after initial dose, then 4 mg tid for 1-2 days after completion of chemotherapy.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Moderate or severe: Max: 8 mg/day.

Oral

Nausea and vomiting associated with cancer chemotherapy or radiotherapy

Adult: Less emetogenic chemotherapy and/or radiotherapy: 8 mg 2 hr prior to treatment followed by 8 mg 8-12 hr later.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Moderate or severe: Max: 8 mg/day.

Oral

Prevent delayed emesis following chemotherapy

Adult: 8 mg bid, for up to 5 days after the end of a course of chemotherapy.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Moderate or severe: Max: 8 mg/day.

Oral

Prophylaxis of chemotherapy-induced nausea and vomiting

Adult: Moderate emetogenic cancer chemotherapy: Initially, 8 mg 30 min prior to chemotherapy; repeat dose 8 hr after initial dose, then 8 mg 12 hrly for 1-2 days after completion of chemotherapy. Highly emetogenic cancer chemotherapy: 24 mg as a single dose 30 min prior to chemotherapy.

Child: Moderate emetogenic cancer chemotherapy: 4-11 yr Initially, 4 mg 30 min prior to chemotherapy; repeat dose at 4 and 8 hr after the initial dose, then 4 mg 8 hrly for 1-2 days after completion of chemotherapy.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Moderate or severe: Max: 8 mg/day.

Oral

Prophylaxis of nausea and vomiting associated with radiation therapy

Adult: Usual dose: 8 mg tid. Undergoing total body irradiation: 8 mg 1-2 hr prior to each fraction of therapy daily. Undergoing single high-dose fraction radiation therapy to the abdomen: 8 mg 1-2 hr prior to radiation, repeat dose 8 hrly for 1-2 days after completion of therapy. Undergoing daily fractioned radiation to the abdomen: 8 mg 1-2 hr prior to radiation, then 8 hrly; repeat therapy daily.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Moderate or severe: Max: 8 mg/day.

CONTRAINDICATIONS:

Use with apomorphine (profound hypotension).

PRECAUTIONS:

May cause QT prolongation; caution when used in cardiac diseases, patients who are on medications that can prolong QT or patients with electrolyte abnormalities. Severe hepatic impairment. May mask progressive ileus and/or gastric distension. Pregnancy, lactation

INTERACTIONS:

Rifampicin and other CYP3A4 inducers reduce levels/effects of ondansetron.

Potentially Fatal: Concurrent use may increase the hypotensive effect of apomorphine; avoid concurrent use.

ADVERSE DRUG REACTIONS:

Headache, malaise/fatigue, constipation; drowsiness, fever, dizziness, anxiety, cold sensation; pruritus, rash; diarrhoea; gynaecological disorder, urinary retention; elevated transaminase; local inj site reaction (pain, redness, burning); paresthesia; hypoxia. Rarely: Anaphylaxis, angina, bronchospasm, ECG changes, extrapyramidal symptoms, grand mal seizure, hypokalaemia, tachycardia, vascular occlusive events.

# 204. ORCIPRENALINE 10MG TAB

# SALIENT ACTIONS:

Orciprenaline is a direct acting sympathomimetic with predominantly  $\beta_2$ -adrenoceptor stimulant activity. It has minimal effect on heart rate.

# INDICATIONS & DOSAGE REGIMENS:

Oral

# Chronic management of reversible airways obstruction

Adult: As sulfate: 20 mg 3 or 4 times daily.

Child: As sulfate: Up to 1 yr: 5-10 mg tid; 1-3 yr: 5-10 mg 4 times daily; 3-12 yr: 40-60 mg daily in divided doses.

Oral

# Bradycardia

Adult: As sulfate: Up to 240 mg daily in divided doses.

# CONTRAINDICATIONS:

Cardiac arrhythmias associated with tachycardia.

# PRECAUTIONS:

CV disease (e.g. arrhythmia, hypertension, CHF), DM, glaucoma, hyperthyroidism, hypokalaemia, seizure disorders. Pregnancy and lactation.

# DRUG INTERACTIONS:

Effects may be antagonised by  $\beta$ -blockers e.g. propranolol. Duration of bronchodilation may be increased with inhaled ipratropium. Increased adverse effects with MAOIs, TCAs, sympathomimetics.

Potentially Fatal: Increased risk of malignant arrhythmias with halothane.

ADVERSE DRUG REACTIONS: Tachycardia, nervousness, increased serum glucose, increased potassium levels, tremor, palpitation, headache, dizziness, insomnia, nausea, vomiting, bad taste, heartburn, xerostomia, trembling, muscle cramps, weakness, coughing, pharyngitis, increased diaphoresis, paradoxical bronchospasm, hypertension, chest pain, angina, drowsiness, diarrhoea, taste change.

# 205. OSELTAMIVIR 75MG CAP

# SALIENT ACTIONS:

Oseltamivir is a prodrug of oseltamivir carboxylate. Oseltamivir carboxylate inhibits a neuraminidase (sialidase), a viral surface enzyme which is responsible for the replication and infectivity of influenza virus A and B, thereby preventing the release of viruses from infected cells.

# INDICATIONS & DOSAGE REGIMENS:

Oral

# Influenza A and B

Adult: 75 mg bid for 5 days. Initiate w/in 2 days of onset of symptoms.

Child: 0-1 mth 2 mg/kg; >1-3 mth 2.5 mg/kg; >3-12 mth 3 mg/kg. >1 yr ≤15 kg: 30 mg; >15-23 kg: 45 mg; >23-40 kg: 60 mg; >40 kg: 75 mg. All doses to be given bid for 5 days. Initiate w/in 2 days of onset of symptoms.

Renal impairment: Haemodialysis patient: 30 mg after each dialysis session. Peritoneal dialysis patient: 30 mg as a single dose.

CrCl (ml/min	Dosage Recommendation
≤10	Not recommended.
>10-30	30 mg once daily.
>30-60	30 mg bid.

Reconstitution: Reconstitute w/55 mL of water to a final concentration of 6 mg/mL susp.

# Prophylaxis of influenza A and B

**Adult:** 75 mg once daily for at least 10 days. Initiate w/in 2 days of exposure. For community outbreak: May continue dosing for up to 6 wk.

Child: 0-1 mth 2 mg/kg; >1-3 mth 2.5 mg/kg; >3-12 mth 3 mg/kg. >1 yr  $\leq$ 15 kg: 30 mg; >15-23 kg; 45 mg; >23-40 kg: 60 mg; >40 kg: 75 mg. All doses to be given once daily for 10 days. Initiate w/in 2 days of exposure. For community outbreak: May continue dosing for up to 6 wk.

Renal impairment: Haemodialysis patient: 30 mg after every 2nd dialysis session. Peritoneal dialysis patient: 30 mg once wkly.

CrCl (ml/min)	Dosage Recommendation
≤10	Not recommended.
>10-30	30 mg every 2nd day.
>30-60	30 mg once daily.

Reconstitution: Reconstitute w/ 55 mL of water to a final concentration of 6 mg/mL susp.

# CONTRAINDICATIONS:

Hypersensitivity to oseltamivir.

# PRECAUTIONS:

Patient w/ resp disease, chronic cardiac disease. Renal and severe hepatic impairment. Immunocompromised patient. Childn. Pregnancy and lactation. *Monitoring Parameters* Monitor closely for signs and symptoms of behavioural changes.

# DRUG INTERACTIONS:

May potentially inhibit replication of influenza virus in live/attenuated influenza virus vaccine **ADVERSE DRUG REACTIONS:** Nausea, vomiting, abdominal pain, insomnia, bronchitis, vertigo, diarrhoea, cough, dizziness, headache, fatigue, unstable angina, anaemia, arrhythmias, GI bleeding, haemorrhagic or pseudomembranous colitis, pneumonia, pyrexia, peritonsillar abscess, aches and pains, upper resp infections, dyspepsia, rhinorrhoea. In childn: Vomiting and other GI disturbances, bronchitis, asthma, conjunctivitis, dermatitis, ear disorders, otitis media, epistaxis, lymphadenopathy, sinusitis, pneumonia.

Potentially Fatal: Anaphylaxis and skin rashes (e.g. Stevens-Johnson syndrome, erythema multiforme, epidermal necrolysis; neuropsychiatric events (e.g. delirium, hallucinations, abnormal behaviour). Rarely, fulminant hepatitis or hepatic failure.

# 206. OXCARBAZEPINE TAB

#### SALIENT ACTIONS:

Oxcarbazepine and monohydroxy derivative (MHD) block voltage-sensitive Na channels, stabilising hyperexcited neuronal membranes, inhibiting repetitive firing, and decreasing the propagation of synaptic impulses. These actions are believed to prevent the spread of seizures. Oxcarbazepine and MHD also increase K conductance and modulate the activity of high-voltage activated Ca channels.

# INDICATIONS & DOSAGE REGIMENS:

Oral

# Partial seizures

Adult: As monotherapy or adjunctive therapy: Initially, 600 mg daily in 2 divided doses, may increase if necessary in max increments of 600 mg daily at wkly intervals. Maintenance dose: 600-1,200 mg daily or up to 2,400 mg daily in adjunctive therapy or in refractory patients switched from other antiepileptics.

Child: ≥6 yr 8-10 mg/kg daily in 2 divided doses, may increase if necessary in increments of 10 mg/kg daily at wkly intervals. Maintenance dose: 30 mg/kg daily in adjunctive therapy. Max: 46 mg/kg/day.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation	
<30	Initially, 300 mg daily, increased at wkly intervals or longer.	

#### CONTRAINDICATIONS:

Lactation.

#### PRECAUTIONS:

Patient carrying the HLA-B\*1502 allele. Avoid abrupt withdrawal. Severe renal and hepatic impairment. Pregnancy. *Patient Counselling* May impair ability to drive or operate machinery. *Monitoring Parameters* Monitor seizure frequency, serum Na, symptoms of CNS depression, hypersensitivity reactions, serum levels of concomitant antiepileptic drugs during titration; periodic thyroid function test and CBC.

#### DRUG INTERACTIONS:

May increase plasma concentrations of other anticonvulsants (e.g. phenobarbital, phenytoin). May decrease plasma concentrations of OC and Ca channel blockers. Decreased plasma concentrations w/ potent inducers of CYP isoenzymes (e.g. carbamazepine, phenytoin, phenobarbital).

Additive sedative effect w/ alcohol.

# ADVERSE DRUG REACTIONS:

Hyponatraemia; suicidal behaviour or ideation; neuropsychiatric effects (e.g. impaired cognitive or psychomotor performance, somnolence or fatigue, incoordination); dizziness, somnolence, diplopia, fatigue, nausea, vomiting, ataxia, abnormal vision, abdominal pain, tremor, dyspepsia, abnormal gait, hypothyroidism. Rarely,

pancytopenia, agranulocytosis, leucopenia.

Potentially Fatal: Stevens-Johnson syndrome, toxic epidermal necrolysis; anaphylaxis, angioedema; Drug Reaction w/ Eosinophilia and Systemic Symptoms (DRESS).

# 207. OXYBUTYNIN CHLORIDE TAB

# SALIENT ACTIONS:

Oxybutynin exerts direct antispasmodic effect on the smooth muscle by inhibiting the muscarinic action of acetylcholine. It exhibits moderate anticholinergic effect, but has potent antispasmodic effects on urinary smooth muscle.

# INDICATIONS & DOSAGE REGIMENS:

Oral

#### Overactive bladder

Adult: 2.5-5 mg bid-tid. May be increased to max 5 mg 4 times daily if necessary. As extended-release preparation: Initially, 5 mg once daily increased by 5 mg every wk if necessary to max 30 mg daily. Child: >7 yr for nocturnal enuresis: 2.5-3 mg bid increased if necessary to 5 mg bid-tid. Last dose should be given before bedtime. As extended-release preparation: 5 mg once daily, increased by 5 mg wkly if necessary to max 20 mg daily.

Elderly: Initially, 2.5-3 mg bid increased to 5 mg bid if necessary.

Oral

# Neurogenic bladder disorders

Child: >5 yr: 2.5 or 3 mg bid increased to 5 mg bid according to response. Max 5 mg tid.

Transdermal

# Overactive bladder

Adult: 1 transdermal system (delivering 3.9 mg per day) applied to dry, intact skin on the abdomen, hip, or buttock twice wkly.

# CONTRAINDICATIONS:

GI obstruction or atrophy, severe toxic megacolon, significant bladder outflow obstruction, glaucoma, urinary retention.

#### PRECAUTIONS:

Elderly; hepatic or renal impairment; neuropathy; hyperthyroidism; prostatic hyperplasia; hiatus hernia; cardiac disease, reflux oesophagitis, ulcerative colitis, myasthenia gravis; pregnancy and lactation. High environmental temperature might cause heat prostration (fever with heat stroke due to decreased sweating).

# DRUG INTERACTIONS:

Co-administration with other anticholinergic drugs may cause undesirable increased anticholinergic effects. Additive sedation with CNS depressants and alcohol. Concentration may be increased by CYP3A4 inhibitirs (e.g. imidazole antifungals, macrolide antibiotics).

# ADVERSE DRUG REACTIONS:

Dry mouth, constipation, nausea, abdominal pain; blurred vision; headache, dizziness, drowsiness; dry skin, rash; photosensitivity, diarrhoea, insomnia, palpitation, weakness, dry eyes, confusion, hypertension, UTI, dyspepsia.

# 208. PANCREATIN CAP

# SALIENT ACTIONS:

Pancreatin are pancreatic enzymes which hydrolyse fats to glycerol and fatty acids, break down protein into peptides, proteoses and derived substances, and convert starch into dextrins and sugars.

# INDICATIONS & DOSAGE REGIMENS:

# Pancreatic insufficiency

Adult: Dose is adjusted according to dosage form and patient's needs. Usual dose with each meal: 5,000-56,000 units of lipase activity (with varying proportions of protease and amylase activity, depending on the preparation).

Child: Dose dependant upon dosage form and patient's needs. Children with cystic fibrosis max dose: 10,000 units lipase/kg/day.

# CONTRAINDICATIONS:

Acute pancreatitis or acute exacerbation of chronic pancreatic disease.

# PRECAUTIONS:

Avoid high doses in patients with cystic fibrosis. Maintain adequate hydration. Some products contain pork

protein. Inactivated by heat; do not mix with hot food or liquids. May irritate oral mucosa; should not be held in mouth. Pregnancy and lactation.

# DRUG INTERACTIONS:

May impair the oral absorption of folic acid when taken together; antagonises hypoglycaemic effect of acarbose.

# ADVERSE DRUG REACTIONS:

GI effects e.g. abdominal discomfort, nausea and vomiting. Buccal and perianal irritation, particularly in infants. Colonic strictures may occur, mainly in children with cystic fibrosis receiving high doses of pancreatin preparations. Hyperuricaemia and hyperuricosuria may occur.

#### 209. PANTOPRAZOLE 20MG TAB

# SALIENT ACTIONS:

Pantoprazole is a substituted benzimidazole, and also known as PPI due to its property to block the final step of acid secretion by inhibiting H<sup>+</sup>/K<sup>+</sup> ATPase enzyme system in gastric parietal cell. Both basal and stimulated acid are inhibited.

# INDICATIONS & DOSAGE REGIMENS:

Oral

# Gastro-oesophageal reflux disease

Adult: 20-40 mg once daily in the morning for 4 wk, increased to 8 wk if necessary. Maintenance: 20-40 mg/day. Alternatively, 20 mg/day on recurring symptoms.

Child: ≥5 yr 15-40 kg: 20 mg; >40 kg: 40 mg All doses to be taken once daily in the morning.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Max: 20 mg/day or 40 mg on alternate days.

Oral

# Peptic ulcer

Adult: 40 mg once daily in the morning for 2-4 wk for duodenal ulceration or 4-8 wk for benign gastric ulceration.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Max: 20 mg/day or 40 mg on alternate days.

Oral

# H.pylori infection

Adult: 1-wk triple therapy: 40 mg bid combined w/ clarithromycin 500 mg bid and amoxicillin 1 g bid or combined w/ clarithromycin 250 mg bid and metronidazole 400 mg bid.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Max: 20 mg/day or 40 mg on alternate days.

Oral

# Prophylaxis of NSAID-induced ulcers

**Adult:** 20 mg once daily in the morning. **Elderly:** No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Max: 20 mg/day or 40 mg on alternate days.

Oral

# Zollinger-Ellison syndrome

**Adult:** Initially, 80 mg once daily in the morning, adjusted up to 240 mg/day if needed. Daily doses >80 mg should be given in 2 divided doses.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Max: 20 mg/day or 40 mg on alternate days.

Oral

# Erosive oesophagitis

**Adult:** 20-40 mg once daily in the morning for 4 wk, increased up to 16 wk if necessary. Maintenance: 20-40 mg/day. Alternatively, 20 mg/day on recurring symptoms.

Child: ≥5 yr 15-40 kg: 20 mg; >40 kg: 40 mg. All doses to be taken once daily in the morning. Duration: Up to 8 wk.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Max: 20 mg/day or 40 mg on alternate days.

# CONTRAINDICATIONS:

Concomitant use w/ rilpivirine, atazanavir and nelfinavir. Lactation.

#### PRECAUTIONS:

Gastric malignancy should be ruled out. Consider Zn<sup>++</sup> supplementation during IV therapy in patients who are prone to Zn<sup>++</sup> deficiency. Pregnancy. *Monitoring Parameters* Monitor Mg levels prior to initiation and periodically during prolonged use.

# DRUG INTERACTIONS:

Increased risk of digoxin-induced cardiotoxic effects. Increased risk of hypomagnesaemia w/ diuretics. May increase INR and prothrombin time of warfarin. May increase serum concentration of methotrexate and saquinavir. Delayed absorption and decreased bioavailability w/ sucralfate. Decreased absorption of ketoconazole, itraconazole.

Potentially Fatal: May decrease serum levels and pharmacological effects of rilpivirine, atazanavir and nelfinavir.

# ADVERSE DRUG REACTIONS:

Increased risk of *Clostridium difficile*-associated diarrhoea (CDAD). Headache, dizziness, nausea, vomiting, abdominal pain, flatulence, diarrhoea, constipation, dyspepsia, arthralgia, insomnia, rhinitis, inj site reaction (e.g. thrombophlebitis and abscess). Long-term treatment may lead to atrophic gastritis, symptomatic and asymptomatic hypomagnesaemia, cyanocobalamin malabsorption, and increased risk of osteoporosis-related fracture.

Potentially Fatal: Stevens-Johnson syndrome, toxic epidermal necrolysis and anaphylaxis.

# 210. PARACETAMOL IP 500MG TAB

# SALIENT ACTIONS:

Belong to the class of NSAIDs and act by non selectively inhibiting the COX-1 and COX-2 Ezymes. It has analgesic and antipyretic action and no anti-inflammatory action.

# INDICATIONS & DOSAGE REGIMENS:

# Tablets:

Mild to moderate pain and fever: Adult: 0.5-1 g 4-6 hrly as necessary. Max: 4 g daily.

Child: Neonate 28-32 wk post menstrual age: 20 mg/kg as a single dose then 10-15 mg/kg 8-12 hrly (max 30 mg/kg daily in divided doses); neonate >32 wk post menstrual age: 20 mg/kg as a single dose then 10-15 mg/kg 6-8 hrly (max 60 mg/kg daily in divided doses); child 1-3 mth: 30 mg 8 hrly (max 60 mg/kg daily in divided doses); 3 mth-1 yr: 60-120 mg 4-6 hrly (max 4 doses in 24 hr); 1-5 yr: 120-250 mg 4-6 hrly (max 4 doses in 24 hr); 6-12 yr: 250-500 mg 4-6 hrly (max 4 doses in 24 hr).

Post-immunization pyrexia: Child: 2-3 mth: Initially, 60 mg repeated 4-6 hrly if necessary.

# CONTRAINDICATIONS:

Gastro-duodenal ulcer, chronic alcoholic.

# PRECAUTIONS:

Pregnancy Category (US FDA) – B. Renal or hepatic impairment; alcohol-dependent patients; G6PD deficiency **INTERACTIONS:** 

Reduced absorption of cholestyramine within 1 hr of admin. Accelerated absorption with metoclopramide.

Decreased effect with barbiturates, carbamazepine, hydantoins, rifampicin and sulfinpyrazone. Paracetamol may increase effect of warfarin.

Potentially Fatal: Paracetamol increases the risk of liver damage in chronic alcoholics. Increased risk of toxicity with other hepatotoxic drugs or drugs which induce microsomal enzymes e.g. barbiturates, carbamazepine, hydantoins, rifampicin and sulfinpyrazone.

# ADVERSE EFFECTS:

Nausea, allergic reactions, skin rashes, acute renal tubular necrosis.

Potentially Fatal: Very rare, blood dyscrasias (e.g. thrombocytopenia, leucopenia, neutropenia, agranulocytosis); liver damage.

# 211. PAROXETINE HCL TABLET

# SALIENT ACTIONS:

Paroxetine selectively inhibits the reuptake of serotonin. It has limited direct action at other neurotransmitter

sites including muscarinic receptors.

# INDICATIONS & DOSAGE REGIMENS:

Oral

# Depression

Adult: 20 mg daily, increase gradually, if necessary, by 10-mg increments wkly; max: 50 mg/day. Elderly: Initially, 10 mg daily, increase if needed by 10 mg/day at 1 wk intervals; max: 40 mg daily.

**Renal impairment:** Severe: 10 mg daily, increase to a max of 40 mg daily as necessary. **Hepatic impairment:** Severe: 10 mg daily, increase to a max of 40 mg daily as necessary.

Oral

# Obsessive compulsive disorder

Adult: Initially, 20 mg daily, increase wkly in 10-mg increments. Maintenance: 40-60 mg daily. Elderly: Initially, 10 mg daily, increase if needed by 10 mg/day at 1 wk intervals; max: 40 mg daily.

**Renal impairment:** Severe: 10 mg daily, increase to a max of 40 mg daily as necessary. **Hepatic impairment:** Severe: 10 mg daily, increase to a max of 40 mg daily as necessary. Oral

# Panic disorder with or without agoraphobia

*Adult:* Initially, 10 mg daily, increase wkly in 10-mg increments according to clinical response. Maintenance: 40-60 mg daily.

Elderly: Initially, 10 mg daily, increase if needed by 10 mg/day at 1 wk intervals; max: 40 mg daily.

**Renal impairment:** Severe: 10 mg daily, increase to a max of 40 mg daily as necessary. **Hepatic impairment:** Severe: 10 mg daily, increase to a max of 40 mg daily as necessary. Oral

Social anxiety disorder

Adult: Initially, 20 mg daily, increase after several wk by 10-mg increments; max dose: 50-60 mg/day. Elderly: Initially, 10 mg daily, increase if needed by 10 mg/day at 1 wk intervals; max: 40 mg daily.

**Renal impairment:** Severe: 10 mg daily, increase to a max of 40 mg daily as necessary. **Hepatic impairment:** Severe: 10 mg daily, increase to a max of 40 mg daily as necessary. *Oral* 

# Anxiety

Adult: Initially, 20 mg daily, increase in wkly increments of 10 mg; max dose: 50 mg/day.

Elderly: Elderly: Initially, 10 mg daily, increase if needed by 10 mg/day at 1 wk intervals; max: 40 mg daily.

Renal impairment: Severe: 10 mg daily, increase to a max of 40 mg daily as necessary.

Hepatic impairment: Severe: 10 mg daily, increase to a max of 40 mg daily as necessary. Oral

#### Posttraumatic stress disorder

Adult: 20 mg daily, may be increased in 10-mg increments if necessary; max dose: 50 mg/day.

Elderly: Initially, 10 mg daily, increase if needed by 10 mg/day at 1 wk intervals; max: 40 mg daily.

**Renal impairment:** Severe: 10 mg daily, increase to a max of 40 mg daily as necessary. **Hepatic impairment:** Severe: 10 mg daily, increase to a max of 40 mg daily as necessary. Oral

# Premenstrual dysphoric disorder

**Adult:** As hydrochloride, modified-release preparation: Initially, 12.5 mg once daily, usually in the morning; may increase up to 25 mg once daily after at least 1 wk, if necessary; given throughout the menstrual cycle or limited to the luteal phase.

Elderly: Initially, 10 mg daily, increase if needed by 10 mg/day at 1 wk intervals; max: 40 mg daily.

Renal impairment: Severe: 10 mg daily, increase to a max of 40 mg daily as necessary.

Hepatic impairment: Hepatic impairment: Severe: 10 mg daily, increase to a max of 40 mg daily as necessary.

# CONTRAINDICATIONS:

Use with or within 14 days of MAOIs; concurrent use with thioridazine or pimozide.

# PRECAUTIONS:

Epilepsy, glaucoma, history of mania, cardiac disease, DM, history of bleeding disorders, on drugs with increased risk of bleeding; renal and hepatic impairment; patients receiving electroconvulsive therapy; achlorhydria or high gastric pH (reduced absorption of oral suspension). Pregnancy and lactation. The risk of suicidal behaviour may be higher in young adults, closely monitor. May impair ability to drive or perform tasks. Avoid abrupt withdrawal.

#### DRUG INTERACTIONS:

Levels/effects inhibited by cyproheptadine, phenytoin. Levels/effects increased by carbamazepine, cimetidine, CYP2D6 inhibitors (e.g. chlorpromazine, delavirdine, fluoxetine, miconazole, pergolide, quinidine, quinine, ritonavir, ropinirole). Increases levels/effects of atomoxetine, carvedilol, clozapine, CYP2B6 substrates (e.g. bupropion, promethazine, propofol, selegiline, sertraline), CYP2D6 substrates (e.g. amphetamines, selected beta-blockers, dextromethorphan, fluoxetine, lidocaine, mirtazapine, nefazodone, risperidone, ritonavir, thioridazine, TCAs, venlafaxine), duloxetine, galantamine, mexilitine, pimozide, procyclidine, propafenone. Decreases levels/effects of CYP2D6 prodrug substrates (e.g. codeine, hydrocodone, oxycodone, tramadol). Inhibits the metabolism of dextromethorphan, haloperidol, thioridazine. Enhances bradycardic effect of beta-blockers. Enhances toxic effects of other CNS depressants. Increased risk of serotonin syndrome with amphetamines, SSRIs, meperidine, nefazodone, trazodone, serotonin agonists, sibutramine, sympathomimetics, tramadol, venlafaxine. Increases risk of bleeding with NSAIDs, aspirin, warfarin, or other drugs affecting coagulation. Increases sensitivity to amphetamines. Neurotoxicity with lithium. Additive hyponatraemia with loop diuretics. Mania or hypertension with selegiline.

Potentially Fatal: Fatal reactions with nonselective MAOI.

# ADVERSE DRUG REACTIONS:

Somnolence, insomnia, headache, dizziness; decreased libido; nausea, xerostomia, constipation, diarrhoea; ejaculatory disturbances; weakness, tremor, diaphoresis; vasodilation, chest pain, palpitation, hypertension, tachycardia, nervousness, anxiety, agitation, abnormal dreams, impaired concentration, yawning, depersonalisation, amnesia, emotional lability, vertigo, confusion, chills; rash, pruritus; orgasmic disturbance, dysmenorrhoea; anorexia, decreased appetite, dyspepsia, flatulence, abdominal pain, appetite increased, vomiting, taste perversion, weight gain; impotence, genital disorder, urinary frequency, UTI; paresthesia, myalgia, back pain, myoclonus, myopathy, myasthenia, arthralgia; blurred vision, abnormal vision; tinnitus; respiratory disorder, pharyngitis, sinusitis, rhinitis; infection.

# 212. PENICILLIN G POTASSIUM TAB U.S.P

# SALIENT ACTIONS:

Benzathine benzylpenicillin interferes w/ bacterial cell wall synthesis during active multiplication causing cell wall death and resultant bactericidal activity against susceptible bacteria.

# INDICATIONS & DOSAGE REGIMENS:

Infections caused by organisms sensitive to penicillin.

2,00,000-4,00,000 u tid or 8,00,000 u bid.

# CONTRAINDICATIONS:

Hypersensitivity to penicillins.

# PRECAUTIONS:

Patient w/ previous hypersensitivity reactions to cephalosporins, history of allergy, asthma, seizure disorder. Not intended for IV or intra-arterial admin or inj near major peripheral nerves of blood vessels. Prolonged use may result in bacterial or fungal superinfection. Renal impairment. *Monitoring Parameters* Periodic evaluation of renal and haematopoietic functions. Assess culture and sensitivity test prior to initiation of therapy. Monitor for hypersensitivity reactions and opportunistic infections.

# DRUG INTERACTIONS:

Patient w/ previous hypersensitivity reactions to cephalosporins, history of allergy, asthma, seizure disorder. Not intended for IV or intra-arterial admin or inj near major peripheral nerves of blood vessels. Prolonged use may result in bacterial or fungal superinfection. Renal impairment. *Monitoring Parameters*Periodic evaluation of renal and haematopoietic functions. Assess culture and sensitivity test prior to initiation of therapy. Monitor for hypersensitivity reactions and opportunistic infections.

# ADVERSE DRUG REACTIONS:

Hypersensitivity reactions including skin eruptions, urticaria, laryngeal oedema, serum sickness-like reactions, allergic vasculitis, pruritus, fatigue, asthenia, pain, headache; fever; haemolytic anaemia, leucopenia, thrombocytopenia; neuropathy; nephropathy; hypotension, tachycardia, palpitations, pulmonary HTN, pulmonary embolism, vasodilation, vasovagal reaction, cerebrovascular accident, syncope; nausea, vomiting, intestinal necrosis, blood in stool, intestinal necrosis; lymphadenopathy; inj site reactions (e.g. pain, inflammation), joint disorder, periostitis, exacerbation of arthritis, myoglobinuria, rhabdomyolysis; nervousness, tremors, dizziness, somnolence, confusion, anxiety, euphoria, transverse myelitis, seizures, coma; hypoxia, apnoea, dyspnoea; diaphoresis; blurred vision, blindness; neurogenic bladder, haematuria, proteinuria, renal failure, impotence, priapism.

Potentially Fatal: Anaphylaxis, antibiotic-associated pseudomembranous colitis.

# 213. PERINDOPRIL ERBUMINE TABLET

#### SALIENT ACTIONS:

Perindopril competitively inhibits ACE from converting angiotensin I to angiotensin II (a potent vasoconstrictor) resulting in increased plasma renin activity and reduced aldosterone (a hormone that causes water and Na retention) secretion. This produces hypotensive effect and beneficial effect in CHF.

#### INDICATIONS & DOSAGE REGIMENS:

Oral

# Hypertension

Adult: Initially, 4 mg (as erbumine) or 5 mg (as arginine) once daily, 1st dose preferably at bedtime. Patient w/ renovascular HTN, volume depletion, severe HTN or patient on diuretics: Initially, 2 mg (as erbumine) or 2.5 mg (as arginine) once daily. Dose may be increased to max 8 mg (erbumine) or 10 mg (arginine) after 1 mth if needed.

*Elderly:* Initially, 2 mg (as erbumine) or 2.5 mg (as arginine) once daily. Dose may be increased to max 8 mg (erbumine) or 10 mg (arginine) after 1 mth if needed.

Renal impairment:

CrCl (ml/	min) Dosage Recommendation
<15	2 mg (as erbumine) or 2.5 mg (as arginine) on dialysis days.
15-30	2 mg (as erbumine) or 2.5 mg (as arginine) on alternate days.
30-60	2 mg (as erbumine) or 2.5 mg (as arginine) daily.

Oral

#### Heart failure

Adult: Initially, 2 mg (as erbumine) or 2.5 mg (as arginine) in the morning increased after at least 2 wk to a maintenance dose of 4 mg (as erbumine) or 5 mg (as arginine) once daily.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation
<15	2 mg (as erbumine) or 2.5 mg (as arginine) on dialysis days.
15-30	2 mg (as erbumine) or 2.5 mg (as arginine) on alternate days.
30-60	2 mg (as erbumine) or 2.5

Oral

# Ischaemic heart disease

Adult: Initially, 4 mg (as erbumine) or 5 mg (as arginine) once daily for 2 wk then titrate up to a maintenance dose of 8 mg (erbumine) or 10 mg (arginine) once daily if tolerated.

Elderly: Initially, 2 mg mg (as erbumine) or 2.5 mg (as arginine) once daily on the 1st wk.

Renal impairment:

CrCl (ml/min) Dosage Recommendation	
<15	2 mg (as erbumine) or 2.5 mg (as arginine) on dialysis days.
15-30	2 mg (as erbumine) or 2.5 mg (as arginine) on alternate days.
30-60	2 mg (as erbumine) or 2.5 mg (as arginine) daily.

#### CONTRAINDICATIONS:

History of angioedema related to previous ACE inhibitor treatment; hereditary or idiopathic angioedema. Concomitant use w/ aliskiren in patients w/ diabetes or renal impairment. Pregnancy.

#### PRECAUTIONS:

Patients w/ history of angioedema unrelated to ACE inhibitor treatment. Risk factors for hyperkalaemia. Collagen vascular disease. Unstented unilateral/bilateral renal artery stenosis; aortic stenosis. Patients undergoing surgery or during anaesthesia. Renal and hepatic impairment. Lactation. *Patient Counseling*May impair ability to drive or operate machinery. *Monitoring Parameters* Correct volume and/or salt depletion prior to treatment. Monitor BP, serum electrolytes and creatinine levels frequently.

# DRUG INTERACTIONS:

May enhance hypotensive effect w/ diuretics. Additive hyperkalaemic effect w/ K supplements, K-sparing diuretics, and other drugs (e.g. ciclosporin, heparin, indometacin). May increase serum levels and toxicity of lithium. Antihypertensive effect may be reduced by aspirin or other NSAIDs. Coadministration w/ NSAIDs may also increase the risk of renal impairment. Increased risk of hypoglycaemia w/ antidlabetic agents. Rarely,

nitritoid reactions occur w/ concomitant use of gold (sodium aurothiomalate).

Potentially Fatal: Increased risk of hypotension, hyperkalaemia and changes in renal function (including acute renal failure) w/ aliskiren in patients w/ diabetes or renal impairment.

# ADVERSE DRUG REACTIONS:

Renal dysfunction, pancreatitis, blood disorders (e.g. agranulocytosis, neutropenia, thrombocytopenia). Cough, dizziness, vertigo, hypotension, headache, asthenia, back pain, sinusitis, chest pain, abnormal ECG, sleep disorders, viral infection, upper extremity pain, hypertonia, fever, proteinuria, ear infection, palpitation, GI disorders (e.g. nausea, dyspepsia, abdominal pain), rash.

Potentially Fatal: Angioedema and severe anaphylactic reactions. Rarely, hepatic necrosis.

# 214. PHENIRAMINE MALEATE 50 MG TABLET

# SALIENT ACTIONS:

Pheniramine is an alkylamine derivative with histamine H<sub>1</sub>-receptor antagonist effects. It also has anticholinergic and moderate sedative effects

#### INDICATIONS & DOSAGE REGIMENS:

Oral

#### Allergic conditions

Adult: As maleate: Syrup: 15-30 mg bid or tid. Tablet: Up to 45 mg tid. Max: 3 mg/kg/day.

Child: As maleate: 5-10 yr: Half a 45-mg tablet up to tid; >10 yr: Syrup: 15-30 mg bid or tid. Tablet: Up to 45 mg tid. Max: 3 mg/kg/day.

Elderly: As maleate: Syrup: 15-30 mg bid or tid. Tablet: Up to 45 mg tid. Max: 3 mg/kg/day.

Oral

# Prophylaxis of motion sickness

Adult: As maleate: Syrup: 15-30 mg bid or tid. Tablet: Up to 45 mg tid. Max: 3 mg/kg/day. Take 1st dose at least 30 min before travelling.

*Child:* As maleate: 5-10 yr: Half a 45-mg tablet up to tid; >10 yr: Syrup: 15-30 mg bid or tid. Tablet: Up to 45 mg tid. Max: 3 mg/kg/day. Take 1st dose at least 30 min before travelling.

# CONTRAINDICATIONS:

Symptomatic prostatic hypertrophy; neonates and premature infants

# PRECAUTIONS:

May impair ability to drive or operate machinery. Has potential for abuse. Narrow angle glaucoma, asthma or severe CV disease. Antiemetic effect may mask signs of other conditions. Pregnancy and lactation. Elderly.

# INTERACTIONS:

May mask ototoxicity produced by aminoglycoside antibiotics.

Potentially Fatal: Potentiation of CNS depression by alcohol, sedatives, opioids, barbiturates, hypnotics, narcoleptics. May increase antimuscarinic effect of MAOIs, atropine and TCAs.

#### ADVERSE EFFECTS:

Sedation, hypersensitivity reactions. Lassitude, dizziness, tinnitus, inability to concentrate, incoordination, irritability, insomnia and tremors. Urinary retention. Palpitations, headache. Blurred vision, increased intraocular pressure. Muscular weakness. Rarely, blood dyscrasias e.g. agranulocytosis, haemolytic anaemia

# 215. PHENOBARBITONE 60 MG TAB

# SALIENT ACTIONS:

Phenobarbital is a long-acting barbiturate. It depresses the sensory cortex, reduces motor activity, changes cerebellar function and produces drowsiness, sedation and hypnosis. Its anticonvulsant property is exhibited at high doses.

# INDICATIONS & DOSAGE REGIMENS:

Oral

#### Sedation

Adult: 30-120 mg daily in 2-3 divided doses.

Child: 6 mg/kg daily or 180 mg/m<sup>2</sup> daily in 3 divided doses.

Elderly: Reduce dose.

**Renal impairment:** Reduce dose. Severe: Contraindicated. **Hepatic impairment:** Reduce dose. Severe: Contraindicated.

Oral

Status epilepticus

Adult: 100-300 mg daily at bedtime. Child: 3-5 mg/kg or 125 mg/m<sup>2</sup> daily.

Elderly: Reduce dose.

Renal impairment: Reduce dose. Severe: Contraindicated. Hepatic impairment: Reduce dose. Severe: Contraindicated.

Oral

Emergency management of acute seizures

Adult: 100-300 mg daily at bedtime. Child: 3-5 mg/kg or 125 mg/m<sup>2</sup> daily.

Elderly: Reduce dose.

Renal impairment: Reduce dose. Severe: Contraindicated. Hepatic impairment: Reduce dose. Severe: Contraindicated.

Oral

As a hypnotic

Adult: 100-320 mg. Do not admin for >2 wk for the treatment of insomnia.

Elderly: Reduce dose.

Renal impairment: Reduce dose. Severe: Contraindicated. Hepatic impairment: Reduce dose. Severe: Contraindicated.

Oral

Preoperative sedation

Child: 1-3 mg/kg pre-op.

Renal impairment: Reduce dose. Severe: Contraindicated. Hepatic impairment: Reduce dose. Severe: Contraindicated.

**CONTRAINDICATIONS:** 

Severe resp depression, acute intermittent porphyria. Severe renal and hepatic impairment. Intra-arterial and SC admin.

#### PRECAUTIONS:

Patient w/ history or sedative/hypnotic addiction; resp disease, depression or suicidal tendencies, hypoadrenalism. Avoid abrupt withdrawal. Mild to moderate renal and hepatic impairment. Elderly or debilitated patient, childn. Pregnancy and lactation. *Patient Counselling* May impair ability to drive or operate machinery. *Monitoring Parameters* Monitor CBC, LFTs, mental status and seizure activity.

#### DRUG INTERACTIONS:

May reduce plasma levels of oral anticoagulants (e.g. warfarin, dicoumarol, acenocoumarol, phenprocoumon), corticosteroids, griseofulvin, doxycycline, Na valproate and valproic acid. May increase CNS depressant effect w/ phenytoin, antihistamines, sedative/hypnotics, tranquilisers. May prolong the effect w/ MAOIs. May reduce the effect of estradiol, progesterone, estrone and other steroidal hormones.

# ADVERSE DRUG REACTIONS:

Bradycardia, syncope, hypotension; anxiety, agitation, ataxia, CNS excitation or depression, confusion, dizziness, drowsiness, hallucinations, hangover effect, headache, hyperkinesias; constipation, nausea, vomiting; agranulocytosis, thrombocytopenia, megaloblastic anaemia; oliguria; pain at inj site, thrombophlebitis (w/ IV use); laryngospasm, resp depression, apnoea (esp w/ rapid IV use), hypoventilation; gangrene (w/ unintentional intra-arterial inj).

Potentially Fatal: Stevens-Johnson syndrome, toxic epidermal necrolysis.

# 216. PHENYTOIN SODIUM IP 100MG TAB

#### SALIENT ACTIONS:

Phenytoin acts as an anticonvulsant by increasing efflux or decreasing influx of sodium ions across cell membranes in the motor cortex during generation of nerve impulses; thus stabilising neuronal membranes and decreasing seizure activity. It acts as an antiarrhythmic by extending the effective refractory period and suppressing ventricular pacemaker automaticity, shortening action potential in the heart.

# INDICATIONS & DOSAGE REGIMENS:

Oral

Epilepsy

**Adult:** Initially, 3-4 mg/kg daily as single dose or in divided doses. Alternatively, 150-300 mg daily increased gradually to 600 mg daily if necessary. Maintenance: 200-500 mg daily.

*Child:* Initially, 5 mg/kg daily in 2-3 divided doses. Maintenance: 4-8 mg/kg daily in divided doses. Max dose: 300 mg daily.

# CONTRAINDICATIONS:

Pregnancy. IV admin in sinus bradycardia, heart block, or Stokes-Adams syndrome.

#### PRECAUTIONS:

Cardiovascular disease, e.g. sinus bradycardia, heart blocks; DM; hepatic impairment; hypoalbuminemia; porphyria; seizures (may increase frequency of petit mal seizures); debilitated patients; elderly. Caution in IV admin in hypotension, heart failure or MI, monitor BP and ECG during therapy. IV must be given slowly (too rapid admin may cause hypotension, CNS depression, cardiac arrhythmias and impaired heart conduction). Extravasation and intra-arterial admin must be avoided. Do not discontinue abruptly (may increase seizure frequency), unless safety concerns require a more rapid withdrawal. May impair ability to drive or operate machinery.

#### DRUG INTERACTIONS:

Effects with other sedative drugs or ethanol may be potentiated. Enhances toxic effects of paracetamol, lithium. Increased risk of osteomalacia with acetazolamide. Decreased serum levels/effects with acyclovir, antineoplastics, benzodiazeines, ciprofloxacin, CYP2C9 inducers (e.g. carbamazepine), CYP2C19 inducers (e.g. rifampin), folic acid, vigabatrin. Increased serum concentrations with allopurinol, capecitabine, cimetidine, CYP2C9 inhibitors (e.g. fluconazole), CYP2C19 inhibitors (e.g. delavirdine), disulfiram, methylphenidate, metronidazole, omeprazole, SSRI, trazodone, trimethoprim. Increases metabolism of antiarrhythmics, anticonvulsants, antipsychotics, beta-blockers, calcium channel blockers, chloramphenicol, corticosteroids, doxycycline, oestrogens, HMG-CoA reductase inhibitors, methadone, theophylline, TCAs. Decreases levels/effects of clozapine, ciclosporin, tacrolimus, CYP2B6 substrates (e.g. bupropion, selegiline), CYP2C8 substrates (e.g. amiodarone), CYP2C9 substrates (e.g. celecoxib), CYP2C19 substrates (e.g. citalopram), CYP3A4 substrates (e.g. benzodiazepines), digoxin, itraconazole, levodopa, neuromuscular-blocking agents, thyroid hormones, topiramate. Increases levels/effect of dopamine, ticlopidine. Valproic acid may displace phenytoin from binding sites; and affect phenytoin serum concentrations. Transiently increases the hypothrombinaemia response to warfarin initially, followed by an inhibition of the response.

Potentially Fatal: Enhances the hypotensive properties of dopamine and the cardiac depressant properties of

# ADVERSE DRUG REACTIONS:

Hypersensitivity, lack of appetite, headache, dizziness, tremor, transient nervousness, insomnia, GI disturbances (e.g. nausea, vomiting, constipation), tenderness and hyperplasia of the gums, acne, hirsutism, coarsening of the facial features, rashes, osteomalacia. Phenytoin toxicity as manifested as a syndrome of cerebellar, vestibular, ocular effects, notably nystagmus, diplopia, slurred speech, and ataxia; also with mental confusion, dyskinesias, exacerbations of seizure frequency, hyperglycaemia. Solutions for inj may cause local irritation or phlebitis. Prolonged use may produce subtle effects on mental function and cognition, especially in children.

Potentially Fatal: Toxic epidermal necrolysis, Stevens-Johnson syndrome

# 217. PIOGLITAZONE HCL TABLET

#### SALIENT ACTIONS:

lidocaine.

Pioglitazone is as a potent and highly selective agonist for the peroxisome proliferator activated receptor-γ (PPAR-γ). Activation of these receptors promotes the production of gene products involved in lipid and glucose metabolism. It also improves insulin response to target cells w/o increasing the pancreatic secretion of insulin.

# INDICATIONS & DOSAGE REGIMENS:

Oral

# Type 2 diabetes mellitus

Adult: 15 or 30 mg once daily, increased gradually if necessary. Max: 45 mg/day.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Moderate to severe: Avoid.

# CONTRAINDICATIONS:

Type 1 DM or diabetic ketoacidosis. Severe heart failure (NYHA class III or IV). Active or history of bladder cancer. Moderate to severe hepatic impairment. Patients w/ uninvestigated macroscopic haematuria.

#### PRECAUTIONS:

Symptomatic and congestive heart failure (NYHA class I or II). Mild hepatic impairment. Pregnancy and lactation. *Monitoring Parameters* Monitor for signs and symptoms of heart failure (e.g. dyspnoea, rapid wt.

gain, unexplained fatigue or cough), bladder cancer (e.g. blood in urine, urinary urgency, pain on urination, or back or abdominal pain), and fluid retention. Periodically monitor fasting plasma glucose levels. LFT should be performed prior to treatment and monitor periodically. *Patient Counselling* Adequate contraception is recommended in premenopausal anovulatory women as pioglitazone may cause resumption of ovulation.

# DRUG INTERACTIONS:

Increased risk of oedema w/ insulin, metformin and sulfonylureas. Increased plasma levels w/ gemfibrozil and ketoconazole. Decreased plasma levels w/ rifampicin.

# ADVERSE DRUG REACTIONS:

Oedema, wt. gain, sinusitis, upper resp tract infections, hepatic dysfunction (e.g. vomiting, unexplained nausea, anorexia, dark urine, abdominal pain, fatigue), bone loss and fracture, myalgia, visual disturbances; decreased haemoglobin and haematocrit counts (dose related); decreased serum triglycerides, increased HDL-cholesterol; abnormal LFT.

Potentially Fatal: Rare: Mixed hepatocellular-cholestatic liver injury and liver failure; hepatitis.

# 218. PIRACETAM(NOOTROPIL 1200MG TAB)

# SALIENT ACTIONS:

Piracetam protects the cerebral cortex against hypoxia. It also inhibits platelet aggregation and reduces blood viscosity.

# INDICATIONS & DOSAGE REGIMENS:

Oral

# Adjunct in cortical myoclonus

Adult: 7.2 g daily in 2-3 divided doses, increased by 4.8 g/day every 3-4 days. Max dose: 20 g daily.

# Renal impairment:

CrCl (ml/min)	Dosage Recommendation
1638 16556	2/3 usual dose
30-49	1/3 usual dose
20-29	1/6 usual dose
<20	Contra-indicated

Oral

# As a cognitive enhancer in cerebrocortical insufficiency

Adult: 2.4 g daily, given as 2-3 divided doses. Up to 4.8 g daily may be used in severe cases.

# Renal impairment:

CrCl (ml/min)	Dosage Recommendation
53/290/3/14/3964-1	2/3 usual dose
30-49	1/3 usual dose
20-29	i/6 usual dose
<20	Contra-indicated

# CONTRAINDICATIONS:

Hepatic and severe renal impairment. Cerebral haemorrhage. Pregnancy and lactation.

# PRECAUTIONS:

Avoid abrupt withdrawal. Impaired renal function. Cardiac disorders. Haemostatic disorders. Patients who have recently undergone major surgery. Elderly.

# DRUG INTERACTIONS:

May increase prothrombin time in patients who are on warfarin.

# ADVERSE DRUG REACTIONS:

Hyperkinesia, nervousness, depression, diarrhoea, rashes. CNS stimulation, sleep disturbances, dizziness, excitement, insomnia, somnolence, wt gain.

# 219. PIRFENIDONE TAB

# SALIENT ACTIONS:

**Pirfenidone** is a medication used for the treatment of <u>idiopathic pulmonary fibrosis</u> (IPF). It works by reducing lung fibrosis through downregulation of the production of <u>growth factors</u> and <u>procollagens</u> I and II.

# INDICATIONS & DOSAGE REGIMENS:

treatment of mild-to-moderate idiopathic pulmonary fibrosis

treatment of scars and fibrotic tissue

Idiopathic Pulmonary Fibrosis

Conduct liver function tests before initiating therapy (also see Dosage Modifications and Cautions)
Initial dose titration

- Take with food
- Days 1-7: 267 mg (1 capsule) PO TID
- Days 8-14: 534 mg (2 capsules) PO TID
- Day 15 and thereafter: 801 mg (3 capsules) PO TID

# Maintenance dose

- · 801 mg (3 capsules) PO TID with food
- Not to exceed 2403 mg/day (9 capsules/day)

# INTERACTIONS:

#### CYP1A2 inhibitors

- Strong inhibitors (eg, fluvoxamine, enoxacin): Reduce maintenance dose to 267 mg (1 capsule) TID
- Moderate inhibitors (eg, ciprofloxacin): Reduce maintenance dose to 534 mg (2 capsules) TID (with ciprofloxacin 750 mg BID)

# Elevated liver enzymes

- AST/ALT >3 to ≤5 x ULN (without symptoms): Discontinue confounding medications, exclude other
  causes, repeat liver function tests as needed; the full daily dosage may be maintained, if clinically
  appropriate, or reduced or interrupted (eg, until liver chemistry tests are within normal limits), with
  subsequent retitration to the full dosage as tolerated
- AST/ALT >5 x ULN or >3 times ULN with signs/symptoms of severe liver damage: Permanently discontinue; do not rechallenge

# PRECAUTIONS:

# Hepatic impairment

- Mild-to-moderate (Child Pugh A or B): Use caution; monitor and consider dosage modification or discontinuation as needed
- Severe (Child Pugh C): Not recommended (not studied)

# Renal impairment

- Mild, moderate, or severe: Use caution; monitor and consider dosage modification or discontinuation as needed
- ESRD requiring dialysis: No recommended (not studied)

# ADVERSE DRUG REACTIONS:

#### Gastrointestinal

Pirfenidone is frequently associated with gastrointestinal side effects such as <u>dyspepsia</u>, <u>nausea</u>, gastritis, <u>gastroesophageal reflux disease</u> (GERD) and <u>vomiting</u>. To reduce the severity of these reactions, pirfenidone is to be taken after meals.

#### Skin

Pirfenidone is known to cause <u>photosensitivity</u> reactions, <u>rash</u>, <u>pruritus</u> and <u>dry skin</u>. Patients are usually advised to avoid direct exposure to sunlight, including <u>sun lamps</u>, and to use protective clothing and <u>sunscreening</u> <u>agents</u>. Continuing photosensitivity reactions are usually managed by dose adjustment and temporary discontinuation of treatment if required, along with local symptomatic treatment

#### Hepatic dysfunction

Pirfenidone can increase hepatic enzyme levels, especially those of <u>aspartate transaminase</u> (AST), <u>alanine transaminase</u> (ALT) and <u>gamma-glutamyl transpeptidase</u>(GGT); periodic monitoring of hepatic enzyme levels is required during therapy: once before the initiation of therapy, monthly monitoring until 6 months after initiation of therapy, and 3 monthly thereafter. Extra precaution is required while prescribing the drug in patients with hepatic impairment and in patients who are concomitantly taking a <u>CYP1A2 inhibitor</u>. The drug is contraindicated in patients who have severe hepatic impairment.

# Dizziness and fatigue

Dizziness and fatigue have been reported in patients undergoing pirfenidone treatment. Dizziness typically resolves, although patients should know how they react to pirfenidone before undertaking activities that need mental alertness or coordination. If severe, dose adjustment or treatment discontinuation may be required.

#### Weight loss

Weight loss has been reported in patients treated with pirfenidone. Doctors should monitor patients' weight and encourage increased caloric intake if necessary.

# 220. PRAMIPEXOLE DIHYDROCHLORIDE TAB

#### SALIENT ACTIONS:

Pramipexole is a nonergot-derivative dopamine receptor agonist which alleviates Parkinsonian motor deficits by directly stimulating postsynaptic dopamine activity on the striatum and substantia nigra It is used as an adjunct to levodopa for the symptomatic management of parkinsonian syndrome in patients w/ advanced disease. It is also used as monotherapy for the initial symptomatic management of parkinsonian syndrome.

# INDICATIONS AND DOSAGE:

Oral

Parkinson's disease

Adult: As an adjunct to levodopa therapy: As HCl: Initially, 125 mcg tid on the 1st wk, increased to 250 mcg tid on the 2nd wk and 500 mcg tid on the 3rd wk according to response. Daily dose may be increased by 750 mcg at wkly intervals. Max: 4.5 mg/day.

Elderly: No dosage adjustment needed.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation
20-50	125 mcg bid. Max: 2.25 mg/day.
<20	125 mcg once daily. Max: 1.5 mg/day.

Hepatic impairment: No dosage adjustment needed.

Oral

Restless leg syndrome

Adult: As HCl: 125 mcg once daily 2-3 hr before bedtime. May increase, if necessary by 250 mcg every 4-7 days. Max: 750 mcg/day.

Elderly: No dosage adjustment needed.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation
20-60	Increase titration interval to 14 days.

Hepatic impairment: No dosage adjustment needed

Precautions:

Psychotic disorder, severe CV disease, augmentation (earlier onset, increase and spread of symptoms). Risk of neuroleptic malignant syndrome w/ abrupt withdrawal. Taper dose at 750 mcg/day for a wk, then reduce by 375 mcg/day thereafter. Renal impairment. Pregnancy and lactation. Patient CounsellingPatients should be informed to refrain from activities involving mental alertness and physical coordination after drug intake. Monitoring Parameters Monitor BP, signs and symptoms of fibrosis and orthostatic hypotension, development of impulse control disorder, behavioural changes. Perform periodic skin examinations. Regular ophthalmological testing due to risk of visual disorders.

# DRUG INTERACTIONS:

Antagonism of effects occur w/ concomitant use w/ antipsychotics or methyldopa. Increased plasma concentration w/ cimetidine. Additive sedative effect w/ CNS depressants. May increase orthostatic hypotensive effect w/ MAOI.

# ADVERSE EFFECTS:

Dyskinesia, sudden onset of sleep and somnolence, hallucinations, abnormal dreams, insomnia, confusion, headache, nausea, dizziness, vomiting, fatigue, constipation, peripheral oedema, visual impairment, decreased appetite.

# 221. PRASUGREL HCL TAB

# SALIENT ACTIONS:

Prasugrel is a prodrug that inhibits platelet activation and aggregation. The active metabolite irreversibly blocks the P2Y12 component of adenosine diphosphate (ADP) receptors on the platelet, which prevents activation of the GPIIb/IIIa receptor complex, thereby reducing platelet activation and aggregation.

# INDICATIONS AND DOSAGE REGIMENS:

Oral

Acute coronary syndrome

Adult: 60 mg as loading dose, followed by 10 mg once daily for up to 12 mth, given in combination w/ aspirin.

Elderly: ≥75 yr Maintenance: 5 mg once daily.

Hepatic impairment: Severe (Child-Pugh class C): Contraindicated.

Special Populations: Patient w/ low body wt (<60 kg): 5 mg once daily as maintenance dose.

# **CONTRAINDICATION:**

Active pathological bleeding, history of stroke or transient ischaemic attack. Severe hepatic impairment (Child-Pugh class C).

# PRECAUTIONS:

Patient w/ propensity to bleed, low body wt (<60 kg). Patient who will undergo CABG and other surgical procedure; coronary angiography in UA/NSTEMI patients. Elderly (≥75 yr). Pregnancy and lactation. Monitoring Parameters Monitor Hb and haematocrit periodically; may consider platelet function testing

DRUG INTERACTIONS: Increased risk of bleeding w/ oral anticoagulants (e.g. warfain), clopidogrel, NSAIDs and fibrinolytics.

**ADVERSE EFFECT:** Angioedema, anaphylaxis, HTN, hyperlipidaemia, headache, back pain, dyspnoea, nausea, dizziness, cough, hypotension, fatigue, non-cardiac chest pain, AF, bradycardia, leucopenia, rash, pyrexia, peripheral oedema, extremity pain, diarrhoea.

Potentially Fatal: Serious bleeding, thrombotic thrombocytopenic purpura.

## 222. PRAZOSIN HCL TAB

# SALIENT ACTIONS:

Prazosin competitively blocks postsynaptic α1-adrenoceptors of veins and arterioles causing vasodilation, reduction in BP and total peripheral resistance usually w/o reflex tachycardia.

# INDICATION & DOSAGE REGIMENS:

Oral

Hypertension

Adult: Initially, 0.5 mg bid or tid for 3-7 days, increased to 1 mg bid or tid for the next 3-7 days, and gradually increased thereafter according to patient's response. Max: 20 mg/day in divided doses.

Elderly: Dose reduction needed.

Renal impairment: Dose reduction needed. Hepatic impairment: Dose reduction needed.

Oral

Heart failure

Adult: Initially, 0.5 mg 2-4 times daily gradually increased according to response. Maintenance: 4-20 mg/day in divided doses.

Elderly: Dose reduction needed.

Renal impairment: Dose reduction needed. Hepatic impairment: Dose reduction needed.

Oral

Benign prostatic hyperplasia

Adult: Initially, 0.5 mg bid, increased to a maintenance dose not exceeding 2 mg bid.

Elderly: Dose reduction needed.

Renal impairment: Dose reduction needed.

Hepatic impairment: Dose reduction needed.

Oral

Raynaud's syndrome

Adult: Initially, 0.5 mg bid, increased to a maintenance dose not exceeding 2 mg bid.

Elderly: Dose reduction needed.

Renal impairment: Dose reduction needed.

Hepatic impairment: Dose reduction needed.

Special precautions: Prostate cancer should be ruled out before starting therapy. Patients w/ history of micturition syncope, angina pectoris. Treatment of heart failure due to mechanical obstruction (e.g. aortic or mitral valve stenosis, pulmonary embolism and restrictive pericardial disease). During cataract surgery, Intraoperative Floppy Iris Syndrome (IFIS) may occur. Renal and hepatic impairment. Elderly. Pregnancy and lactation. Patient Counselling May impair ability to drive or operate machinery. A low starting dose is given in the evening to lessen the risk of collapse. Hypotensive effects may be exaggerated by exercise and heat. Monitoring Parameters Monitor renal function. Careful monitoring of BP during initial titration or subsequent upward dosage adjustment.

#### DRUG INTERACTIONS:

Hypotensive effects may be enhanced w/ diuretics and other antihypertensives. Increased risk of 1st dose hypotension w/ $\beta$ -blockers or Ca channel blockers. Concomitant admin w/ phosphodiesterase type 5 (PDE5) inhibitors (e.g. sildenafil) may result in additive hypotensive effects and symptomatic hypotension

#### ADVERSE EFFECTS:

During cataract surgery, Intraoperative Floppy Iris Syndrome (IFIS) may occur. Postural hypotension, syncope, tachycardia, palpitations, lack of energy, dizziness, drowsiness, headache, nausea, constipation, diarrhoea, vomiting, vertigo, oedema, chest pain, dyspnoea, depression, nervousness, sleep disturbances, hallucinations, paraesthesia, nasal congestion, epistaxis, dry mouth, urinary frequency and incontinence, reddened sclera, blurred vision, tinnitus, abnormal liver enzyme values, pancreatitis, arthralgia, alopecia, lichen planus, skin rashes, pruritus, and diaphoresis; impotence and priapism.

# 223. PREDNISOLONE Tab 5 mg / 10 mg SALIENT ACTIONS:

Prednisolone decreases inflammation by inhibition of migration of polymorphonuclear leukocytes and reversal of increased capillary permeability. It suppresses the immune system by reducing the activity and production of the lymphocytes and eosinophils.

# INDICATIONS & DOSAGE:

- 1. **Allergic and inflammatory disorders:** *Adult:* 5-60 mg daily, usually given in 2-4 divided doses. Usual maintenance dose range: 2.5-15 mg daily. Withdrawal should be gradual after long-term therapy. *Child:* 1 mth-18 yr: For autoimmune inflammatory disorders: Initially, 1-2 mg/kg once daily, may reduce dose gradually after a few days if needed. Max: 60 mg daily. For autoimmune hepatitis: Initially, 2 mg/kg once daily, then reduce to minimum effective dose. Max: 40 mg daily.
- 2. **Poorly controlled, moderate to severe asthma:** *Adult:* For patients with at least 2 exacerbations/yr requiring oral corticosteroids: 40-60 mg daily in 1-2 divided doses; usually given as a short course treatment over 3-10 days until symptom resolution and patient achieves a peak expiratory flow (PEF) of at least 80% of his or her personal best. May be used with maintenance dosages of inhaled corticosteroid and a long-acting inhaled β<sub>2</sub>-agonist bronchodilator. *Child:* For patients with >3 exacerbations/yr in children ≤4 yr or at least 2 exacerbations/yr in children 5-11 yr: 1-2 mg/kg daily for 3-5 days may be used with existing asthma treatment, dose may be given in 1-2 divided doses. Max: 60 mg daily.
- 3. **Nephrotic syndrome:** Child: 1 mth-18 yr: Initially, 60 mg/m<sup>2</sup> (max: 80 mg) OD for 4 wk until urine is protein-free followed by 40 mg/m<sup>2</sup> every other day for 4 wk then withdraw dose gradually. For prevention of relapse: 0.5-1 mg/kg OD every other day for 3-6 mth.
- 4. **Rheumatoid arthritis:** *Adult:* Initially, 5-7.5 mg daily adjusted as necessary. *Elderly:* 5 mg daily. Multiple sclerosis *Adult:* 200 mg daily for 1 wk followed by 80 mg every other day for 1 mth.
- 5. **Infantile spasms:** Child: 1 mth-2 yr: Initially, 10 mg 4 times daily for 14 days; increase to 20 mg 3 times daily for 7 days if seizures are not controlled after 7 days; reduce dose slowly over 15 days until therapy is stopped. For patients taking 40 mg daily, reduce dose in steps of 10 mg every 5 days, then stop; patients taking 60 mg daily, reduce dose to 40 mg daily for 5 days, then 20 mg daily for 5 days, then 10 mg daily for 5 days, then stop.
- 6. **Idiopathic thrombocytopenic purpura:** Child: 1-10 yr: 1-2 mg/kg daily (max: 14 days) or 4 mg/kg daily (max: 4 days).

# CONTRAINDICATIONS:

Hypersensitivity; live vaccines; herpes simplex keratitis, systemic infections

# PRECAUTIONS:

Pregnancy Category (US FDA)- C. Patients with hypothyroidism, cirrhosis, ulcerative colitis, CHF, convulsive disorders, thrombophloebitis, peptic ulcer, elderly. DM, hypertension, psychological disturbances, osteoporosis; pregnancy, lactation. Adrenal suppression and infection. May cause irreversible growth retardation, glaucoma, corneal perforation

# INTERACTIONS:

Increased requirement of insulin and oral hypoglycaemics. Actions blunted by barbiturates, phenytoin, rifampicin. Increased bioavailability with oestrogens and oral contraceptives. Increases plasma salicylate levels. Increased risk of convulsions when used with ciclosporin. Increased clearance by carbimazole or carbamazepine. Increased risk of GI bleeding and ulceration when used with NSAIDs. May decrease methotrexate clearance.

#### ADVERSE EFFECTS:

Cushing's syndrome and growth retardation in childn; osteoporosis, fractures. Peptic ulceration; glaucoma,

cataracts; hyperglycaemia, pancreatitis; increased appetite, obesity.

# 224. PREGABALIN CAP

# SALIENT ACTIONS:

Pregabalin is an analog of the neurotransmitter GABA. It binds potently to the  $\alpha$ 2- $\delta$  subunit resulting in modulation of Ca channels and reduction in the release of several neurotransmitters, including glutamate, norepinephrine, serotonin, dopamine, calcitonin gene-related peptide and substance P.

# INDICATIONS AND DOSAGE REGIMENS:

Oral

Neuropathic pain

Adult: Initially, 150 mg/day, may increase to 300 mg/day after 3-7 days. Max: 600 mg/day after a 7-day interval. All doses to be given in 2 or 3 divided doses.

Renal impairment: Haemodialysis: 25-100 mg immediately after each 4-hr haemodialysis session.

CrCl (ml/min)	Dosage Recommendation
30 to <60	75 mg/day. Max: 300 mg/day. All doses to be given in 2 or 3 divided doses.
15 to <30	Initially, 25-50 mg/day. Max: 150 mg/day. All doses to be given as a single dose or in 2 divided doses.
<15	Initially, 25 mg/day. Max: 75 mg/day. All doses to be given as a single dose.

Oral

Adjunct in partial seizures

Adult: Initially, 150 mg/day, may increase to 300 mg/day after a wk. Max: 600 mg/day. All doses to be given in 2 or 3 divided doses.

Renal impairment: Haemodialysis: 25-100 mg immediately after each 4-hr haemodialysis session.

CrCl (ml/min)	Dosage Recommendation
30 to <60	75 mg/day. Max: 300 mg/day. All doses to be given in 2 or 3 divided doses.
15 to <30	Initially, 25-50 mg/day. Max: 150 mg/day. All doses to be given as a single dose or in 2 divided doses.
<15	Initially, 25 mg/day. Max: 75 mg/day. All doses to be given as a single dose.

Oral

Fibromyalgia

Adult: Initially, 150 mg/day, may increase to 300 mg/day after a wk. Max: 450 mg/day, if needed. All doses to be given in 2 or 3 divided doses.

Renal impairment: Haemodialysis: 25-100 mg immediately after each 4-hr haemodialysis session.

CrCl (ml/min)	Dosage Recommendation
30 to <60	75 mg/day. Max: 300 mg/day. All doses to be given in 2 or 3 divided doses.
15 to <30	Initially, 25-50 mg/day. Max: 150 mg/day. All doses to be given as a single dose or in 2 divided doses.
<15	Initially, 25 mg/day. Max: 75 mg/day. All doses to be given as a single dose.

Oral

Anxiety

Adult: Initially, 150 mg/day, may increase in increments of 150 mg wkly. Max: 600 mg/day. All doses to be given in 2 or 3 divided doses.

Renal impairment: Haemodialysis: 25-100 mg immediately after each 4-hr haemodialysis session.

CrCl (ml/min)	Dosage Recommendation
30 to <60	75 mg/day. Max: 300 mg/day. All doses to be given in 2 or 3 divided doses.
15 to <30	Initially, 25-50 mg/day. Max: 150 mg/day. All doses to be given as a single dose or in 2 divided doses.
<15	Initially, 25 mg/day. Max: 75 mg/day. All doses to be given as a single dose.

Precautions: Patient w/ history of angioedema episodes, severe CV disease, renal impairment. Avoid abrupt withdrawal. Pregnancy and lactation. Patient Counselling May impair ability to drive, operate machinery or engage in hazardous activities. Monitoring Parameters Monitor visual disturbances. Closely observe for clinical worsening, suicidality and unusual changes in behavior

# DRUG INTERACTION:

May potentiate the effects of lorazepam. Additive CNS depressant effects w/ opiates and benzodiazepines. May increase risk of angioedema w/ ACE inhibitors. May increase risk of wt gain and peripheral oedema w/ thiazolidinediones.

#### ADVERSE EFFECTS:

Somnolence, dizziness, headache, diplopia, blurred vision, vertigo, fatigue, irritability, arthralgia, muscle cramp, back and limb pain, cervical spasm, disorientation, insomnia, nasopharyngitis, ataxia, tremor, dysarthria, amnesia, paraesthesia, hypoaesthesia, lethargy, sedation, oedema, peripheral oedema, dry mouth, constipation, diarrhoea, vomiting, nausea, flatulence, abdominal distension, increased appetite, wt gain, euphoria, confusion, reduced libido, erectile dysfunction; attention, memory, coordination and gait disturbances; fall, feeling drunk, abnormal feeling. Rarely, Stevens-Johnson syndrome, rhabdomyolysis, breast enlargement, gynaecomastia. Potentially Fatal: Angioedema.

# 225. PRIMAQUINE Tab 7.5 mg SALIENT ACTIONS:

Primaquine is an 8-aminoquinoline antimalarial which eliminates the exoerythrocytic forms of malarial parasite *P.vivax*, *P. falciparum* by disrupting mitochondria and binding to DNA. By this action primaquine achieves radical cure of vivax malaria. It is also active against gametocytes of *P.falciparum*.

# INDICATIONS & DOSAGE REGIMENS:

Radical treatment of vivax or ovale malaria: Adult: A course of treatment with a blood schizontocide should be given first to kill any erythrocytic parasites. 15 mg daily for 14 days, increased to higher doses or longer course if resistance in *P.vivax* occurs. Child: 250 mcg/kg daily for 14 days.

**Prophylaxis of chloroquine-resistant malaria:** *Adult:* 30 mg once daily; to be started 1-2 days before travel and continue for 7 days after departure from the malaria-endemic area. *Child:* 0.5 mg/kg OD for 14 days. Max: 30 mg/day. Alternatively, for patients with mild G6PD deficiency: 45 mg once wkly for 8 wk.Should be taken with food. (Take w/ meals to avoid GI discomfort.)

#### CONTRAINDICATIONS:

Hypersensitivity. Children <1 yr. Acute flare-ups of systemic diseases (RA, SLE) having tendency for agranulocytopaenia, Pregnancy and lactation.

#### PRECAUTIONS:

Pregnancy Category (US FDA)- C. G6PD deficiency; pregnancy; NADH methaemoglobin reductase deficient patients. Monitor Hb levels and blood counts routinely. Patients with systemic diseases that have an increased risk of granulocytopenia. Withdraw treatment if signs of haemolysis or methaemogloinaemia occur.

# INTERACTIONS:

Primaquine may inhibit metabolism of chloroquine. Avoid ethanol. *Potentially Fatal*: Mepacrine may potentiate toxicity of primaquine. Potentially haemolytic drugs eg, sulphonamides, nitrofurans and bone marrow suppressants eg, methotrexate, phenylbutazone, chloramphenicol should not be co-admin with primaquine.

# ADVERSE EFFECTS:

Nausea, vomiting, epigastric distress, abdominal cramps, leukopaenia, leucocytosis, agranulocytosis, methaemoglobinemia in NADH methaemoglobin reductase-deficient individuals.

Potentially Fatal: Haemolytic anaemia (G6PD deficient), thrombocytopenia, leucopaenia, AV block.

# 226. PROCHLORPERAZINE MALEATE Tab 5 mg SALIENT ACTIONS:

Prochlorperazine blocks both postsynaptic dopamine receptors as well as the medullary chemo receptor trigger zone. It depresses hypothalamic and hypophyseal hormone release and posssesses  $\alpha$ -adrenergic and anticholinergic inhibitory activity.

# INDICATIONS & DOSAGE REGIMENS:

- 1. Prophylaxis of nausea and vomitting: Adult: As: 5-10 mg bid/tid. May also be given rectally.
- 2. Nausea and vomiting: Adult: 20 mg, further doses are given if needed. Recommended buccal dose: As maleate: 3-6 mg bid.
- 3. Psychoses: Adult: 12.5 mg bid for 7 days, adjusted gradually to 75-100 mg daily according to response.

Usual maintenance dose: 25-50 mg daily. Child: 1-5 yr: 1.25-2.5 mg; 5-12 yr: 2.5-5 mg. May be given up to tid, if necessary.

4. Adjunct in severe anxiety disorders: Adult: 5-10 mg, up to 3-4 times daily.

5. Vertigo: Adult: 15-30 mg daily, given in divided doses. May reduce gradually to 5-10 mg daily. Recommended buccal dose: 3-6 mg bid.

# CONTRAINDICATIONS:

CNS depression, comatose patients. Bone marrow depression, phaechromocytoma, prolactin-dependent tumours, hypersensitivity. Childn <2 yr. Pregnancy and lactation.

# PRECAUTIONS:

Pregnancy Category (US FDA) – C. Extrapyramidal syndrome, hypotension, epilepsy, impaired hepatic, renal, CV, cerebrovascular or respiratory function, glaucoma. May impair ability to drive or perform tasks requiring mental alertness or physical coordination. Parenteral use in children is not recommended. History of jaundice, parkinsonism, diabetes mellitus, hypothyroidism, myasthenia gravis, paralytic ileus, prostatic hyperplasia or urinary retention. Regular eye examinations are recommended in patients on long-term treatment.

#### INTERACTIONS:

Extrapyramidal syndrome, hypotension, epilepsy, impaired systemic functions, glaucoma. May impair ability to drive or perform tasks requiring mental alertness or physical coordination. History of jaundice, parkinsonism, diabetes mellitus, hypothyroidism, myasthenia gravis, paralytic ileus, prostatic hyperplasia or urinary retention. Regular eye examinations are recommended in patients on long-term treatment.

# ADVERSE EFFECTS:

Cholestatic jaundice, cardiac arrhythmias, orthostatic hypotension, leucopaenia, thrombocytopaenia, dry mouth, blurring of vision, glaucoma, urinary retention, constipation, galactorrhoea, gynaecomastia, amenorrhoea and impotence. Potentially Fatal: Bone-marrow suppression. Cardiac arrhythmias or aspiration.

# 227. PROGESTERONE Cap 200 mg

# SALIENT ACTIONS:

Progesterone is the main hormone secreted by corpus luteum. It induces secretory changes in the endometrium, promotes mammary gland development, relaxes uterus, blocks follicular maturation and ovulation, and maintains pregnancy.

# INDICATIONS & DOSAGE REGIMENS:

Should be taken on an empty stomach (i.e. At least one hour before food or two hours after food).

# Progestogen component of menopausal hormonal replacement therapy

200 mg daily as a single daily dose at night for 12-14 days of each mth.

#### Amenorrhea

400 mg daily for 10 days.

# Dysfunctional uterine bleeding

400 mg daily for 10 days.

# CONTRAINDICATIONS:

Hypersensitivity; thrombophloebitis; cerebral apoplexy; severe hepatic impairment; undiagnosed vag inal bleeding, incomplete abortion, hormone-dependent carcinoma, as a diagnostic test for pregnancy; pregnancy. History or current high risk of arterial disease, Migraine and embolic disorders; Epilepsy, migraine, asthma, cardiac or renal dysfunction. History of depression, glucose tolerance and diabetic patients. May impair ability to drive or operate machinery. Lactation.

#### PRECAUTIONS:

Avoid sudden withdrawal; Discontinue if there is sudden partial or complete loss of vision, proptosis or diplopia, Pregnancy category (US-FDA) - B

# INTERACTIONS:

Enhanced clearance with enzyme-inducing drugs eg, carbamazepine, griseofulvin, Phenobarbital, phenytoin and rifampicin.Ketoconazole may increase serum levels of progesterone. May inhibit cyclosporine metabolism. Lab Interference- May alter serum lipid profile and rarely, LFTs.

# ADVERSE EFFECTS:

Gl disturbances, appetite/wt change, fluid retention, oedema, acne, skin rash, urticaria, depression, headache, fatigue, breast changes, hirsutism, altered libido, altered menstrual cycles or irregular menstrual bleeding (rare).

#### 228. PROMETHAZINE TAB

Injection: 25 mg (hydrochloride)/ml in 2-ml ampoule.

Oral liquid: 5 mg (hydrochloride)/5 ml. Tablet: 10 mg; 25 mg (hydrochloride).

Promethazine is a phenothiazine derivative which blocks postsynaptic mesolimbic dopaminergic receptors in the brain. It exhibits strong  $\alpha$ -adrenergic blocking effect and depresses the release of hypothalamic and hypophyseal hormones. It competes w/ histamine for the H1-receptor; muscarinic blocking effect may be responsible for antiemetic activity. It also reduces stimuli to the brainstem reticular system.

# INDICATIONS:

management of postoperative and drug-induced nausea and vomiting; labyrinthine disorders, motion sickness; premedication (section 1.3).

#### CONTRAINDICATIONS:

porphyria; child under 2 years (risk of respiratory depression).

# DOSAGE REGIMEN:

Nausea and vomiting, by mouth, ADULT, 25 mg at night, increased to 50-75 mg at night or 25 mg 2-3 times daily if necessary (maximum, 100 mg in 24 hours).

Nausea and vomiting, by deep intramuscular injection or by slow intravenous injection (diluted to 2.5 mg/ml in water for injection), ADULT, 12.5–25 mg, repeated

at intervals of not less than 4 hours (usual maximum, 100 mg in 24 hours).

Prevention of motion sickness, by mouth, ADULT, 20-25 mg at bedtime on night

before travel, repeated on the morning of travel if necessary; CHILD

2-5 years, 5 mg at bedtime on night before travel and also on morning of

travel if necessary; CHILD 5-10 years, 10 mg at bedtime on night before

travel and also on morning of travel if necessary.

DILUTION AND ADMINISTRATION. According to manufacturer's directions

# CONTRAINDICATIONS:

Patients in coma or suffering from CNS depression of any cause. Childn <2 yr. SC and intra-arterial admin. Concurrent use w/ or w/in 14 days of MAOI use.

# PRECAUTIONS:

prostatic hypertrophy; urinary retention; glaucoma; pyloroduodenal obstruction; hepatic disease (Appendix 5); epilepsy; the elderly and children (more susceptible to adverse effects); pregnancy (Appendix 2) and breastfeeding (Appendix 3); interactions: Appendix 1. SKILLED TASKS. May impair ability to perform skilled tasks, for example operating machinery or driving.

# DRUG INTERACTIONS:

May enhance the action of any anticholinergic agent, TCA, sedative or hypnotic. Potentially Fatal: Increased risk of extrapyramydal effects w/ MAOIs.

# ADVERSE EFFECTS:

Drowsiness, dizziness, sedation (paradoxical stimulation may occur, especially with high doses or in children and the elderly); headache, nightmares, confusion, psychomotor impairment; urinary retention, dry mouth, blurred vision, gastrointestinal disturbances; extrapyramidal effects; hypersensitivity reactions; rash, photosensitivity reactions; jaundice; blood disorders; cardiovascular adverse effects (after injection); venous thrombosis at site of intravenous injection; pain on intramuscular injection.

# 229. PROPRANOLOL Tab 10 mg

# SALIENT ACTIONS:

Propranolol competitively blocks  $\beta1$ - and  $\beta2$ -receptors resulting to decreased heart rate myocardial contractility, BP and myocardial oxygen demand. It only possesses membrane-stabilizing properties.

INDICATIONS & DOSAGE: Should be taken on an empty stomach

- 1. **Hypertension:** Adult: Initially, 40-80 mg bid. Usual range: 160-320 mg daily. Child: Initially, 1 mg/kg daily in divided doses, may increase to 2-4 mg/kg daily in 2 divided doses.
- 2. Phaeochromocytoma: Adult: 60 mg daily given on the 3 days before the operation with α-blockade. 30 mg OD if tumour is inoperable. Child: 250-500 mcg/kg 3-4 times daily.

- 3. Myocardial infarction: 40 mg QID for 2-3 days followed by 80 mg BD, OR 180-240 mg daily in divided doses.within 5-21 days of MI.
- 4. Cardiac arrhythmias: Adult: 30-160 mg daily in divided doses. Child: 250-500 mcg/kg 3-4 times daily.
- 5. Prophylaxis of migraine: Adult: Initially, 40 mg bid-tid increased to 160 mg, max 240 mg daily. Max 4-6 wks if not responding. Child: <12 yr: 20 mg bid-tid.
- 6. Portal hypertension: Adult: Initially, 40 mg bid increased up to 160 mg bid.
- 7. Angina pectoris: Adult: 40 mg bid-tid, may increase to 120-240 mg daily, up to 320 mg daily.
- 8. Hypertrophic cardiomyopathy, Hyperthyroidism: Adult: 10-40 mg, given 3-4 times daily.
- 9. Anxiety: Adult: 40 mg once daily, may increase to bid-tid.
- 10. Essential tremor: Adult: 40 mg bid-tid. May increase at wkly intervals to 160 mg daily. Up to 320 mg daily may be necessary.

## CONTRAINDICATIONS:

Sinus bradycardia, cardiogenic shock, pulmonary oedema, severe hyperactive airway disease, compensated cardiac failure, Raynaud's disease, hypoglycaemia, severe haemorrhage, metabolic acidosis, severe peripheral arterial disease, 2nd or 3rd degree heart block. Pregnancy (2nd and 3rd trimesters).

## PRECAUTIONS:

Pregnancy.Compensated heart failure, peripheral vascular disease, diabetes. Switching from conventional to sustained-release preparations, elderly. Ischaemic heart disease, congestive cardiac failure, renal or hepatic dysfunction. Increased risk of bradycardia and hypotension in patients with underlying cardiac disorders. 1st degree heart block. May mask symptoms of hyperthyroidism and hypoglycaemia. May unmask myasthenia gravis. Abrupt withdrawal may lead to angina, MI, ventricular arrhythmias and death. Lactation.

## INTERACTIONS:

Decreased effect with aluminum and calcium salts, NSAIDs, ampicillin, rifampicin.Concurrent use with chlorpromazine results in raised blood levels of both drugs and additive hypotensive effect. Hypotensive effect reduced by indometacin. Additive effect with other antihypertensives and diuretics. May reduce the clearance of bupivacaine. Plasma levels may be increased by hydralazine and propafenone. Increased serum levels of thioridazine when used with propranolol. Potentially Fatal: Marked hypertension and bradycardia with adrenaline. Rebound hypertension due to abrupt withdrawal of clonidine is increased. Severe bradycardia may occur with digitalis.

# ADVERSE EFFECTS:

Cold extremities, insomnia, fatigue, dizziness, vivid dreams, lassitude, GI upset, impotence. Weakness, paraesthesia, wheezing, pharyngitis, bronchospasm. CNS disturbances at higher doses and mood alterations. Thrombocytopenic & nonthrombocytopenic purpura, agranulocytosis, thrombocytopenia, hallucinations. Potentially Fatal: Heart failure, heart block and bronchospasm.

# 230. PYRAZINAMIDE TAB

## SALIENT ACTIONS:

Pyrazinamide may be bacteriostatic or bactericidal in action, depending on the concentration of the drug attained at the site of the infection and the susceptibility of the infecting organism. Its activity appears to partly depend on conversion of the drug to pyrazinoic acid (POA), which lowers the pH of the environment below that which is necessary for growth of Mycobacterium tuberculosis. Susceptible strains of M. tuberculosis produce pyrazinamidase, an enzyme that deaminates pyrazinamide to POA, and the in vitrosusceptibility of a given strain of the organism appears to correspond to its pyrazinamidase activity.

# INDICATIONS:

Tuberculosis, in combination with other drugs.

Availability: TABLETS 300, 500 and 750 mg; 1 and 1.5g; suspension 100 ml (5%).

# DOSAGE REGIMENS:

Oral Adult and Child- 20 to 35 mg/kg body weight as a single dose (max. 3g daily).

# CONTRAINDICATIONS:

Severe hepatic impairment; porphyria.

PRECAUTIONS: Hepatic impairment (monitor hepatic function; renal impairment; diabetes mellitus (monitor blood glucose-may change suddenly); gout; pregnancy and lactation; hypouricemia. Patients or their caretakers should be told how to recognize signs of liver disorder and advised to discontinue treatment and seek immediate medical attention if symptoms such as persistent nausea, vomiting, malaise or jaundice develop.

# DRUG INTERACTION:

Antagonises the effect of uricosuric agents (e.g. probenecid, sulfinpyrazone). May reduce the contraceptive

effect of oestrogens. May inactivate oral typhoid vaccine. May increase the serum concentration of ciclosporin. May enhance the hepatotoxic effect of rifampicin.

#### ADVERSE EFFECTS:

Hepatotoxicity including fever, anorexia, hepatomegaly, splenomegaly, jaundice, liver failure; nausea, vomiting; arthralgia; gout; sideroblastic anaemia; rash, photosensitivity; porphyria, dysuria, thrombocytopenia, hyperplasia, myalgia.

# 231. PYRIDOXINE Tab 40 mg

## SALIENT ACTIONS:

Pyridoxine is a water-soluble vitamin which functions in the metabolism of carbohydrates, proteins and fats. It is essential in Hb formation and GABA synthesis within the CNS. It aids in the release of glycogen stored in the liver and muscles.

# INDICATIONS & DOSAGE REGIMENS:

Treatment and prophylaxis of vitamin B<sub>6</sub> deficiency states: Adult: Up to 150 mg daily. May also be given via SC, IM or IV routes.

Sideroblastic anaemia: Adult: Up to 400 mg daily. Should be taken with food.

# CONTRAINDICATIONS:

Hypersensitivity to pyridoxine or any component.

### PRECAUTIONS:

Pregnancy Category (US FDA): A

## INTERACTIONS:

Isoniazid, penicillamine and oral contraceptives - greater requirement in pyridoxine dose.

Reduces the effects of levodopa, phenobarbitone and phenytoin.

Lab Interference May result in false-positive results for urobilinogen in the spot test using Ehrlich's reagent.

#### ADVERSE EFFECTS:

Severe peripheral neuropathies (with long-term admin. of large doses).

# 232. RABEPRAZOLE Tab 20 mg

#### SALIENT ACTIONS:

Proton pump inhibitor. It suppresses gastric acid secretion by inhibiting the gastric H<sup>+</sup>/K<sup>+</sup> ATPase at the secretory surface of the gastric parietal cell.

# INDICATIONS & DOSAGE REGIMENS:

Gastro-esophageal reflux disease: Adult: For erosive esophagitis: 20 mg once daily in the morning for 4-8 wk. Maintenance: 10-20 mg once daily according to response. For non-erosive esophagitis: 10 mg once daily for 4 wk, upon symptom resolution, may continue with 10 mg once daily when necessary.

**Hypersecretory conditions**: Adult: Initially, 60 mg daily adjusted according to response. Max dose: 120 mg daily.

Active peptic ulcer disease: Adult: 20 mg daily given for 4-8 wk for duodenal ulcer and 6-12 wk for gastric ulcer.

*H.pylori* infection: *Adult:* As a combination with two antibacterial: 20 mg bid combined with clarithromycin 500 mg bid and either amoxicillin 1 g bid or metronidazole 400 mg bid. To be taken for a wk.

# CONTRAINDICATIONS:

Overdosage-drowsiness, headache and tachycardia. Hypersensitivity.

Special Precautions- Severe hepatic impairment, gastric malignancy. Increased risk of GI infections due to acid suppressive effects. Pregnancy.

#### PRECAUTIONS:

Pregnancy Category (US FDA): B.

#### INTERACTIONS

Reduces absorption of ketoconazole and itraconazole. Prolongs elimination of diazepam, phenytoin and warfarin. Delayed absorption with high-fat meals.

# ADVERSE EFFECTS:

Headache, diarrhoea, rash, infection and flu-like syndrome. Dizziness, fatigue, constipation, nausea and vomiting. *Potentially Fatal:* Anaphylaxis, agranulocytosis.

# 233. RAMIPRIL Tab 2.5 mg/5 mg

# SALIENT ACTIONS:

Ramipril is an ACE inhibitor, metabolised into the active metabolite ramiprilat. It competitively inhibits angiotensin-converting enzyme (ACE) from converting angiotensin I to angiotensin II resulting in increased plasma renin activity and reduced aldosterone secretion. It also increases bradykinin levels. By these mechanisms, ramipril produces a hypotensive effect and a beneficial effect in CHF.

# INDICATIONS & DOSAGE REGIMENS:

Hypertension, Heart failure: Adult: 1.25 mg once daily. Max Dosage: 10 mg daily in 1-2 divided doses. Post myocardial infarction: Adult: 2.5 mg bid increased after 2 days to 5 mg bid. Start treatment 3-10 days after infarction.

**Prophylaxis** of cardiovascular events in high-risk patients: Adult: 2.5 mg once daily increased to 5 mg once daily after 1 wk if tolerated. Maintenance: 10 mg once daily after a further 3 wk.

#### CONTRAINDICATIONS:

Hypersensitivity, bilateral renal artery stenosis, or a single kidney with unilateral renal artery stenosis. Aortic stenosis or outflow tract obstruction. Pregnancy and lactation.

#### PRECAUTIONS:

Pregnancy Category (US FDA) – C, in 2nd & 3rd trimesters –D.Reduce dose in patients with renal impairment. Monitor renal function before and during treatment. Special Precautions in hypovolaemia, hyperkalaemia, valvular stenosis; before, during or immediately after anaesthesia. Severe resistant hypertension, elderly, PVD or generalised atherosclerosis. Use with caution with history of idiopathic or hereditary angioedema. Regular monitoring of WBC in patients with vascular collagen disorders is recommended.

## INTERACTIONS:

Antacids -Ramipril bioavailability may be decreased. Diuretics - Increased risk of hypotension. Indomethacin, salicylates - May reduce hypotensive effects, especially in low-renin or volume-dependent hypertensive patients. Lithium - increased lithium levels and symptoms of lithium toxicity. Loop diuretics - Effects decreased. Potassium supplements, potassium-sparing diuretics - increased potassium serum levels.

#### ADVERSE EFFECTS:

Overdosage- severe hypotension. Potentially Fatal: Severe hypotension and renal failure, angioedema. Nausea, vomiting, diarrhoea, dizziness, fatigue, headache, abdominal pain, cough. Rarely symptomatic hypotension. Angioneurotic oedema of face, lips, tongue, glottis and larynx, syncope, renal impairment, hypersensitivity reactions.

# 234. RANITIDINE TAB

#### SALIENT ACTIONS:

Ranitidine competitively blocks histamine at H2-receptors of the gastric parietal cells which inhibits gastric acid secretion. It does not affect pepsin secretion, pentagastrin-stimulated intrinsic factor secretion or serum gastrin.

# INDICATIONS:

Benign gastric and duodenal ulceration, GERD, Zollinger-Ellison syndrome, other conditions where gastric acid reduction is beneficial. Prophylaxis during NSAIDs treatment in patients with high risk for peptic ulceration, eradication of H.pylori, as preoperative medication, systemic mastocytosis Availability: TABLETS 150 and 300 mg. INJECTION 2 ml ampoule (25 mg/ml), SYRUP 375 mg/5 ml.

#### DOSAGE REGIMENS:

Oral Adult- Benign gastric and duodenal ulceration: 150 mg twice daily or 300 mg at night for 4 to 8 weeks, up to 6 weeks in chronic episodic dyspepsia and up to 8 weeks in NSAID-associated ulceration (in duodenal ulcer 300 mg can be given twice daily for 4 weeks to achieve a higher healing rate); maintenance, 150 mg at night. Prophylaxis of NSAID-induced duodenal ulcer: 150 mg twice daily. Reflux oesophagitis: 150 mg twice daily or 300 mg at night for up to 8 weeks, or if necessary 12 weeks (moderate to severe, 150 mg 4 times daily for up to 12 weeks). Long-term treatment of healed oesophagitis: 150 mg twice daily. Zollinger- Ellison syndrome: 150 mg 3 times daily (up to 6g daily in divided doses has been used). Gastric acid reduction (prophylaxis of acid aspiration) in obstetrics: 150 mg at onset of labour, then every 6 h. Surgical procedures: 150 mg 2 h before induction of anaesthesia and also, when possible on the preceding evening. Child- Peptic ulcer: 2 to 4 mg/kg twice daily (max. 300 mg daily). Intramuscular injection Adult- Benign gastric and duodenal ulceration, reflux oesophagitis, ZollingerEllison syndrome: 50 mg every 6 to 8 h. Surgical procedures: 50 mg 45 to 60 min before induction of anaesthesia. Slow intravenous injection Benign gastric and duodenal ulceration, reflux oesophagitis, Zollinger-Ellison syndrome: 50 mg diluted to 20 ml and given over at least 2 min, may be repeated every 6 to 3 h. Surgical procedures: 50 mg 45 to 60 min before induction of anaesthesia (intravenous injection diluted to 20 ml and given over at least 2 min). Intravenous infusion Benign gastric and duodenal ulceration, reflux oesophagitis, Zollinger-Ellison syndrome: 25 mg/h for 2 h, may be repeated every 6 to 8 h. Prophylaxis of stress ulceration: initial slow intravenous injection of 50 mg diluted to 20 ml and given over at least 2 min then by continuous intravenous infusion, 125- 250  $\mu$ g/kg per h (may be followed by 150 mg twice daily by mouth when oral feeding commences). ContraINDICATIONS: Porphyria

### CONTRAINDICATIONS:

History of acute porphyria.

#### PRECAUTIONS:

Hepatic impairment; renal impairment; lactation; middleaged or older patients and those whose symptoms change-may mask gastric cancer; interactions; pregnancy.

## DRUG INTERACTIONS:

Delayed absorption and increased peak serum concentration w/ propantheline bromide. Ranitidine minimally inhibits hepatic metabolism of coumarin anticoagulants, theophylline, diazepam and propanolol. May alter absorption of pH-dependent drugs (e.g. ketoconazole, midazolam, glipizide). May reduce bioavailability w/ antacids.

#### ADVERSE EFFECTS:

Diarrhoea and other gastrointestinal disturbances; headache; dizziness; rash; tiredness; acute pancreatitis; bradycardia, tachycardia; AV block, confusion; depression; rarely, hallucinations (particularly in the elderly or the very ill); hypersensitivity reactions (including fever, arthralgia, myalgia, anaphylaxis); blood disorders (including agranulocytosis, leukopenia, pancytopenia, thrombocytopenia); hepatitis; agitation; visual disturbances; erythema multiforme; alopecia; gynaecomastia and impotence; malaise; somnolence. Storage Store protected from light and moisture.

#### 235. RIFAMPICIN CAP

# SALIENT ACTIONS:

It is highly bacteriocidal to Mycobacterium tuberculosis. Rifampicin suppresses initiation of chain formation for RNA synthesis in susceptible bacteria by binding to the  $\beta$  subunit of DNA-dependent RNA polymerase, thus blocking RNA transcription.

#### INDICATIONS:

PB leprosy; MB leprosy; tuberculosis.

Availability: CAPSULES 150, 300, 450 and 600 mg; tablets 150, 300, 350, 450, 500, 600 and 750 mg; Syrup 100 mg/5 ml.

# DOSAGE REGIMENS:

Oral Adult- 450 to 600 mg single dose before breakfast. Child- 10 to 20 mg/kg body weight daily.

#### CONTRAINDICATIONS:

Hypersensitivity; jaundice; patients with earlier drug induced liver disease.

## PRECAUTIONS:

Reduce dose in hepatic impairment; liver function tests and blood counts required in liver disorders, alcohol dependency, elderly and on prolonged therapy; renal impairment (if dose above 600 mg daily); lactation; porphyria; discolours soft contact lenses; advise patients on oral contraceptives to use additional means); pregnancy. Patients or their caretakers should be told how to recognize signs of liver disorders and advised to discontinue treatment and seek immediate medical attention if symptoms such as persistent nausea, vomiting, malaise or jaundice develop.

#### DRUG INTERACTIONS:

May accelerate the metabolism and reduce the effect of drugs that are metabolised by CYP450 enzymes (e.g. quinidine, phenytoin, theophylline). Decreased concentrations of atovaquone and increased concentrations of rifampicin when taken concomitantly. Concurrent use of ketoconazole and rifampicin may result in decreased serum concentrations of both drugs. May decrease serum concentrations of enalaprilat. Reduced absorption by antacids. Increased risk of hepatotoxicity w/ halothane or isoniazid.

Potentially Fatal: Increased potential for hepatotoxicity when taken concomitantly w/ saquinavir/ ritonavir combination.

# ADVERSE EFFECTS:

Severe gastrointestinal disturbances including anorexia, nausea, vomiting and diarrhoea (antibiotic-associated colitis reported); headache, drowsiness; rashes, fever, influenza-like syndrome and respiratory symptoms, collapse, shock, haemolytic anaemia, acute renal failure and thrombocytopenic purpura-m ore frequent with intermittent therapy; alterations of liver function-jaundice and potentially fatal hepatitis (dose-related, do not exceed max. daily dose of 600 mg); oedema, muscular weakness and myopathy, exfoliative dermatitis, toxic

epidermal necrolysis, pemphigoid reactions, leukopenia, eosinophilia and menstrual disturbances; urine, tears, saliva and sputum coloured orange-red; cerebral haemorrhage, visual disturbances.

# 236. RIFAXIMIN TAB

## SALIENT ACTIONS:

Rifaximin is a semisynthetic antibiotic, poorly absorbed from the gut. Rifaximin is active against Escherichia coli bacterial strains that cause traveler's diarrhea, preventing growth of the bacteria by preventing them from manufacturing proteins needed for their replication and survival. By suppressing growth of then bacteria, Rifaximin reduces symptoms of traveler's diarrhea.

## INDICATIONS:

Traveler's diarrhea, hepatic encephalopathy, irritable bowel syndrome

## DOSAGE REGIMENS:

Oral; 200-550 mg twice or thrice daily

# CONTRAINDICATIONS:

Hypersensitivity

## PRECAUTIONS:

Dysentery

## ADVERSE EFFECTS:

Taste loss, dysentery, weight decrease, anorexia, nausea and nasal passage irrigation.

# 237. RIVAROXABAN TAB

## SALIENT ACTIONS:

Rivaroxaban is an anticoagulant medication, which is taken by mouth. It is commonly used to prevent blood clots.

# INDICATIONS AND DOSAGE:

Indicated for prophylaxis of deep vein thrombosis (DVT).

10 mg PO qDay for 12 days

Nonvalvular Atrial Fibrillation,

20 mg/day PO with the evening meal

D VT or PE Treatment

15 mg PO q12hr for 21 days with food, THEN 20 mg PO qDay for 6 months

# CONTRAINDICATIONS:

Hypersensitivity, Active, major bleeding

#### PRECAUTIONS:

Neuraxial anesthesia, Risk for thrombotic events increased with premature discontinuation (see Black Box Warnings), Safety and efficacy not established in patients with prosthetic heart valves. Increases risk of bleeding and can cause serious and fatal bleeding; reports of major hemorrhages, including epidural hematomas, adrenal bleeding, and intracranial, gastrointestinal, and retinal hemorrhages; promptly evaluate S/S of blood loss and consider the need for blood replacement; discontinue with active pathological hemorrhage

# ADVERSE EFFECTS:

The most serious adverse effect is bleeding, including severe internal bleeding. Rivaroxaban is associated with lower rates of serious and fatal bleeding events than warfarin but is associated with higher rates of bleeding in the gastrointestinal tract. .

# 238. RIVASTIGMINE CAP

# SALIENT ACTIONS:

Rivastigmine reversibly inhibits hydrolysis of acetylcholine by cholinesterases thus increasing acetylcholine present in the CNS. It is selective for the CNS and is used for the symptomatic treatment of dementia in Alzheimer's disease and idiopathic Parkinson's disease.

#### INDICATIONS:

Moderate to severe dementia.

Availability: Tablets 3 and 4.5 mg; Capsules 1.5, 3, 4.5 and 6.0 mg. Transdermal patches containing 9 mg in 5cm2 and 18 mg in 10cm2.

# DOSAGE REGIMENS:

Adult - Initially 1.5 mg twice daily; (max. dose 6 mg twice daily).

#### CONTRAINDICATIONS:

Hypersensitivity to carbamate derivatives and severe hepatic impairment, children, lactation.

### PRECAUTIONS:

Renal or hepatic impairment, acid peptic disease, pregnancy, asthma, sick-sinus syndrome. ADVERSE EFFECTS: Mild peripheral cholinergic effect, nausea, vomiting, anorexia, dyspepsia, asthenia, abdominal pain, depression, gastrointesti- nal haemorrhage, weight loss, urinary tract infections, insomnia, hallucinations, hypertension, elevated LFTs. Smaller patch associated with fewer adverse effects.

## DRUG INTERACTION:

Not to be used with other cholinomimetic drugs that might interfere with the activity of anticholinergic medications. May exaggerate the effects of succinylcholine-type muscle relaxants during anaesthesia. Tobacco smoking may increase its clearance.

#### ADVERSE EFFECTS:

Accidental trauma, fatigue, asthenia, dizziness, headache, somnolence, agitation, insomnia, confusion, depression, nausea, vomiting, diarrhoea, abdominal pain, loss of appetite, dyspepsia, upper respiratory tract infection, urinary tract infection. Rarely, angina pectoris, gastric and duodenal ulcers, GI haemorrhage; bradycardia, seizures, rashes and syncope.

Potentially Fatal: Serious GI reactions such as anorexia, vomiting and weight loss.

#### 239. ROPINIROLE 1MG TAB

#### **SALIENT ACTIONS:**

Ropinirole is a non-ergot dopamine  $D_2$ -agonist with similar actions to those of bromocriptine. It is used in the management of Parkinson's disease, either alone or as an adjunct to levodopa.

#### INDICATION & DOSAGE:

Oral

As monotherapy in Parkinson's disease

Adult: Initially, 250 mcg TID, may increase by 750 mcg at wkly intervals for the first 4 wk. Subsequent increments can be made in steps of 1.5 mg at wkly intervals up to 9 mg/day, then in steps of 3 mg at wkly intervals. Usual dose ranges from 3-9 mg daily. Max: 24 mg/day. Higher dose may be necessary if used in conjunction with levodopa. Gradual withdrawal is recommended.

Hepatic impairment: Dosing adjustments may be necessary.

Oral

Restless leg syndrome

Adult: Initially, 250 mcg daily for 2 days, taken 1-3 hr before bedtime. May increase to 500 mcg daily for the next few days. Subsequent increments may be made in steps of 500 mcg at wkly intervals until 3 mg daily is reached. Max: 4 mg daily.

Hepatic impairment: Dosing adjustments may be required.

# CONTRAINDICATION:

Lactation.

#### PRECAUTION:

Pregnancy. May impair ability to drive or operate machinery. Withdrawal should be gradual. Hepatic or renal impairment. May cause daytime sleepiness or episodes of falling asleep during activities. May cause or worsen pre-existing dyskinesia.

# INTERACTION:

Inhibitors of CYP1A2 e.g. cimetidine, ciprofloxacin, erythromycin, fluvoxamine, isoniazid, ritonavir and zileuton may increase serum concentrations of ropinirole. Oestrogens and tobacco smoking may decrease clearance of ropinirole. Efficacy may be reduced by dopamine antagonists such as phenothiazines and metoclopramide.

#### ADVERSE REACTION:

Sudden onset of sleep with or without any prior feeling of drowsiness. Nausea, abdominal pain; dizziness, somnolence, headache, hallucinations; dyskinesias.

# 240. ROPIVACAINE HYDROCHLORIDE

## SALIENT ACTIONS:

Ropivacaine blocks both initiation and conduction of nerve impulses by decreasing the neuronal membrane's permeability to Na ions, resulting in inhibition of depolarisation w/ resultant blockade of conduction.

# INDICATION & DOSAGE:

Parenteral

Surgical anaesthesia

Adult: Lumbar epidural block: 0.5% soln: 75-150 mg (15-30 mL); 0.75% soln: 112.5-187.5 mg (15-25 mL); 1% soln: 150-200 mg (15-20 mL). Caesarean section: 0.5% soln: 100-150 mg (20-30 mL); 0.75% soln: 112.5-150 mg (15-20 mL). Thoracic epidural block to establish a block for post-operative pain relief: 0.5% soln: 25-75 mg (5-15 mL); 0.75% soln: 37.5-112.5 mg (5-15 mL). Peripheral nerve block: 0.5% soln: 175-250 mg (35-50 mL); 0.75% soln: 225-300 mg (30-40 mL). Infiltration anaesth and field block: 0.5% soln: Up to 200 mg (40 mL); 0.75% soln: Up to 225 mg (30 mL).

Parenteral

Acute pain

Adult: 0.2% soln: Lumbar epidural block: 20-40 mg (10-20 mL) as an initial bolus followed by 20-30 mg (10-15 mL) at intervals of not less than 30 min. Alternatively, 12-20 mg/hr (6-10 mL/hr) as continuous epidural infusion. Doses up to 28 mg/hr (14 mL/hr) may be used if additional pain relief is required. Thoracic epidural block: 12-28 mg/hr (6-14 mL/hr) as continuous infusion. Infiltration anaesth: 0.2% soln: 2-200 mg (1-100 mL); 0.5% sol.: 5-200 mg (1-40 mL).

# CONTRAINDICATION:

Hypovolaemia. Not intended for IV regional anaesth and obstetric para-cervical block.

#### PRECAUTION:

Patient w/ partial or complete heart block, acute porphyria. May cause chondrolysis when given via intraarticular infusion. Severe hepatic impairment. Pregnancy and lactation. Patient Counselling May temporarily impair locomotion and alertness. Monitoring Parameters Monitor heart rate, BP; ECG monitoring (if used w/ anti- arrhythmic).

#### INTERACTION:

Additive systemic toxic effects w/ other local anaesth or agents structurally related to amide-type local anaesth (e.g. certain anti-arrhythmic, lidocaine and mexiletine). May potentiate adverse effects of general anaesth or opioids. Reduced plasma clearance leading to increased Ropivacaine plasma levels w/ fluvoxamine and enoxacin.

# ADVERSE REACTION:

Anxiety, headache, paraesthesia, dizziness, symptoms of CNS toxicity (e.g. convulsions, seizures), bradycardia, tachycardia, cardiac arrhythmias, hypotension, HTN, syncope, dyspnoea, nausea, vomiting, urinary retention, back pain, hyperthermia, rigors, hypothermia, allergic reactions.

Potentially Fatal: Cardiac arrest.

#### 241. ROSEHIP EXTRACT CAP

# SALIENT ACTIONS:

Rosehip extract contains polyphenols and anthocyanins, which are believed to ease joint inflammation and prevent joint damage. It's also rich in vitamin C, which has antioxidant properties. Antioxidants are substances that can override harmful molecules (free radicals) which are produced within your cells and which may cause tissue damage or disease. Other studies have found that it can reduce the production of specific enzymes that break down cartilage.

# INDICATION & DOSAGE:

The standard dose for rose hip is 5-10g a day, divided into two doses. Rose hip powder is usually the preferred form of the supplement. Rose hip should be taken with meals.

Doses as high as 40g have been used in studies. Aside from some intestinal distress, taking this much rose hip is not harmful.

# PRECAUTION:

Special Precautions & Warnings:

Pregnancy and breast-feeding: There is not enough reliable information about the safety of taking rose hip if you are pregnant or breast feeding. Stay on the safe side and avoid using amounts larger than those found in food. Bleeding conditions: Rugosin E, a chemical found in rose hip, might slow blood clotting. Taking rose hip might increase the risk of bleeding in people with bleeding disorders.

Diabetes: The vitamin C in rose hip might affect the control of diabetes, but not all experts agree on this. Glucose-6-phosphate dehydrogenase deficiency (G6PD deficiency): Large amounts of the vitamin C in rose hip might increase the risk of complications.

Kidney stones: Large amounts of the vitamin C in rose hop might increase the risk for kidney stones.

Iron-related disorders such as hemochromatosis, thalassemia, or anemia: Use rose hip with caution if you have any of these conditions. The vitamin C in rose hip can increase iron absorption, which could make your condition worse.

Sickle cell disease: It is rare, but the vitamin C in rose hip might make blood more acidic, and this could bring on a sickle cell crisis. It's best to avoid use.

Surgery: Rugosin E, a chemical found in rose hip, might slow blood clotting. There is concern that rose hip might cause bleeding if used before surgery. People taking rose hip should stop at least 2 weeks before surgery.

#### INTERACTION:

Estrogens, Lithium, Warfarin

#### ADVERSE REACTION:

allergic reactions, constipation, diarrhoea, heartburn.

#### 242. ROSUVASTATIN TAB

#### SALIENT ACTIONS:

Rosuvastatin is a selective and competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme in cholesterol synthesis. It increases the number of hepatic LDL receptors on the cell surface, enhancing uptake and catabolism of LDL. It also decreases apo-lipoprotein B, triglycerides and increases HDL.

#### INDICATION & DOSAGE:

Oral

Hyperlipidaemias, Prophylaxis of cardiovascular events in high-risk patients

Adult: Initially, 5 or 10 mg once daily, may increase dose at 4-wkly intervals to 20 mg daily if necessary. Max: 40 mg once daily.

Child: Heterozygous familial hyper-cholesterolaemia: ≥10 yr Initially, 5 mg once daily, may be adjusted at intervals of at least 4 wk. Max: 20 mg once daily.

Renal impairment:

CrCl (ml/r	nin) Dosage Recommendation
30-60	Initially, 5 mg once daily to max 20 mg once daily
<30	Contraindicated.

Special Populations: Asian patients: Initial: 5 mg once daily. 40 mg dose is contraindicated.

## CONTRAINDICATION:

Active liver disease or unexplained persistent elevated serum transaminases. Severe renal impairment. Concomitant use w/ cyclosporine and gemfibrozil. Pregnancy and lactation.

#### PRECAUTION:

Patients w/ predisposing factors for myopathy (e.g. untreated hypothyroidism, renal impairment), history of chronic liver disease and alcoholism. Monitoring Parameters Monitor creatine kinase (CK) periodically and LFT. Discontinue treatment if there is significant or persistent increase in CK levels, serum aminotransferase levels or evidence of myopathy.

#### INTERACTION:

May increase serum levels of warfarin and oral contraceptives. May increase serum levels w/ Itraconazole, HIV protease inhibitors. May decrease serum levels w/ erythromycin and antacids. May increase risk of myopathy w/ fenofibrate, niacin.

Potentially Fatal: Increased risk of rhabdomyolysis w/ gemfibrozil and cyclosporine.

## ADVERSE REACTION:

Headache, dizziness, constipation, nausea, vomiting, abdominal pain, myalgia, chest pain, peripheral oedema, depression, insomnia, rash, paraesthesia, asthenia, abnormal LFT, elevated serum transaminase levels. Potentially Fatal: Severe rhabdomyolysis w/ acute renal failure. Hepatitis, pancreatitis. Rare: Stevens-Johnson syndrome, anaphylaxis, toxic epidermal necrolysis.

#### 243. ROXITHROMYCIN Tab 150 mg

#### SALIENT ACTIONS:

Roxithromycin inhibits protein synthesis by irreversibly binding to the 50s ribosomal subunits blocking the transpeptidation or translocation reactions of susceptible organisms resulting in stunted cell growth.

#### INDICATIONS & DOSAGE:

Oral - Susceptible infections. Used in the systemic treatment of infections. Adult: 150 mg bid or 300 mg once daily for 5-10 days in susceptible infections. Child: 6-40 kg: 5-8 mg/kg daily.

Renal impairment: Dosage adjustment required. Hepatic impairment: Usual daily doses should be halved.

Cirrhosis: 150 mg once daily. Should be taken on an empty stomach. (Take before meals.)

## CONTRAINDICATIONS:

Hypersensitivity, Porphyria.

# PRECAUTIONS:

Hepatic impairment. Prolonged treatment increases risk of hepatotoxicity. Monitor liver function. History of arrhythmias.

### INTERACTIONS:

May raise serum levels of ciclosporin and digoxin. Increased risk of rhabdomyolysis when used with simvastatin.

#### ADVERSE EFFECTS:

Nausea, vomiting, abdominal pain, diarrhoea, weakness, malaise, anorexia, constipation, dyspepsia, flatulence; hepatitis; rashes, headache, dizziness, weakness, changes in blood counts; increased liver enzyme values; eosinophilia; rarely, acute pancreatitis.

# 244. SALBUTAMOL Tab 2 mg , Syrup 1mg/5ml, 100 ml bottle SALIENT ACTIONS:

Selective beta-2-adrenoreceptor agonistic action, (bronchi, uterus and blood vessels). Causes relaxation of smooth muscles through the increase of the intracellular cAMP: bronchial and uterine muscles are relaxed, the peripheral vessels are dilated, heart rate increases, and there are metabolic effects (e.g. decreases plasma potassium levels. Hence, cardiac effects are moderate at usual therapeutic doses).

#### INDICATIONS:

Obstructive airway diseases - Asthma, Chronic bronchitis, Emphysema. Prevention of premature labour. **DOSAGE REGIMENS:** 

Adults: 4mg three or four times a day - Max 8mg three or four times a day. Children under 2 years: Not recommended. Children 2-6 years: 1-2mg three or four times a day. Children 6-12 years: 2mg three or four times a day. Children over 12 years: 2-4mg three or four times a day. Premature labour: The maintenance dose is 4mg three or four times a day.

#### CONTRAINDICATIONS:

Premature labour complicated by placenta praevia, ante-partum haemorrhage or toxaemia of pregnancy. Should not be used for threatened abortion.

#### PRECAUTIONS:

Pregnancy Category (US FDA) –C, Pregnancy and breast-feeding. Hypersensitivity, threatened abortion during the first six months of pregnancy, taking beta-blockers. Thyrotoxicosis, diabetes, history of heart disease, irregular heart rhythm or angina. Recently taken any other medicines especially: guanethidine, reserpine or methyldopa, MAO–I, TCA, beta-blockers, corticosteroids, Theophylline.

#### INTERACTIONS:

Serious hypokalaemia - potentiated by concomitant treatment with steroids, diuretics and xanthine derivatives (theophylline). Non-cardioselective beta-adrenoceptor blockers antagonise the effects of salbutamol. Increased blood glucose levels, exacerbated by concomitant administration of high doses of corticosteroids.

# **ADVERSE EFFECTS:**

Tremors, inner agitation, palpitation due to sinus tachycardia, muscle cramps or headaches. These effects are more frequent following repeated use and oral administration. An allergic reaction (hypersensitivity): angioedema, urticaria, dyspnoea, hypotension, circulatory collapse. Cardiac arrhythmias, Bronchospasm. Hypokalaemia - potentiated by hypoxia: muscle twitching or weakness, an irregular heart beat. Others: hyperglycemia, an irregular heart beat, ketoacidosis. Overdose - Intensified tremor, tachycardia, changes in blood pressure, sedation, nervousness and Hypokalaemia.

## 245. S AMLODIPINE TAB

# SALIENT ACTIONS:

Amlodipine relaxes peripheral and coronary vascular smooth muscle. It produces coronary vasodilation by inhibiting the entry of Ca ions into the slow channels or select voltage-sensitive channels of the vascular smooth muscle and myocardium during depolarisation. It also increases myocardial oxygen delivery in patients w/. Vasospastic angina.

# INDICATION & DOSAGE:

Oral

Prinzmetal's angina

Adult: Initially, 5 mg once daily increased to 10 mg once daily if necessary.

Elderly: Initially, 2.5 mg once daily.

Hepatic impairment: Initially, 2.5 mg once daily.

Oral

Stable angina

Adult: Initially, 5 mg once daily increased to 10 mg once daily if necessary.

Elderly: Initially, 2.5 mg once daily.

Hepatic impairment: Initially, 2.5 mg once daily.

Oral

Hypertension

Adult: Initially, 5 mg once daily increased to 10 mg once daily if necessary.

Child: 6-17 yr Initially, 2.5 mg once daily, increased to 5 mg once daily if necessary.

Elderly: Initially, 2.5 mg once daily.

Hepatic impairment: Initially, 2.5 mg once daily.

#### CONTRAINDICATION:

severe hypotension, shock (including cardiogenic shock), obstruction of the outflow tract of the left ventricle (e.g. aortic stenosis), haemodynamically unstable heart failure after acute MI.

#### PRECAUTION:

Patients w/ cardiac failure. Hepatic and renal impairment. Elderly. Pregnancy and lactation. Patient Counselling May impair ability to drive and operate machinery. Monitoring Parameters Monitor BP and heart rate.

#### INTERACTION:

Plasma concentrations may be elevated w/ CYP3A4 inhibitors (e.g. azole antifungals, ritonavir). Concomitant therapy w/ simvastatin may increase risk of myopathy including rhabdomyolysis. May increase ciclosporin plasma levels and conivaptan.

#### ADVERSE REACTION:

Somnolence, dizziness, headache, ankle swelling, oedema, flushing, fatigue, palpitations, abdominal pain, nausea. Rarely, confusion, rash, gingival hyperplasia, muscle cramps, dyspnoea.

#### 246. SECNIDAZOLE 1GM TAB

#### SALIENT ACTIONS:

Secnidazole is active against E histolytica, G lamblia, T vaginalis, Clostridium spp, B fragilis, Gardnerellaspp. The drug enters the microorganisms by diffusion and is reduced intracellularly by low oxidation-reduction potential ferredoxin which then result in DNA damage.

#### INDICATION & DOSAGE:

Oral

Severe invasive amoebiasis

Adult: 1.5 g daily as single or in divided doses for 5 days.

Child: 30 mg/kg daily for 5 days.

Oral

Trichomoniasis

Adult: 2 g as a single dose.

Child: 30 mg/kg as a single dose.

Oral

Amoebiasis

Adult: 2 g as a single dose.

Child: 30 mg/kg as a single dose.

Orai

Giardiasis

Adult: 2 g as a single dose.

Child: 30 mg/kg as a single dose.

## CONTRAINDICATION:

Hypersensitivity; pregnancy (1st trimester) and lactation.

# PRECAUTION:

Avoid alcohol and disulfiram. Avoid in patients with history of blood disorders.

#### INTERACTION:

Concurrent disulfiram admin may cause psychotic reactions. Disulfiram-like reactions with alcohol. Cimetidine may prolong half-life.

Potentially Fatal: May potentiate anticoagulant effect of warfarin and increase risk of haemorrhage.

#### ADVERSE REACTION:

Nausea, gastralgia, change of taste, metallic taste, stomatitis, urticaria, rashes, leucopenia. Rarely vertigo, moderate neurological, digestive disturbances.

# 247. SERRATIOPEPTIDASE Tab 10 mg

#### SALIENT ACTIONS:

Serrapeptase is a proteolytic enzyme of Serratia spp source. When taken orally, it relieves inflammation and oedema associated with trauma, infection or chronic venous insufficiency.

It accelerates elimination of sputum, pus and hematoma by breaking down and liquefying mucous secretions and fibrin clots & Improves circulation at the inflammatory focus. It promotes absorption of the decomposed products through the blood and lymphatics.

#### INDICATIONS:

Inflammation and oedema after operation and traumatic injury. As concomitant therapy for elimination of inflammatory edema and swelling in diseases: Sinusitis, Cystitis, epididymitis, Pericoronitis, alveolar abscess, inadequate expectoration of sputum after anesthesia. Inadequate expectoration of sputum in Bronchital asthma and concomitant therapy with antitubercular agents in pulmonary tuberculosis.

# DOSAGE REGIMENS:

Adult: 5-10 mg tid after meals.

#### CONTRAINDICATIONS:

Hypersensitivity. Caution in pregnancy.

#### PRECAUTIONS:

In patients with blood coagulation abnormalities, severe hepatic and renal disorder or under treatment with anticoagulants.

#### INTERACTIONS:

With an anticoagulant, may intensify the anticoagulant effect.

#### ADVERSE EFFECTS:

Skin rash, diarrhoea, anorexia, GI disturbances, epistaxis (rare). Stevens-Johnson syndrome, toxic epidermal necrolysis, rash, pruritus. Hypersensitivity: Shock, anaphylactic symptoms. Hepatitis, jaundice.

#### 248. SERTRALINE Tab 25 mg / 50 mg

#### SALIENT ACTIONS:

Selective serotonin reuptake inhibitor, enhancing serotonergic function.

# INDICATIONS & DOSAGE REGIMENS:

IF somnolence is noted, give at bedtime. Increase dose at intervals of 1 wk

**Depression & Obsessive compulsive disorder**: Adult: 50 mg once daily, increase in steps of 50 mg / wk. Max: 200 mg daily. Child: For obsessive-compulsive disorder: 6-12 yr: 25 mg once daily; 13-17 yr: 50 mg once daily. Max 200 mg/day.

Panic disorder with or without agoraphobia, Posttraumatic stress disorder, Social anxiety disorder, premenstrual dysphoric disorder: Adult: 50 mg daily. May be given throughout the menstrual cycle or only during the luteal phase. May increase by 50 mg each cycle if needed. Max: 150 mg daily for continuous dosing or 100 mg daily for luteal phase-only dosing. Patients who require 100 mg daily for luteal phase-only dosing should always start with 50 mg daily for the 1st 3 days of each luteal phase dosing period.

## CONTRAINDICATIONS:

Children <18 yr. poorly controlled epilepsy.

#### PRECAUTIONS:

History of hypomania and seizure disorders, hepatic and renal impairment, cardiac disease, history of bleeding disorders, DM and angle-closure glaucoma. Discontinue treatment if seizures develop or there is an increase in seizure frequency. Withdrawal should be gradual. Monitor for signs of clinical worsening, suicidality and unusual changes in behaviour especially during the initial treatment period or when there are dosage adjustments. Pregnancy and lactation.

### INTERACTIONS:

Increased risk of delirium when used with antimuscarinics. Increased risk of extrapyramidal symptoms and

neuroleptic malignant syndrome with aripiprazole. Serum levels reduced by carbamazepine. Concurrent use with dihydroergotamine or linezolid may lead to serotonin syndrome. Increases serum levels of lamotrigine, olanzapine, pimozide, risperidone, methadone, clozapine and amiodarone. Plasma levels increased by cimetidine and ritonavir. Increases the anticoagulant activity of warfarin and acenocoumarol. *Potentially Fatal:* Concomitant admin with MAOIs can result in serious serotonin syndrome. Co-admin with food & grapefruit juice. increases peak plasma concentration of sertraline.

## ADVERSE EFFECTS:

Overdosage- nausea, vomiting and CNS excitation, death. Anorexia, dyspepsia, constipation, diarrhoea, dry mouth, flatulence, vomiting, ejaculation failure, increased sweating, somnolence, agitation, insomnia, headache, dizziness, fatigue, nervousness, tremor, paraesthesia, decreased libido, rash, hot flushes, blurred vision.

#### 249. SILDENAFIL CITRATE TAB

### SALIENT ACTIONS:

Sildenafil inhibits phosphodiesterase type-5 (PDE<sub>5</sub>) which is responsible for cGMP degradation in the corpus cavernosum. Inhibition of PDE<sub>5</sub> increases cGMP levels in the corpus cavernosum which results in smooth muscle relaxation and inflow of blood to the corpus cavernosum.

# INDICATION & DOSAGE:

Oral

Erectile dysfunction

Adult: 50 mg about 1 hr before sexual intercourse. May adjust dose depending on penile response. Max: 100 mg/dose and not to be taken > once in 24 hr.

Elderly: >65 yr: Lower initial dose at 25 mg.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation
<30	Initially, 25 mg.

Hepatic impairment: Initially, 25 mg.

Special Populations: For patients taking drugs which are CYP3A4 inhibitors: initially, 25 mg. For patients on ritanavir, not >25 mg every 48 hr. Patients who are stabilised on  $\alpha$ -blocker treatment should use an initial dose of 25 mg. Higher doses should not be taken within 4 hr of an  $\alpha$ -blocker.

#### CONTRAINDICATION:

Hypersensitivity. Patients concurrently or intermittently using organic nitrates in any form.

#### PRECAUTION:

Caution when used in patients with anatomical deformation of penis or conditions that may predispose them to priapism (e.g. sickle cell anaemia, myeloma, or leukaemia). Mild, transient, dose-related impairment of colour discrimination (blue/green) may occur. Hepatic or severe renal impairment, bleeding disorders, active peptic ulceration, hypotension, recent history of stroke, MI, arrhythmias, unstable angina, heart failure or retinal disorders. May cause sudden loss or decrease in hearing.

# INTERACTION:

Inhibitors of CYP3A4 such as cimetidine and erythromycin are likely to reduce sildenafil clearance. CYP3A4 inducers such as rifampicin may decrease the plasma concentrations of sildenafil. Symptomatic hypotension when used with  $\alpha$ -blockers. Plasma concentrations are increased by ritonavir.

Potentially Fatal: May potentiate hypotensive effects of of organic nitrates and nicorandil.

#### ADVERSE REACTION:

Headache, flushing, respiratory tract infection, angina pectoris, AV block, migraine, syncope, tachycardia, postural hypotension, MI, cerebral thrombosis, cardiac arrest, paraesthesia, tremor, depression, herpes simplex, skin ulcer, oesophagitis, abnormal LFT, rectal haemorrhage, hypoglycaemic reaction, arthritis, deafness, retinal vascular disease, photosensitivity, accidental fall.

# 250. SIMETHICONE TAB

# SALIENT ACTIONS:

Simethicone lowers surface tension and facilitates gas dispersion by causing coalescence of gas bubbles in the GI tract, thus helping in their dispersion.

# INDICATION & DOSAGE: Oral

Flatulence

Adult: 100-250 mg 3-4 times daily as required. May be given with an antacid.

Oral

Infant colic

Child: Infant: 20-40 mg to be given with feeds.

## 251. SODA BICARB 300MG TAB

#### SALIENT ACTIONS:

Sodium bicarbonate is a systemic alkalizer, which increases plasma bicarbonate, buffers excess hydrogen ion concentration, and raises blood pH, thereby reversing the clinical manifestations of acidosis. It is also a urinary alkalizer, increasing the excretion of free bicarbonate ions in the urine, thus effectively raising the urinary pH. By maintaining an alkaline urine, the actual dissolution of uric acid stones may be accomplished. Sodium bicarbonate acts as an antacid and reacts chemically to neutralize or buffer existing quantities of stomach acid but has no direct effect on its output. This action results in increased pH value of stomach contents, thus providing relief of hyperacidity symptoms.

#### INDICATION & DOSAGE:

Sodium bicarbonate is used for the treatment of metabolic acidosis which may occur in severe renal disease, uncontrolled diabetes, circulatory insufficiency due to shock or severe dehydration, extracorporeal circulation of blood, cardiac arrest and severe primary lactic acidosis. Also is indicated in severe diarrhoea which is often accompanied by a significant loss of bicarbonate. Further indicated in the treatment of certain drug intoxications, including barbiturates (where dissociation of the barbiturate protein complex is desired), in poisoning by salicylates or methyl alcohol and in haemolytic reactions requiring alkalinization of the urine to diminish nephrotoxicity of blood pigments.

#### INTERACTION:

Aceproazine, acetazolamide, alclometasone

# 252. SODIUM VALPROATE Tab 200 mg , Syrup 200 mg / 5ml, 100 ml bottle SALIENT ACTIONS:

Valproate, an antiepileptic, dissociates to the valproate ion in the GI tract. Its antiepileptic activity is related to increased brain levels of gamma-aminobutyric acid (GABA).

### INDICATIONS & DOSAGE REGIMENS:

Prophylaxis of migraine: Adult: 250 mg bid. Max: 1 g daily.

Acute manic episodes of bipolar disorder: Adult: 750 mg daily in divided doses, increase as fast as possible to achieve optimal response or desired range of trough plasma concentrations between 50-125 mcg/ml. Max: 60 mg/kg daily.

Complex partial seizures & Simple and complex absence seizures: Adult: 600 mg daily in 2 divided doses, increased by 200 mg every 3 days. Usual range: 1-2 g daily (20 - 30 mg/kg daily). Max: 2.5 g daily.

Child: >20kg: 400 mg/day in 2 divided doses, increased gradually until control achieved. Usual range: 20-30 mg/kg/day. Max: 35mg/kg/day. <20kg: 20mg/kg daily in 2 divided doses, increased to 40mg/kg daily in severe cases, with serum valproic acid monitoring. Monitor clinical chemistry and haematological parameters if doses >40mg/kg daily used.

**Bipolar disorder:**Adult: 900-1800 mg daily in 2 divided doses. Usual dose: 1200 mg daily.Dosage increased every 2-3 days to reach optimal dose in 2 wk with simultaneous and progressive dose reduction of concurrent psychotropic drugs.

# CONTRAINDICATIONS:

Preexisting or family history of hepatic dysfunction, active liver disease, porphyria, urea cycle disorders. Pregnancy.

#### PRECAUTIONS:

Increased risk of hepatotoxicity in children <2 yr, congenital metabolic disorders, organic brain disease or severe seizure disorders. HIV or cytomegalovirus (CMV) infection; renal impairment; SLE; lactation. Monitor LFT before and during the 1st 6 mth of therapy. Monitor blood cell count (including platelet count), bleeding time and coagulation tests before the start of therapy or surgery, and in cases of spontaneous bruising or bleeding. Watch out for signs of pancreatitis (e.g. abdominal pain, nausea, vomiting and anorexia), blood and liver toxicity. Decrease dose or discontinue in patients with excessive somnolence, decreased food or fluid intake. Gradual withdrawal or transition to and from another type of antiepileptic therapy. Suspect hyperammonemic encephalopathy and measure ammonia levels in patients who develop unexplained lethargy, vomiting or changes in mental status. Decrease GI side effects by taking with meals, starting with low dose or taking the enteric coated formulations.

#### INTERACTIONS:

Increased risk of hepatotoxicity and carbamazepine toxicity. Increased risk of hepatotoxicity with olanzepine. Decreased valproate levels with carbapenems, rifampicin, antiepileptics antineoplastic drug regimens. Increased valproic acid levels with highly protein bound drugs, felbamate and aspirin. Concurrent use increased phenobarb, ethosuximide, nimodipine, nifedipine, lamotrigine, zidovudine, amitriptyline, nortriptyline BZDs levels. Concurrent use decreased tigabine and clozapine levels. Increased risk of absence status with clonazepam. Increased risk of hyperammonaemia with topiramate. *Potentially Fatal:* Increased risk of convulsions with mefloquine, carnitine deficiency with pivmecillinam & pivampicillin & toxicity with bupropion. Lab Interference False positive for urinary ketones. May alter thyroid function test. Pregnancy Category (US FDA) – D

## ADVERSE EFFECTS:

Overdosage- Somnolence, heart block, deep coma, death. increased appetite, wt gain, nystagmus, ataxia, somnolence, dizziness, fatigue, hyperammonaemia, hallucinations. Thrombocytopenia (dose related), tremours, elevations of LFT.Potentially Fatal: Fatal hepatotoxicity esp in children <2 yr, multi-organ hypersensitivty reactions, pancreatitis, blood dyscrasias.

# 253. SPIRONOLACTONE TAB

#### SALIENT ACTIONS:

Spironolactone acts on the distal renal tubules as a competitive antagonist of aldosterone. It increases the excretion of NaCl and water while conserving K and hydrogen ions.

Duration: 2-3 days.

Absorption: Well absorbed from the GI tract. Increased absorption w/ food. Bioavailability: Approx 90%. Time to peak plasma concentration: 3-4 hr (mainly as active metabolite).

Distribution: Crosses the placenta; enters breast milk (as canrenone). Plasma protein binding: Approx 90%.

Metabolism: Extensively metabolised to several active metabolites (e.g. canrenone and  $7\alpha$ -thiomethylspirolactore)

thiomethylspirolactone).

Excretion: Via urine and facces as metabolites. Plasma half-life: 1.3 hr (spironelactone):

Excretion: Via urine and faeces as metabolites. Plasma half life: 1.3 hr (spironolactone); 2.8-11.2 hr (active metabolites).

#### INDICATIONS & DOSAGE REGIMENS:

Adult: PO Oedema Initial: 100 mg/day, may adjust dose according to response up to 400 mg/day. Hepatic cirrhosis w/ ascites and oedema Depending on urinary Na/K ratio: If >1: Initial: 100 mg/day; if <1: Initial: 200-400 mg/day. Diagnosis of primary hyperaldosteronism Long test: 400 mg/day for 3-4 wk. Short test: 400 mg/day for 4 days. Pre-op management of hyperaldosteronism 100-400 mg/day. Long-term maintenance in the absence of surgery: Admin the lowest effective dose. HTN As monotherapy: Initial: 50-100 mg in 1-2 divided doses, may adjust dose after 2 wk. Severe CHF As adjunct: Initial: 25 mg once daily to max 50 mg/day. May reduce to 25 mg every other day if 25 mg once daily dose is not tolerated. Diuretic-induced hypokalaemia 25-100 mg/day.

#### INTERACTIONS:

Increased risk of hyperkalaemia w/ other K-sparing diuretics or K supplements, ACE inhibitors, angiotensin II receptor antagonists, trilostane, heparin, LMWH. Increased risk of nephrotoxicity w/ ciclosporin, NSAIDs. Increased risk of lithium toxicity. May reduce ulcer-healing properties of carbenoxolone. May increase serum level of digoxin. May reduce vascular response to norepinephrine. Concurrent use w/ colestyramine may cause hyperkalaemic metabolic acidosis. Potentiation of orthostatic hypotension may occur w/ barbiturates or narcotics.

Potentially Fatal: May enhance hyperkalaemic effect w/ eplerenone.

# PRECAUTIONS:

Patient at risk of developing hyperkalaemia and acidosis, w/ DM. Renal and hepatic impairment. Elderly. Pregnancy and lactation. Patient Counselling This drug may cause dizziness and somnolence, if affected do not drive or operate machinery. Monitoring Parameters Monitor serum electrolytes periodically; BP, renal function.

#### CONTRAINDICATIONS:

Anuria, hyperkalaemia, Addison's disease, acute or progressive renal insufficiency. Concomitant use w/eplerenone.

#### ADVERSE EFFECTS:

Drowsiness, dizziness, headache, lethargy, leg cramps, GI disturbances (e.g. diarrhoea, cramps), ataxia, mental confusion, rashes, pruritus, alopecia, hyponatraemia, electrolyte disturbances, gynaecomastia, hirsutism, menstrual irregularities, breast pain, deepening of the voice, impotence, leucopenia (including agranulocytosis),

thrombocytopenia, transient elevation in BUN concentration. Rarely, breast enlargement. Potentially Fatal: Hyperkalaemia.

# 254. SULFASALAZINE USP 500MG DELAY RELEASE TAB

#### SALIENT ACTIONS:

Sulphasalazine may have direct anti-inflammatory action in the colon. It also systemically interferes with secretion by prostaglandin synthesis inhibition.

Absorption: 15% of the dose is absorbed from small intestine, the rest reaches the colon where the azo bond is cleaved by the intestinal flora, producing sulfapyridine and 5-aminosalicylic acid (mesalazine). 60% of the sulfapyridine and 10-30% of the 5-aminosalicylic acid is absorbed from the colon.

Distribution: Following IV admin, vol of distribution is 7.5 L. Sulfasalazine and sulfapyridine crosses the placenta and found in breast milk. Sulfasalazine is extensively protein bound while sulfapyridine is distributed to most body tissues.

Metabolism: Absorbed sulfapyridine undergoes extensive metabolism by acetylation, hydroxylation, and glucuronidation. Slow acetylators are 2-3 times more likely to experience adverse effects from sulfapyridine compared to fast acetylators. Absorbed 5-aminosalicylic acid undergoes acetylation.

Excretion: Via urine, as unchanged sulfasalazine (15%), sulfapyridine and its metabolites (60%), and 5-aminosalicylic acid and its metabolites (20-33%).

# INDICATIONS & DOSAGE REGIMENS:

#### Oral

Inflammatory bowel disease

Adult: Initially, 1-2 g 4 times daily until remission occurs. Maintenance: 2 g/day in divided doses. Child: ≥2 yr: 40-60 mg/kg/day in divided doses. Maintenance: 20-30 mg/kg/day in divided doses.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation
10-30ml/min	Admin twice daily.
<10ml/min	Admin once daily.

Hepatic impairment: Avoid use.

Oral

Rheumatoid arthritis

Adult: As enteric-coated tablet: Initially, 500 mg daily for the 1st wk increased by 500 mg every wk. Max: 3 g daily in 2-4 divided doses.

Child: For polyarticular juvenile rheumatoid arthritis: ≥6 yr: As enteric-coated tablet: 30-50 mg/kg/day in 2 divided doses. Begin treatment with 1/4 to 2/3 of expected maintenance dose and increase wkly to reach maintenance dose in 1 mth. Max: 2 g daily.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation
10-30 mL/min	Admin twice daily.
<10ml/min	Admin once daily.

Hepatic impairment: Avoid use.

Rectal

Inflammatory bowel disease

Adult: As suppository: 0.5-1 g in the morning and night, either alone or as an adjunct to oral treatment. As enema: 3 g at night, retained for at least 1 hr.

Child: As suppository (may be given as divided doses): 5-8 yr: 500 mg bid; 8-12 yr: 500 mg in the morning and 1 g at night; 12-18 yr: 1 g bid. As enema (to be retained for at least 1 hr): 2-7 yr: 1-1.5 g; 7-12 yr: 1.5-2.25 g; 12-18 yr: 3 g, dose to be given at night.

# INTERACTIONS:

Plasma levels reduced by rifampicin and ethambutol. Interferes with absorption of folic acid. Additive leucopaenia with gold therapy for rheumatoid arthritis. Increased haematological toxicity with azathioprine. Reduced serum levels of digoxin.

#### PRECAUTIONS:

Hepatic/renal impairment, G6PD deficiency, allergic bronchial asthma, lactation.

## CONTRAINDICATIONS:

Hypersensitivity to sulphonamides or salicylates, porphyria, <2 yr of age, intestinal or urinary obstruction, blood

dycrasias, history of leucopenia with gold therapy.

#### ADVERSE EFFECTS:

Headache, anorexia, nausea, vomiting, diarrhoea, abdominal discomfort, photosensitivity, crystalluria, reversible oligospermia, yellow-orange staining of contact lens, skin, urine and other body fluids, alopoecia. Potentially Fatal: Severe hypersensitivity reactions, blood dyscrasias, renal and hepatic toxicity, fibrosing alveolitis.

# 255. TAMSULOSIN Tab 400 mcg/ 0.4 mg SALIENT ACTIONS:

Tamsulosin is a selective  $\alpha_1$  adrenoreceptor-blocking agent.. Blockade of these adrenoceptors can cause smooth muscles in the bladder neck and prostate to relax, resulting in an improvement in urine flow rate and reduction in symptoms in BPH.

#### INDICATIONS & DOSAGE REGIMENS:

Benign prostatic hyperplasia:400 mcg once daily. May increase to 800 mcg once daily after 2-4 wk if necessary. If therapy is interrupted for several days, restart with 400 mcg once daily. Dose to be taken 30 minutes after the same meal each day.

### CONTRAINDICATIONS:

Hypersensitivity to sulfonamide, severe hepatic impairment, lactation. Pregnancy.

#### PRECAUTIONS:

Pregnancy Category (US FDA) – B.Caution in - patients with sulfa allergy, Prostate carcinoma should be ruled out before starting the therapy, Patients who undergo cataract surgery. Orthostatic hypotension or syncope especially with first dose, if dosage is increased or an antihypertensive drug or a phosphodiesterase-5 inhibitor is added to the treatment regimen. May cause priapism (rare).

#### INTERACTIONS:

Concomitant admin with moderate or strong inhibitors of CYP2D6 (eg. fluoxetine) or CYP34A (eg. ketoconazole, cimetidine) increases serum concentration. Food reduced extent and rate of absorption.

#### ADVERSE EFFECTS:

Overdosage - Hypotension, headache. Postural hypotension, dizziness and vertigo, malaise, headache, rhinitis, pharyngitis, cough, sinusitis, diarrhoea, nausea, infection, asthenia, back pain, tooth disorder, chest pain, somnolence, insomnia, decreased libido, abnormal ejaculation, priapism, blurred vision. Risk of intraoperative floppy iris syndrome during phacoemulsification surgery.

# 256. TAMSULOSIN 0.4 mg + FINASTERIDE 5 mg Tab SALIENT ACTIONS:

Finasteride is a competitive inhibitor of the 5-alpha reductase, an enzyme which converts testosterone to dihydrotestosterone (DHT). Tamsulosin is a selective alpha-1 adrenoceptor blocker, which blocks the adrenoceptors leading to the relaxation of smooth muscles in the bladder neck and prostate to relax, resulting in an improvement in urine flow rate and a reduction in symptoms of BPH.

#### INDICATIONS & DOSAGE REGIMENS:

Benign prostatic hyperplasia: Each capsule contains finasteride 5 mg and tamsulosin 0.4 mg: 1 capsule once daily.

# CONTRAINDICATIONS:

Hypersensitivity, pregnancy, lactation. Women and children.

# PRECAUTIONS:

Avoid exposure of pregnant women to finasteride, either via direct contact with crushed tab or through semen of male sexual partners who are on this drug. Undiagnosed prostate cancer, liver diseases. Prostate carcinoma should be ruled out before starting the therapy. Hepatic impairment.

#### INTERACTIONS:

Caution when used with cimetidine or warfarin. Not to be used with other alpha-adrenergic blocking agents. Food may delay the rate and reduce the extent of oral absorption, delaying in the time to reach max concentration. Lab Interference Finasteride may mask or reduce serum markers (PSA) for prostate cancer.

#### ADVERSE EFFECTS:

Gynecomastia, decreased libido, impotence, reduction in the volume of ejaculate, genital abnormalities in the male foetus of pregnant women exposed to finasteride. Hypersensitivity reactions such as swelling of lips and rashes, postural hypotension, dizziness and vertigo; headache, infection, asthenia, back pain, chest pain,

dizziness, somnolence, insomnia, decreased libido, rhinitis, pharyngitis, cough, sinusitis, diarhoea, nausea, tooth disorder, amblyopia.

## 257. TELMISARTAN IP 20 MG TAB

#### SALIENT ACTIONS:

Telmisartan is a nonpeptide  $AT_1$  angiotensin II receptor antagonist. It exerts antihypertensive activity by preventing angiotensin II from binding to  $AT_1$  receptors thus inhibiting the vasoconstricting and aldosterone-secreting effects of angiotensin II.

Onset: 1-2 hr.

Duration: Up to 24 hr.

Absorption: Rapidly absorbed from the GI tract. Food may slightly decrease the bioavailability. Absolute bioavailability: Dose-dependent (approx 42% after 40-mg dose; 58% after 160-mg dose). Time to peak plasma concentration: Approx 0.5-1 hr.

Distribution: Volume of distribution: 500 L. Plasma protein binding: >99%.

Metabolism: Undergoes conjugation w/ glucuronic acid to form inactive metabolites.

Excretion: Via faeces (97%, as unchanged drug). Terminal elimination half-life: Approx 24 hr.

## INDICATIONS & DOSAGE REGIMENS:

Adult: PO HTN Initial: 40 mg once daily, may be adjusted to 20-80 mg once daily. CV risk reduction 80 mg once daily.

#### INTERACTIONS:

May increase plasma levels of digoxin. May increase serum lithium levels and toxicity. May reduce plasma levels of warfarin. Increased risk of hyperkalaemia w/ K-sparing diuretics, K supplements or K-containing salt substitutes. May antagonise hypotensive effect and increase risk of renal impairment w/ NSAIDs.

Potentially Fatal: May increase nephrotoxic, hyperkalaemic and hypotensive effect w/ aliskiren in patients w/ diabetes and renal impairment (GFR <60 mL/min).

#### PRECAUTIONS:

Volume- or salt-depleted patients including patients on prolonged diuretic therapy. Patients w/ renal artery stenosis, aortic or mitral stenosis, obstructive biliary disease. Renal and mild to moderate hepatic impairment. Lactation. Monitoring Parameters Monitor BP, electrolytes and serum creatinine levels.

#### CONTRAINDICATIONS:

Concomitant use w/ aliskiren in patients w/ diabetes and renal impairment (GFR <60 mL/min). Severe hepatic impairment. Pregnancy.

## ADVERSE EFFECTS:

Dizziness, fatigue, headache, sinusitis, upper resp tract infection, pharyngitis, UTI, back pain, myalgia, diarrhoea, abdominal pain, dyspepsia, nausea.

Potentially Fatal: Intermittent claudication and skin ulcer.

#### 258. TERBINAFINE 250MG TAB

#### SALIENT ACTIONS:

Terbinafine causes fungal cell death by inhibiting squalene epoxidase, the main enzyme in sterol biosynthesis, resulting in ergosterol deficiency within fungal cell walls. It has fungicidal activity against dermatophytes and some yeast.

Absorption: Absorbed well from the GI tract with 40% bioavailability (oral), minimal absorption (topical); peak plasma concentrations after 2 hr (oral).

Distribution: Distributed into stratum corneum of the skin, nail plate, hair (concentrations higher than plasma) and breastmilk. Protein-binding: Extensive.

Metabolism: Hepatic; converted to inactive metabolites.

Excretion: Via urine: 17-36 hr (plasma elimination half-life); up to 400 hr (terminal elimination half-life) in prolonged therapy.

#### INDICATIONS & DOSAGE REGIMENS:--

Dermatophytosis

Adult: PO 250 mg once daily. Duration: 2-4 wk (Tinea cruris), 4 wk (Tinea corporis), 6 wk (Tinea pedis) and 6-12 wk (nail infections).

### INTERACTIONS:

Possible increase in levels in drugs metabolised by CYP450 2D6. Decreased terbinafine concentration with rifampicin; increased terbinafine concentration with cimetidine.

#### PRECAUTIONS:

Preexisting liver or renal impairment, pregnancy. Perform liver function tests prior to oral therapy.

#### CONTRAINDICATIONS:

Hypersensitivity, active or chronic liver disease, lactation.

#### ADVERSE EFFECTS:

Anorexia, nausea, abdominal pain, taste disturbances, diarrhoea, rash, urticaria.

Potentially Fatal: Liver failure, Stevens-Johnson syndrome, neutropaenia.

#### 259. THALIDOMIDE CAP USP

#### SALIENT ACTIONS:

Thalidomide is a synthetic glutamic acid derivative immunomodulator with anti-inflammatory, antiangiogenetic, sedative and hypnotic activity.

Absorption: Slowly absorbed from GI tract. Peak plasma concentrations: 3 to 6 hr. Food may delay but does not significantly affect extent of absorption of thalidomide.

Distribution: Crosses the placenta, distributed into the semen. Elimination half-life: 5-7 hr.

Metabolism: Exact metabolic fate unknown, it appears to undergo non-enzymatic hydrolysis in plasma.

#### **INDICATIONS & DOSAGE REGIMENS:**

Oral

Erythema nodosum leprosum (Type 2)

Adult: 100-300 mg once daily at bedtime, reduced gradually by 50 mg every 2-4 wk once a satisfactory reponse is achieved. Not for monotherapy if moderate or severe neuritis present. Max: 400 mg/day. Patients < 50 kg: Initially, 100 mg daily.

Oral

Multiple myeloma

Adult: Initial dose of 200 mg once daily, increased by 100 mg at wkly intervals according to patient tolerance.

Max: 800 mg daily.

## INTERACTIONS:

Thalidomide enhances sedative activity of barbiturates, alcohol, chlorpromazine and reserpine. Avoid use of other drugs that have the potential to cause peripheral neuropathy. Increased risk of thromboembolic events with darbepoetin-alfa and doxorubicin.

Potentially Fatal: Increased risk of bone marrow supression with peg interferon alfa.

#### PRECAUTIONS:

All females of childbearing potential must use 2 reliable forms of contraception simultaneously 4 wk before starting therapy, during and 4 wk after therapy is discontinued. Therapy to be stopped immediately if pregnancy occurs. Male: Use of barrier methods of contraception if partner is of child-bearing potential. Do not donate blood or sperm during therapy. Patient should not drive or operate machinery. Discontinue therapy if any skin rash develops. Do not resume therapy if the rash is exfoliative, purpuric, or bullous, or if Stevens-Johnson syndrome or toxic epidermal necrolysis suspected.

# CONTRAINDICATIONS:

Pregnancy and lactation.

# ADVERSE EFFECTS:

Severe and irreversible peripheral neuropathy, constipation, dizziness, orthostatic hypotension, drowsiness, somnolence, bradycardia, increase of viral load in HIV-infected patients, hypersensitivity reaction. Potentially Fatal: Stevens-Johnson syndrome, toxic epidermal necrolysis and blood dyscrasias.

#### 260. THIOCOLCHICOSIDE CAP IP 4MG

#### SALIENT ACTIONS:

Thiocolchicoside is a muscle relaxant which has been claimed to possess GABA-mimetic and glycinergic actions.

# INDICATIONS & DOSAGE REGIMENS:

Oral

Muscle spasms

Adult: Initially, 16 mg daily.

## INTERACTIONS:

N/A

PRECAUTIONS:

N/A

CONTRAINDICATIONS:

N/A

ADVERSE EFFECTS:

Photosensitivity reactions.

# 261. THYROXIME SODIUM Tab 50 mcg / 100 mcg

SALIENT ACTIONS:

Thyroid hormone- Increases metabolic rate of body tissues; is needed for normal growth and maturation. **INDICATIONS:** 

Replacement therapy in hypothyroidism. Severe and chronic hypothyroidism. TSH suppression.

DOSAGE REGIMENS:

Should be taken on an empty stomach.

Replacement therapy in hypothyroidism: Adult: Initially, 50-100 mcg daily, may increase by 25-50 mcg at 4-wkly intervals until the thyroid deficiency is corrected. maintenance dose: 100-200 mcg daily. Child: Neonates: Initially, 10-15 mcg/kg/day. Neonates at risk for cardiac failure: Consider lower doses of 25 mcg/day. Neonates with thyroxine levels <5 mcg/dl: Initially, 50 mcg/day. Adjust dose every 4-6 wk. Infants and children: Dose based on body wt and age: 0-3 mth: 10-15 mcg/kg/day; 3-6 mth: 8-10 mcg/kg/day; 6-12 mth: 6-8 mcg/kg/day; 1-5 yr: 5-6 mcg/kg/day; 6-12 yr: 4-5 mcg/kg/day; >12 yr: 2-3 mcg/kg/day. Older children: To minimise hyperactivity, initially ¼ of the recommended dose and increase by ¼ dose each wk until full replacement dose is reached. Children who have completed growth and puberty: Initially, 1.7 mcg/kg/day as a single dose. Titrate dose every 6 wk. Average initial dose: About 100 mcg; usual dose: ≤200 mcg/day; dose ≥300 mcg/day is rare and reevaluation should be prompted. Elderly: >50 yr without cardiac disease or <50 yr with cardiac disease: Initially, 12.5-25 mcg/day. Adjust dose every 6-8 wk as needed. >50 yr with cardiac disease: Initially, 12.5-25 mcg/day. Adjust dose by 12.5-25 mcg increments every 4-6 wk. Elderly patients may require <1 mcg/kg/day. Severe and chronic hypothyroidism: Adult: Initially, 12.5-50 mcg/day. Adjust dose in steps of 12.5-25 mcg at 4-wkly intervals. Child: Initially, 25 mcg/day. Adjust dose by 25 mcg every 2-4 wk.

**TSH suppression:** Adult: For thyrotropin-dependent well-differentiated thyroid cancer: Doses >2 mcg/kg/day given as a single dose to suppress TSH to <0.1 MIU/L. For benign nodules and nontoxic multinodular goitre: Target TSH is generally higher at 0.1-0.5 MIU/L for nodules and 0.5-1.0 MIU/L for multinodular goitre.

CONTRAINDICATIONS:

Untreated hyperthyroidism; uncorrected adrenal failure; recent MI. Do not use for treatment of obesity or for wt loss. Pregnancy, lactation.

PRECAUTIONS:

Special Precautions in Angina, heart failure; DM; diabetes insipidus; elderly; long-standing hypothyroidism; adrenal insufficiency; myxoedema.

INTERACTIONS:

Reduced absorption with iron, colestyramine, colestipol, aluminium- and magnesium-containing antacids, calcium carbonate, simethicone, sucralfate. May alter requirements of antidiabetic drugs. Reduced efficacy of thyroid replacement therapy with imatinib. Reduced serum level with amiodarone, carbamazepine, phenytoin, phenobarbital, rifampicin & oestrogens. *Potentially Fatal:* Increased therapeutic and toxic effects of levothyroxine and TCAs. Changes hypoprothrombinaemic response to warfarin & oral anticoagulants (increased response during replacement). Increased risk of significant hypertension and tachycardia with ketamine. *Food Interaction:* Decreased bioavailability and lower serum levels of thyroxine with enteral nutrition. Reduced absorption with soybean infant formula, cottonseed meal, walnuts and dietary fibre.

Lab Interference May alter thyroid function tests.

ADVERSE EFFECTS

Overdosage: Chronic: hyperthyroidism, wt loss, nervousness, sweating, palpitations, insomnia, heat intolerance, menstrual irregularities. psychotic symptoms, fever, premature closure of epiphyses in infants. Acute: fever, hypoglycaemia, CHF, undiagnosed adrenal failure. Others - Nervousness, excitability, tremor, muscle weakness, cramps; sweating, flushing, heat intolerance, headache, insomnia, tachycardia, palpitations, angina pectoris, excessive wt loss; menstrual irregularities; diarrhoea, vomiting. Potentially Fotal: Convulsions, cardiac arrhythmia, heart failure, coma.

#### 262. TICAGRELOR 90 MG TABLET

#### SALIENT ACTIONS:

Belongs to the class of platelet aggregation inhibitors excluding heparin. Used in the treatment of thrombosis.

## INDICATIONS & DOSAGE REGIMENS:

TICAGRELORCo-administered with Acetylsalicylic Acid (ASA) 75-100 mg prevention is indicated of the thrombotic events (cardiovascular death, myocardial infarction and stroke) in patients with acute coronary syndromes (ACS) [unstable angina, non-ST elevation myocardial infarction (NSTEMI) or ST elevation myocardial infarction (STEMI)] including patients managed with percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG).

Initiate TICAGRELOR treatment with a 180 mg (two 90 mg tablets) loading dose and continue treatment with 90 mg twice daily.

After the initial loading dose of aspirin (usually 325 mg), useTICAGRELOR with a daily maintenance dose of aspirin 75-100 mg.

ACS patients who have received a loading dose of clopidogrel may be started on TICAGRELOR.

A patient who misses a dose of TICAGRELORshould take one 90 mg tablet (their next dose) at its scheduled time.

#### INTERACTIONS:

Effects of Other Drugs: Ticagrelor is predominantly metabolized by CYP3A4 and to a lesser extent by CYP3A5. Ticagrelor is also a p-glycoprotein (P-gp) substrate.

CYP3A Inhibitors: Avoid use of strong inhibitors of CYP3A (eg, ketoconazole, itraconazole, voriconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, atazanavir and telithromycin). (See Pharmacology under Actions, Warnings and Precautions.)

CYP3A Inducers: Avoid use with potent inducers of CYP3A (eg, rifampin, dexamethasone, phenytoin, carbamazepine and phenobarbital). (See Pharmacology under Actions, Warnings and Precautions.)

Aspirin: Use of BRILINTA with aspirin maintenance doses >100 mg reduced the effectiveness of Brilinta (see Pharmacology: Pharmacodynamics: Clinical Studies under Actions, Warnings and Precautions).

Effect on Other Drugs: Ticagrelor is an inhibitor of CYP3A4/5 and the P-gp transporter.

Simvastatin and Lovastatin: BRILINTA will result in higher serum concentrations of simvastatin and lovastatin because these drugs are metabolized by CYP3A4. Avoid simvastatin and lovastatin doses greater than 40 mg (see Pharmacology under Actions).

Digoxin: Because of inhibition of the P-gp transporter, monitor digoxin levels with initiation of or any change in therapy

Other Concomitant Therapy: BRILINTA can be administered with unfractionated or low-molecular-weight heparin, GPIIb/IIIa inhibitors, proton-pump inhibitors,  $\beta$ -blockers, angiotensin converting enzyme inhibitors and angiotensin receptor blockers.

## PRECAUTIONS:

General Risk of Bleeding: Drugs that inhibit platelet function including TICAGRELOR increase the risk of bleeding. TICAGRELORincreased the overall risk of bleeding (major + minor) to a somewhat greater extent than did clopidogrel. The increase was seen for non-CABG-related bleeding, but not for CABG-related bleeding. Fatal and life-threatening bleeding rates were not increased (see Adverse Reactions). In general, risk factors for bleeding include older age, a history of bleeding disorders, performance of percutaneous invasive procedures and concomitant use of medications that increase the risk of bleeding [eg, anticoagulant and fibrinolytic therapy, higher doses of aspirin, and chronic nonsteroidal anti-inflammatory drugs (NSAIDs)].

#### CONTRAINDICATIONS:

Hypersensitivity (eg, angioedema) to ticagrelor or to any of the components of TICAGRELOR History of Intracranial Hemorrhage: Patients with a history of intracranial hemorrhage (ICH) because of a high risk of recurrent ICH in this population (see Pharmacology: Pharmacodynamics: Clinical Studies under Actions).

Active Bleeding: Patients with active pathological bleeding eg, peptic ulcer or intracranial hemorrhage (see Warnings, Precautions and Adverse Reactions).

Severe Hepatic Impairment: Patients with severe hepatic impairment because of a probable increase in exposure and it has not been studied in these patients. Severe hepatic impairment increases the risk of bleeding because of reduced synthesis of coagulation proteins

## ADVERSE EFFECTS:

Bleeding: PLATO used the following bleeding severity categorization: Major Bleed: Fatal/Life-Threatening:

Any one of the following: Fatal; intracranial; intrapericardial bleed with cardiac tamponade; hypovolemic shock or severe hypotension due to bleeding and requiring pressors or surgery; clinically overt or apparent bleeding associated with a decrease in hemoglobin (Hb) of more than 5 g/dL; transfusion of 4 or more units [whole blood or packed red blood cells (PRBCs)] for bleeding.

# 263. TINIDAZOLE Tab 300 mg / 500 mg

# SALIENT ACTIONS:

Tinidazole, a 5 nitroimidazole derivative, is active against both protozoa (e.g. *Trichomonas vaginalis*, *Entamoeba histolytica* and *Giardia lamblia*) and obligate anaerobic bacteria. It damages DNA strands or inhibit DNA synthesis in microorganism.

# INDICATIONS & DOSAGE REGIMENS:

Bacterial vaginosis: 2 g as a single dose or 2 g given on 2 consecutive days.

Anaerobic bacterial infections, Endometritis, Lung abscess, Peritonitis, Pneumonia, Skin & soft tissue infections: 2 g on 1st day, followed by 1 g daily as a single dose or 500 mg bid for 5-6 days.

Prophylaxis of postoperative anaerobic bacterial infections- 2 g given 12 hr before surgery.

Eradication of H. pylori associated with peptic ulcer disease -500 mg bid; given with clarithromycin and omeprazole for 7 days.

**Intestinal amoebiasis:** Adult: Single daily dose of 2 g for 2 or 3 days. Tinidazole therapy to be followed by a luminal amoebicide. Child: A single daily dose of 50-60 mg/kg daily for 3 days. Tinidazole therapy to be followed by a luminal amoebicide.

**Hepatic amoebiasis:**Adult: 1.5-2 g as a single daily dose for 3-6 days. Tinidazole therapy to be followed by a luminal amoebicide. Child: A single daily dose of 50-60 mg/kg for 5 days. Tinidazole therapy to be followed by a luminal amoebicide.

Giardiasis: Adult: 2 g as a single dose. Child: 50-75 mg/kg as a single dose, repeat this dose if necessary.

**Trichomoniasis:** Adult: 2 g as a single dose. In trichomoniasis, sexual partners should be treated. Child: 50-75 mg/kg as a single dose, repeat this dose if necessary.

Acute necrotising ulcerative gingivitis:2 g as a single dose.

#### CONTRAINDICATIONS:

Blood dyscrasias, organic neurologic disorders, hypersensitivity to 5-nitroimidazole derivatives, porphyria. Lactation, pregnancy (1st trimester).

#### PRECAUTIONS:

Alcohol should be avoided until 72 hr after stopping therapy. Discontinue if abnormal neurological signs develop .CNS diseases, pregnancy (2nd and 3rd trimester).

#### INTERACTIONS:

Pregnancy Category (US FDA) – C. decreased abs. with colestyramine. increased anticoagulant effect of warfarin. Monitor for toxicity if used with ciclosporin, tacrolimus or lithium. Food Interaction - Disulfiram-like reaction with alcohol.Lab Interference May cause falsely decreased values in tests where determinations are based on the decrease in ultraviolet absorbance that occurs during oxidation of NADH to NAD e.g. ALT, AST, LDH, triglycerides or glucose.

**ADVERSE EFFECTS:** Metallic taste, nausea, headache, vomiting, dark urine, flushing, anorexia, diarrhoea, tiredness, transient leucopenia. *Potentially Fatal:* Hypersensitivity.

#### **264. TOPIRAMATE TAB**

#### SALIENT ACTIONS:

Topiramate is a sulfamate-substituted monosaccharide w/ unknown precise mechanism of action. It may be due to blockade of voltage-dependent Na channels; augmentation of the activity of  $\gamma$ -aminobutyric acid (GABA) at GABA<sub>A</sub> receptors; antagonism of AMPA/kainate glutamate receptors; and inhibition of carbonic anhydrase.

Absorption: Rapidly and well absorbed from the GI tract. Bioavailability: Approx 80%. Time to peak plasma concentration: Approx 2 hr.

Distribution: Crosses the placenta and enters breast milk. Plasma protein binding: Approx 15-41%.

Metabolism: Metabolised minimally in the liver via hydrolysis, hydroxylation, and glucuronidation.

Excretion: Via urine (approx 70% as unchanged drug). Elimination half-life: Approx 21 hr.

#### INDICATIONS & DOSAGE REGIMENS:

Oral

Adjunct for seizures associated with the Lennox-gastaut syndrome

Adult: Initially, 25-50 mg at night for 1 wk, increased in increments of 25 or 50 mg at 1-2 wk interval until

effective dose is reached. Doses >25 mg should be taken in 2 divided doses. Usual dose: 200-400 mg daily. Child: ≥2 yr Initially, 25 mg at night for 1 wk, increased in increments of 1-3 mg/kg at 1-2 wk interval until effective dose is reached. Doses >25 mg should be taken in 2 divided doses. Usual dose: Approx 5-9 mg/kg daily.

Renal impairment: Patient undergoing haemodialysis: Supplemental dose equal to approx 50% of the daily dose, given in divided doses (at the start and upon completion of haemodialysis).

CrCl (ml/min) Dosage Recommendation	
≤70	Reduce usual dose by 50% and titrate more slowly.

Oral

Adjunct in epilepsy

Adult: Initially, 25-50 mg at night for 1 wk, increased in increments of 25 or 50 mg at 1-2 wk interval until effective dose is reached. Doses >25 mg should be taken in 2 divided doses. Usual dose: 200-400 mg daily. Child: ≥2 yr Initially, 25 mg at night for 1 wk, increased in increments of 1-3 mg/kg at 1-2 wk interval until effective dose is reached. Doses >25 mg should be taken in 2 divided doses. Usual dose: Approx 5-9 mg/kg daily.

Renal impairment: Patient undergoing haemodialysis: Supplemental dose equal to approx 50% of the daily dose, given in divided doses (at the start and upon completion of haemodialysis).

CrCl (ml/min) Dosage Recommendation	
≤70	Reduce usual dose by 50% and titrate more slowly.

Oral

Epilepsy

Adult: Initially, 25 mg at night for 1 wk, increased in increments of 25 or 50 mg at 1-2 wk interval until effective dose is reached. Doses >25 mg should be taken in 2 divided doses. Usual dose: 100 mg daily. Max: 500 mg daily.

Child: ≥6 yr Initially, 0.5-1 mg/kg at night for 1 wk, increased in increments of 0.5-1 mg/kg at 1-2 wk interval. Initial target dose: 100 mg (approx 2 mg/kg) daily in 2 divided doses.

Renal impairment: Patient undergoing haemodialysis: Supplemental dose equal to approx 50% of the daily dose, given in divided doses (at the start and upon completion of haemodialysis).

CrCl (ml/m	in) Dosage Recommendation
≤70	Reduce usual dose by 50% and titrate more slowly.

Oral

Prophylaxis of migraine

Adult: Initially, 25 mg at night for 1 wk, increased in increments of 25 mg at wkly interval. Usual dose: 50-100 mg daily in 2 divided doses. Max: 200 mg daily.

Renal impairment: Patient undergoing haemodialysis: Supplemental dose equal to approx 50% of the daily dose, given in divided doses (at the start and upon completion of haemodialysis).

CrCl (ml/r	nin) Dosage Recommendation
≤70	Reduce usual dose by 50% and titrate more slowly

#### INTERACTIONS:

Decreased serum level w/ other antiepileptics (e.g. carbamazepine, phenytoin). May increase effect of CNS depressants. May reduce efficacy and increase risk of breakthrough bleeding of OCs. May increase AR (e.g. metabolic acidosis) of metformin and other carbonic anhydrase inhibitors (e.g. acetazolamide). May increase serum level of lithium.

## PRECAUTIONS:

Patient w/ predisposition to nephrolithiasis, conditions or medications that may increase risk of metabolic acidosis, history of eye disorders. Renal and hepatic impairment. Childn. Pregnancy and lactation. Patient Counselling This drug may cause visual disturbances, drowsiness, and dizziness, if affected do not drive or operate machinery. Maintain proper hydration while on therapy, esp during exercise or exposure to warm weather. Avoid abrupt withdrawal. Monitoring Parameters Monitor electrolytes (e.g. serum bicarbonate) at baseline and periodically during treatment), serum creatinine, symptoms of acute acidosis and complications of long-term acidosis, hydration status, seizure frequency, and suicidality.

#### CONTRAINDICATIONS:

N/A

#### ADVERSE EFFECTS:

Confusion, ataxia, impaired concentration and speech, fatigue, depression, dizziness, paraesthesia or

hypoaesthesia, drowsiness, memory or cognition difficulty, anxiety, agitation, nervousness, emotional lability, mood disorders, anorexia, abdominal pain, asthenia, diplopia, leucopenia, nausea, diarrhoea, nystagmus, insomnia, psychomotor retardation, nasopharyngitis, altered taste, visual disturbances, wt loss, increased risk of renal calculi, reduced sweating w/ hyperthermia. Rarely, acute myopia w/ secondary angle-closure glaucoma.

## 265. TORSEMIDE 10MG TAB

#### SALIENT ACTIONS:

Torasemide, a sulfonylurea loop diuretic, acts from within the lumen of the thick ascending portion of the loop of Henle, where it inhibits the  $Na^+/K^+/2C\Gamma$ -carrier system.

Onset: Diuresis: Oral: Within 1 hr; IV: Within 10 min.

Duration: Diuresis: Oral and IV: 8 hr.

Absorption: Absorbed rapidly and almost completely (oral). Peak serum levels after 1-2 hr. Food decreases rate but not extent of absorption.

Distribution: Protein-binding: >99%. Apparent distribution volume: 16 L.

Metabolism: Metabolised by the cytochrome P450 isoenzyme CYP2C9. Elimination half-life: 3.5 hr.

Excretion: Excreted by urine as unchanged drug (24%) and metabolites.

# INDICATIONS & DOSAGE REGIMENS:

Oral

Hypertension

Adult: 2.5-5 mg once daily. Max: 5 mg daily.

Oral

Oedema in patients with hepatic cirrhosis

Adult: Initially, 5-10 mg once daily, given together with an aldosterone antagonist or a potassium-sparing diuretic, titrated upwards until the desired diuretic response is obtained. Max: 40 mg daily.

Oral

Oedema

Adult: 5 mg once daily, increased to 20 mg once daily if necessary. Max: 40 mg/day.

#### INTERACTIONS:

Increased risk of severe hypokalaemia with amphotercin B, corticosteroids, carbenoxolone, hypokalaemia-causing medications. Increased risk of lithium toxicity. Increased potential for ototoxicity and nephrotoxicity with nephrotoxic or ototoxic medications e.g. aminoglycosides. High dose salicylates may increase the risk of salicylate toxicity. Increased risk of toxicity with digoxin. Reduced diuretic effect with NSAIDs. Increased risk of hypotension with antihypertensives.

#### PRECAUTIONS:

Risk of hyperuricaemia, gout and DM. Correct electrolyte distubances and disorders of micturition before treatment. Monitor electrolyte balance, glucose, uric acid, creatinine and lipids regularly. May impair ability to drive or operate machinery.

#### CONTRAINDICATIONS:

Hypersensitivity to sulfonylureas, rena! failure with anuria, hepatic coma and pre-coma, hypotension, cardiac arrhythmias. Pregnancy and lactation.

# ADVERSE EFFECTS:

Electrolyte disturbances e.g. hypokalaemia, dehydration, dry mouth, headache, dizziness, hypotension, weakness, drowsiness, confusional states, loss of appetite, cramps, increased serum uric acid, glucose, lipids, urea and creatinine, increase in LFT, metabolic alkalosis, tinnitus and hearing loss.

# 266. TRAMADOL Cap 50 mg

#### SALIENT ACTIONS:

Tramadol inhibits reuptake of norepinephrine, serotonin and enhances serotonin release. It alters perception and response to pain by binding to mu-opiate receptors in the CNS.

#### INDICATIONS & DOSAGE REGIMENS:

Moderate to severe pain. Adult: 50-100 mg every 4-6 hr. Max: 400 mg daily. As extended-release tablet: 50-100 mg once or twice daily. Max: 300 mg daily. Elderly: Lower initial dose. Max: 300 mg daily (>75 yr).

# CONTRAINDICATIONS:

Suicidal patients, acute alcoholism; head injuries; raised intracranial pressure; severe renal impairment; lactation.

#### PRECAUTIONS

Incompatible with injections of diazepam, diclofenac sodium, indometacin, midazolam, piroxicam, phenylbutazone, aciclovir, clindamycin and lysine aspirin if mixed in the same syringe. Hypothyroidism; adrenocortical insufficiency; renal or hepatic impairment; history of epilepsy or increased risk of seizures; inflammatory or obstructive bowel disease; myasthaenia gravis; respiratory depression; prostatic hyperplasia. Pregnancy.

#### INTERACTIONS:

Increase in anticoagulation with warfarin. Increased risk of seizures with SSRI, TCA.Increased risk of serotonin syndrome with mirtazapine, venlafaxine, SSRI and MAOI; tramadol should not be given to patients receiving MAOIs or within 14 days of their discontinuation. Reduced analgesic efficacy of tramadol with carbamazepine, 5-HT3-receptor antagonist. Increased respiratory and CNS depression with CNS depressants.

#### ADVERSE EFFECTS:

Overdosage: Miosis, vomiting, cold and clammy skin, respiratory depression, lethargy, flaccid skeletal muscle, coma, seizures, bradycardia, hypotension, cardiac arrest, cardiac collapse and death. Others - Sweating, dizziness, nausea, vomiting, dry mouth, fatigue, asthenia, somnolence, confusion, constipation, flushing, headache, vertigo, tachycardia, palpitations, miosis, insomnia, orthostatic hypotension, seizures, CNS stimulation e.g. hallucinations. Potentially Fatal: Respiratory depression.

# 267. TRANEXAMIC ACID Tab 500 mg SALIENT ACTIONS:

Tranexamic acid is an antifibrinolytic agent that competitively inhibits breakdown of fibrin clots. It blocks binding of plasminogen and plasmin to fibrin, thereby preventing haemostatic plug dissolution.

# INDICATIONS & DOSAGE REGIMENS:

Short-term management of haemorrhage: Adult: 1-1.5 g or 15-25 mg/kg 2-4 times daily. Child: 25 mg/kg bid or tid.

Management of hereditary angioedema: Adult: 1-1.5 g bid or tid. Child: 25 mg/kg bid or tid. Incompatible with benzylpenicillin.

#### CONTRAINDICATIONS:

Severe renal failure, active intravascular clotting, thromboembolic disease, colour vision disorders, subarachnoid bleeding.

#### PRECAUTIONS:

Pregnancy Category US FDA – B. Pregnancy, lactation.Mild to moderate renal impairment, irregular menstrual bleeding, previous history of thromboembolic disease, haematuria. Monitor closely in disseminated intravascular coagulation. Monitor LFT and eye examination regularly during long-term use. Discontinue if disturbance in colour vision occurs.

# INTERACTIONS:

Potentially Fatal: Increased risk of thrombus formation with estrogens, Factor IX complex concentrates or antiinhibitor coagulant concentrates. Increased risk of fatal thrombotic complications with tretinoin in acute promyelocytic leukaemia.

## ADVERSE EFFECTS:

Overdosage: Nausea, vomiting, orthostatic symptoms and/or hypotension. Others- Diarrhoea, nausea, vomiting, disturbances in colour vision, giddiness, thromboembolic events.

# 268. TRANEXAMIC ACID 500 mg + MEFENAMIC ACID 250 mg Tab SALIENT ACTIONS:

Tranexamic acid is an antifibrinolytic that competitively inhibits the activation of plasminogen to plasmin. Tranexamic acid helps with blood clotting. Mefenamic acid reduces swelling. It binds the prostaglandin synthetase receptors COX-1 and COX-2, inhibiting the action of prostaglandin synthetase which have a role as a major mediator of inflammation and/or a role for prostanoid signaling in activity-dependent plasticity, the symptoms of pain are temporarily reduced.

## INDICATIONS:

For powerful control of painful bleeding, Prevention of bleeding after surgery or trauma& surgery in patients taking anti-coagulants, Tooth extraction in patients with hemophilia, Prevention of bleeding in acute promyelocytic leukemia. Prevention of rebleeding of subarachnoid hemorrhage. Treatment of menorrhagia. Treatment & prevention of hemorrhages, epistaxis. Treatment of hereditary and non-hereditary angioedema.

#### DOSAGE REGIMENS:

2-3 tabs after heavy bleeding - three or four times a day, for a maximum of three to four days.

#### CONTRAINDICATIONS:

Pregnancy, lactation, Allergy to any ingredient. Active ulceration or chronic inflammation of either the upper or lower GIT. Preexisting renal disease. Coagulation disorders, bleeding in the brain, urine, or related to kidney, using medicine to help your blood clot. Disturbance of color vision. If the time between the start of periods is less than 21 days or more than 35 days.

#### PRECAUTIONS:

Avoid alcohol & NSAIDs. Children younger than 18 years, pregnancy and lactation. Renal impairment, long term treatment of hereditary angioedema, Ureteral obstruction, previous h/o thromboembolic disease, concomitant adm. with factorIX complex concentrates or anti- inhibitor coagulant concentrates, thoracic or abdominal surgery, DIC, haematuria, active intravascular clotting, and asthama. Monitor blood counts & liver function during long- term therapy. Drowsiness may affect ability to perform skilled tasks.

# INTERACTIONS:

Coagulants, factor IX complex concentrates, or tretinoin (all-trans retinoic acid) because the risk of blood clots may be increased. Anticoagulants (eg, warfarin) - decrease Tranexamic Acid's effectiveness. Tranexamic acid has increased risk of thrombus formation with oestrogens.

#### ADVERSE EFFECTS:

Tranexamic acid and mefenamic acid can cause stomach upset and gastrointestinal bleeding. Tranexamic acid – dizziness, blood clots may be increased, Back pain; headache; joint pain; musclepain, spasms, or cramps; nasal or sinus congestion; stomach pain; tiredness, numbness of an arm or leg; one-sided weakness; seizures; severe or persistent dizziness or light-headedness; shortness of breath; slurred speech; sudden, severe headache or vomiting; vision changes or problems

Mefenamic acid. Diarrhoea, nausea, vomiting, vision, giddiness, hypotension, thromboembolism & thrombosis. Bronchospasm; headache, drowsiness, insomnia, visual disturbances; utricaria, rash, thrombocytopaenia, plastic anaemia, agranulocytosis. Autoimmune; convulsions (0verdosage).

# 269. TRIFLUOPERAZINE Tab 1 mg

#### SALIENT ACTIONS:

Trifluoperazine inhibits dopamine D2 receptors in the brain. It has weak anticholinergic and sedative effects but strong extrapyramidal and antiemetic effects. It controls severely disturbed, agitated or violent behaviour but may also be used for nonpsychotic anxiety.

#### INDICATIONS & DOSAGE REGIMENS:

Elderly: Initiate at lower dose and increase gradually.

Psychoses: Adult: 2-5 mg bid gradually increased to 15-20 mg daily, or 40 mg daily in severe or resistant psychoses. Child: Max: 5 mg daily in divided doses adjusted according to age, body weight and response.

Nausea and vomiting: Adult: 1-2 mg bid. Max 6 mg daily. Child: 3-5 yrs: max 1 mg daily in divided doses; 6-12 yrs: max 4 mg daily.

Short-term management of anxiety: Adult: 1-2 mg bid. Max: 6 mg daily. Max duration: 12 wk. Child: 3-5 yr: max 1 mg daily in divided doses; 6-12 yr: max 4 mg daily in divided doses.

#### CONTRAINDICATIONS:

Preexisting CNS depression and coma; bone marrow depression, blood dyscrasias, liver disease, hypersensitivity to phenothiazines, prolactin dependent tumours. Pregnancy (1st trimester), lactation.

#### PRECAUTIONS:

Pregnancy Category (US FDA) – C.Cardiovascular disease, epilepsy, angle-closure glaucoma, exposure to extreme temperatures, elderly, parkinson's disease, myasthenia gravis, benign prostatic hyperplasia, DM, renal and hepatic impairment. Discontinue trifluoperazine at least 48 hr before myelography and do not resume for at least 24 hr after procedure. Do not use trifluoperazine in control of nausea and vomiting occurring either prior to myelography or postprocedure with metrizamide.

# INTERACTIONS:

Increased CNS depression with CNS depressants such as opiates or other analgesics, barbiturates or other sedatives, general anaesthetics, or alcohol.Increased risk of side effects with drugs with antimuscarinic properties (TCA, antiparkinsonian drugs.) Antagonised effects of dopaminergic drugs such as levodopa. Increased risk of hypotension with antihypertensives, trazodone. Reverses antihypertensive effect of guanethidine. Increased risk of severe extrapyramidal side-effects or severe neurotoxicity with lithium. Possible decrease in absorption with antacids.

#### ADVERSE EFFECTS:

Overdosage: extrapyramidal side effects, CNS depression, somnolence, agitation, restlessness, convulsions, ECG changes, cardiac arrhythmias, fever, autonomic reactions such as hypotension, dry mouth and ileus. Others - Drowsiness, dry mouth, blurred vision, dizziness, sedation, antimuscarinic affects, postural hypotension, akathisia, muscle weakness, anorexia, insomnia, rash, amenorrhoea, fatigue, increased prolactin levels, extrapyramidal side effects. Potentially Fatal: Neuroleptic malignant syndrome, blood dyscrasias.

# 270. TRIFLUOPERAZINE + BENZHEXOL Tab SALIENT ACTIONS:

Trifluoperazine inhibits dopamine D2 receptors in the brain. It has weak anticholinergic and sedative effects but strong extrapyramidal and antiemetic effects. It controls severely disturbed, agitated or violent behaviour but may also be used for nonpsychotic anxiety. Benzhexol is anticholinergic drug and prevent Parkinson induced by Trifluoperazine.

# INDICATIONS & DOSAGE REGIMENS:

**Psychoses:** Adult: 2-5 mg bid gradually increased to 15-20 mg daily, or 40 mg daily in severe or resistant psychoses. Child: Max: 5 mg daily in divided doses adjusted according to age, body weight and response. Elderly: Initiate at lower dose and increase gradually.

#### CONTRAINDICATIONS:

Preexisting CNS depression and coma; bone marrow depression, blood dyscrasias, liver disease, hypersensitivity to phenothiazines, prolactin dependent tumours. Pregnancy (1st trimester), lactation.

#### PRECAUTIONS:

Pregnancy .Cardiovascular disease, epilepsy, angle-closure glaucoma, exposure to extreme temperatures, elderly, parkinson's disease, myasthenia gravis, benign prostatic hyperplasia, DM, renal amd hepatic impairment. Discontinue trifluoperazine at least 48 hr before myelography and do not resume for at least 24 hr after procedure. Do not use trifluoperazine in control of nausea and vomiting occurring either prior to myelography or postprocedure with metrizamide.

# INTERACTIONS:

Increased CNS depression with CNS depressants such as opiates or other analgesics, barbiturates or other sedatives, general anaesthetics, or alcohol.Increased risk of side effects with drugs with antimuscarinic properties (TCA, antiparkinsonian drugs.) Antagonised effects of dopaminergic drugs such as levodopa. Increased risk of hypotension with antihypertensives, trazodone. Reverses antihypertensive effect of guanethidine. Increased risk of severe extrapyramidal side-effects or severe neurotoxicity with lithium. Possible decrease in absorption with antacids.

#### ADVERSE EFFECTS:

Drowsiness, dry mouth, blurred vision, dizziness, sedation, antimuscarinic affects, postural hypotension, akathisia, muscle weakness, anorexia, insomnia, rash, amenorrhoea, fatigue, increased prolactin levels, extrapyramidal side effects. Potentially Fatal: Neuroleptic malignant syndrome, blood dyscrasias. Anticholiergic symptoms like urinary retention, dry mouth etc

# 271. TRIHEXYPHENIDYL HCL IP 2MG TAB

SALIENT ACTIONS:

Trihexyphenidy! HCl is a tertiary amine antimuscarinic which exerts a direct inhibitory effect on the parasympathetic nervous system. It also exhibits a direct spasmolytic action on smooth muscle, weak mydriatic, antisialagogue and cardiovagal blocking effects.

Onset: W/in 1 hr. Duration: 6-12 hr.

Absorption: Rapidly and well absorbed from the GI tract. Time to peak plasma concentration: 1.3 hr.

Metabolism: Undergoes hydroxylation of the alicyclic group.

Excretion: Via urine (as unchanged drug) and bile. Elimination half-life: 33 hr.

# INDICATIONS & DOSAGE REGIMENS:

Ora!

Drug-induced extrapyramidal symptoms

Adult: Initially, 1 mg daily, increased to 5-15 mg daily in 3-4 divided doses.

Elderly: May require lower doses.

Oral

Parkinsonism

Adult: Initially, 1 mg daily, gradually increased at intervals of 3-5 days by increments of 2 mg until 6-10 mg daily in 3-4 divided doses. Postencephalitic patients: Up to 12-15 mg daily.

Elderly: May require lower doses.

### INTERACTIONS:

Increased antimuscarinic side effects w/ phenothiazines, clozapine, antihistamines, disopyramide, nefopam and amantadine. Synergistic effect when concomitantly used w/ TCAs. Concurrent admin w/ MAOIs may cause dry mouth, blurred vision, urinary hesitancy or retention and constipation. May antagonise effect of metoclopramide and domperidone on GI function. Reduced absorption of levodopa. May antagonise effect of parasympathomimetics.

# PRECAUTIONS:

Patient w/ arteriosclerosis, history of drug idiosyncrasy. CV disease, glaucoma, GI obstruction, prostatic hyperplasia and/or urinary stricture. Not intended for treatment of tardive dyskinesia. Avoid abrupt withdrawal. Hepatic and renal impairment. Elderly. Pregnancy and lactation. Patient Counselling May impair mental or physical abilities e.g. operating machinery or driving. Monitoring Parameters Perform gonioscopic examination prior to initiation of therapy. Monitor intraocular pressure at regular intervals during prolonged treatment.

**CONTRAINDICATIONS:** 

N/A

#### ADVERSE EFFECTS:

Dryness of the mouth, nausea, constipation, vomiting, dizziness, drowsiness, headache, blurred vision, mydriasis, nervousness, tachycardia, urinary hesitancy or retention, increased intraocular tension, angle-closure glaucoma, weakness, rashes, dilatation of the colon, paralytic ileus, and suppurative parotitis. Rarely, psychiatric disturbances (e.g. delusion, amnesia, depersonalization, sense of unreality, paranoia)

#### 272. TRYPSIN + CHYMOTRYPSIN Tab

#### SALIENT ACTIONS:

Anti-inflammatory enzyme used locally like streptokinases for reducing inflammation, haemotomas and bruising. Trypsin -Chymotrypsin are proteolytic anti-inflammatory enzymes, which is used to resolve inflammation, reduce oedema and hasten healing of wound. The pain produced by inflammation is reduced as the inflammation subsides. After trauma and muscle and soft tissue injury, it reduces the recovery time and reduces pain early in the healing phase.

#### INDICATIONS:

Pelvic inflammatory diseases, Sprains, Fractures, Accidental injuries

#### DOSAGE REGIMENS:

1 tab. 4 times/day, half an hour before meals.

#### CONTRAINDICATIONS:

Hypersensitivity.

### PRECAUTIONS:

Severe hepatic or renal disease. Lactation, or in the elderly, children, pregnancy (use only, if clearly indicated) and patients with irregularities of blood clotting mechanism.

# INTERACTIONS:

Acids, alkalis and antiseptics (i.e. alcohol) may inactivate chymotrypsin and trypsin. Chloramphenicol inhibits chymotrypsin activity. Epinephrine 1:100 will inactivate chymotrypsin within 1 hour.

#### ADVERSE EFFECTS:

Occasional gastrointestinal irritation, nausea, vomiting and allergic reactions.

#### 273. URSODEOXYCHOLIC ACID IP 150 MG TAB

# SALIENT ACTIONS:

Ursodeoxycholic acid suppresses hepatic synthesis and secretion of cholesterol and also inhibits intestinal absorption of cholesterol.

Absorption: Absorbed from the GI tract.

Distribution: Plasma protein binding: Approx 70%.

Metabolism: Undergoes extensive enterohepatic recycling. Free and conjugated forms undergo 7a-dehydroxylation to lithocholic acid under the influence of intestinal bacteria; some of which are further conjugated and sulfated hepatically.

Excretion: Via faeces; urine (<1%). Half-life: Approx 4-6 days.

#### INDICATIONS & DOSAGE REGIMENS:

Oral

Dissolution of cholesterol-rich gallstones

Adult: 8-12 mg/kg once daily at bedtime or in 2 divided doses continued for 3-4 mth after radiological disappearance of gallstones. Duration of treatment: Up to 2 yr. Obese patients: Up to 15 mg/kg daily. Oral

Primary biliary cirrhosis

Adult: 10-16 mg/kg daily in 2-4 divided doses, may be taken once daily in the evening after the 1st 3 mth.

Prophylaxis of gallstones in patients undergoing rapid weight loss

Adult: 300 mg bid.

#### INTERACTIONS:

Reduced absorption w/ Al-containing antacids, bile acid sequestrants (e.g. cholestyramine, colestipol), charcoal. Possibly reduced efficacy w/ clofibrate, oestrogens and OCs. May increase the absorption of ciclosporin.

#### PRECAUTIONS:

Pregnancy and lactation. Monitoring Parameters Monitor LFTs mthly for the 1st 3 mth and every 6 mth thereafter.

## CONTRAINDICATIONS:

Acute inflammation of gallbladder or biliary tract, occlusion of biliary tract, frequent episodes of biliary colic, radio-opaque calcified gallstones, impaired contractility of gallbladder, non-functioning gallbladder, inflammatory bowel disease, hepatic and intestinal conditions interfering w/ enterohepatic recirculation of bile acids, extrahepatic and intrahepatic cholestasis, ileal resection and stoma, regional ileitis, active duodenal and gastric ulcer; acute, chronic or severe hepatic disease.

## ADVERSE EFFECTS:

Nausea, vomiting, diarrhoea, other GI disturbances, pruritus, viral infection, headache, upper resp tract infection, sinusitis, pharyngitis, arthralgia, back pain, cough, bronchitis, UTI, arthritis, myalgia, cholecystitis, rhinitis, fatigue, dysmenorrhoea, musculoskeletal pain, asthenia, peripheral oedema, HTN. Rarely, gallstone calcification, liver function deterioration.

# 274. URSODIOL Tab 150 mg

## SALIENT ACTIONS:

Ursodeoxycholic acid suppresses hepatic synthesis and secretion of cholesterol and also inhibits intestinal absorption of cholesterol.

#### **INDICATIONS & DOSAGE REGIMENS:**

**Dissolution of cholesterol-rich gallstones**: Adult: 6-12 mg/kg daily as a single dose at bedtime or in 2-3 divided doses continued for 3-4 mth after radiological disappearance of stones. Doses may be divided unequally with a higher dose given before bedtime to counteract increase in biliary cholesterol saturation which occurs in early morning. Max: 15 mg/kg. Chronic liver disease (except primary biliary cirrhosis): use with caution.

Primary biliary cirrhosis: Adult: 10-15 mg/kg daily in 2-4 divided doses.

Prophylaxis of gallstones in patients undergoing rapid weight loss: Adult: 300 mg bid.

Shold be taken with food.

#### CONTRAINDICATIONS:

Calcified and pigment gallstones, radio opaque gallstones. Nonfunctioning gall bladders; chronic liver and peptic ulcer disease. Inflammatory disease of colon and small intestine. Pregnancy.

#### PRECAUTIONS:

Pregnancy Category (US FDA) – B.50% of successfully treated patients will develop further gallstones within 10 yr. Lactation.

#### INTERACTIONS:

Cholestyramine, charcoal and antacids may reduce effectiveness. Aluminum-based antacids may reduce absorption. Oestrogens and clofibrate may counteract effectiveness of ursodeoxycholic acid by increasing cholesterol elimination in bile. Possible increase in ciclosporin serum concentration. Decreased effectiveness of dapsone. Possible decrease in serum ciprofloxacin and nitrendipine.

# ADVERSE EFFECTS:

Diarrhoea, pruritus, nausea, vomiting, gallstone calcification.

# 275. VALACYCLOVIR USP 1000MG TAB

#### SALIENT ACTIONS:

Belongs to the class of nucleosides and nucleotides excluding reverse transcriptase inhibitors. Used in the systemic treatment of viral infections.

# INDICATIONS & DOSAGE REGIMENS:

Treatment of Herpes Zoster: Adults: 1,000 mg 3 times daily for 7 days.

Treatment of Herpes Simplex Infections: Adults: 500 mg twice daily.

For recurrent episodes, treatment should be for 5 days. For initial episodes, which can be more severe, treatment may have to be extended to 10 days. Dosing should begin as early as possible. For recurrent episodes of herpes simplex, this should ideally be during the prodromal period or immediately after the 1st signs or symptoms appear. Valtrex can prevent lesion development when taken at the 1st signs and symptoms of an HSV

Prevention (Suppression) of Recurrences of Herpes Simplex Infections in Immunocompetent Adult: 500 mg once daily.

Some patients with very frequent recurrences (eg, ≥10/year) may gain additional benefit from the daily dose of 500 mg being taken as a divided dose (250 mg twice daily).

Immunocompromised Adults: 500 mg twice daily.

Reduction of Transmission of Genital Herpes: In immunocompetent heterosexual adults with <10 recurrences per year and with the susceptible partner discordant for HSV-2 antibodies, 500 mg once daily by the infected

The efficacy of reducing transmission beyond 8 months in discordant couples has not been established.

There are no data on the reduction of transmission in other patient populations.

Elderly: Dosage modification is not required unless renal function is significantly impaired (see Renal Impairment as follows).

Adequate hydration should be maintained.

Renal Impairment: Caution is advised when administering valaciclovir to patients with impaired renal function. Adequate hydration should be maintained.

# INTERACTIONS:

N/A

#### PRECAUTIONS:

Renal & hepatic impairment. Maintain adequate hydration. Elderly.

# CONTRAINDICATIONS:

hypersensitivity

#### ADVERSE EFFECTS:

Headache & nausea. Renal insufficiency, microangiopathic hemolytic anemia & thrombocytopenia in severely immunocompromised patients w/ high doses & prolonged periods but these have also been observed in patients not on valaciclovir having the same underlying conditions.

# 276. VALSARTAN TAB

#### SALIENT ACTIONS:

Valsartan, an angiotensin II type 1 (AT<sub>1</sub>) receptor antagonist, produces its BP lowering effects by inhibiting angiotensin II-induced vasoconstriction, aldosterone release and renal reabsorption of Na. Onset: Approx 2 hr.

Duration: 24 hr.

Absorption: Rapidly absorbed. Food may decrease rate and extent of absorption. Bioavailability: Approx 23% (tab), approx 39% (oral soln). Time to peak plasma concentration: 2-4 hr (tab), 1-2 hr (cral soln).

Distribution: Volume of distribution: 17 L. Plasma protein binding: 94-97%.

Metabolism: Not significant.

Excretion: Via faeces (approx 83%) and urine (approx 13%). Terminal elimination half-life: Approx 6 hr.

# INDICATIONS & DOSAGE REGIMENS:

Oral

Hypertension

Adult: Initially, 80 mg once daily, may be increased to 160 mg once daily if needed. Max: 320 mg once daily. Child: As tab: ≥6 yr <35 kg: Initially, 40 mg once daily. Max: 80 mg once daily; 35-80 kg: Initially, 80 mg once daily. Max: 160 mg once daily; >80 kg: Initially, 80 mg once daily. Max: 320 mg once daily. As oral soln: Started at half the equivalent tab dose in valsartan-naive patients. If switching from tab to oral soln, the dose

should be halved; if switching from soln to tab, same dose should be used initially. Dose should be titrated further according to response.

Elderly: No dosage adjustment needed.

Hepatic impairment: Mild to moderate: Max: 80 mg once daily. Severe: Contraindicated.

Oral

Heart failure

Adult: Initially, 40 mg bid, may be increased to 160 mg bid if tolerated.

Elderly: No dosage adjustment needed.

Hepatic impairment: Mild to moderate: Max: 80 mg once daily. Severe: Contraindicated.

Oral

Post myocardial infarction

Adult: Start as early as 12 hr after MI in stable patients at an initial dose of 20 mg bid, doubled at intervals over a few wk up to 160 mg bid if tolerated.

Elderly: No dosage adjustment needed.

Hepatic impairment: Mild to moderate: Max: 80 mg once daily. Severe: Contraindicated.

#### INTERACTIONS:

May antagonise hypotensive effects and increase the risk of renal impairment w/ NSAIDs. Increased risk of hyperkalaemia w/ K-sparing diuretics, K supplements or K-containing salt substitutes.

Potentially Fatal: Increased risk of hypotension, hyperkalemia and changes in renal function (including acute renal failure) when used w/ aliskiren in patients w/ diabetes and renal impairment (GFR <60 mL/min).

#### PRECAUTIONS:

Patients w/ renal artery stenosis, heart failure, aortic or mitral stenosis, severe Na and/or volume depletion. Renal and mild to moderate hepatic impairment. Lactation. Monitoring Parameters Monitor BP, electrolytes, renal function. Monitor serum K levels every dose increment and periodically thereafter.

#### **CONTRAINDICATIONS:**

Concomitant use w/ aliskiren in patients w/ diabetes and renal impairment (GFR <60 mL/min). Severe hepatic impairment. Pregnancy.

## ADVERSE EFFECTS:

Dizziness, hypotension, hyperkalaemia, neutropenia, viral infection, back pain, arthralgia, fatigue, abdominal pain, diarrhoea, cough, blurred vision. Increase in BUN and serum creatinine.

#### 277. VENLAFAXINE HCL TAB

#### SALIENT ACTIONS:

Venlafaxine and its active metabolite O-desmethylvenlafaxine selectively inhibit the neuronal reuptake of serotonin, norepinephrine and to a lesser extent dopamine. It has minimal affinity for muscarinic, histamine, or  $\alpha_1$ -adrenergic receptors. It appears to be as effective as standard antidepressants but w/ a lower incidence of anticholinergic, sedative and CV side effects.

Absorption: Readily absorbed from GI tract. Bioavailability: Approx 45%. Time to peak plasma concentration: Approx 2 hr (venlafaxine); approx 4 hr (O-desmethylvenlafaxine).

Distribution: Crosses the placenta and distributed into breast milk. Plasma protein binding: 27% (venlafaxine); 30% (O-desmethylvenlafaxine).

Metabolism: Extensively hepatic; converted mainly to O-desmethylvenlafaxine by CYP2D6 isoenzyme and to a less active metabolite N-desmethylvenlafaxine by CYP3A4 isoenzyme.

Excretion: Via urine (as free or conjugated metabolites), via faeces (approx 2%). Elimination half-life: Approx 5 hr (venlafaxine); approx 11 hr (O-desmethylvenlafaxine).

# INDICATIONS & DOSAGE REGIMENS:

Oral

Depression

Adult: Conventional tab: Initially, 75 mg/day in 2 or 3 divided doses, may increase in increments of up to 75 mg/day at intervals of 4 days or more. Max: 375 mg/day. Extended-release: Initially, 37.5-75 mg once daily; in patients initiated at 37.5 mg once daily, may increase to 75 mg once daily after 4-7 days; dose may then be increased in increments of up to 75 mg/day at intervals of 4 days or more. Max: 225 mg/day.

Renal impairment: GFR <30 mL/min and patient requiring haemodialysis: Reduce dose by 50%.

Hepatic impairment: Mild to moderate: Reduce dose by 50%.

Oral

Panic disorder

Adult: Extended-release: Initially, 37.5 mg once daily for a wk, may increase to 75 mg once daily after 7 days; increase in increments of up to 75 mg/day at intervals of 7 days or more. Max: 225 mg/day.

Renal impairment: GFR <30 mL/min and patient requiring haemodialysis: Reduce dose by 50%.

Hepatic impairment: Mild to moderate: Reduce dose by 50%.

Oral

Anxiety

Adult: Extended-release: Initially, 37.5-75 mg once daily; in patients initiated at 37.5 mg once daily, may increase to 75 mg once daily after 4-7 days; dose may then be increased in increments of up to 75 mg/day at intervals of 4 days or more. Max: 225 mg/day.

Renal impairment: GFR <30 mL/min and patient requiring haemodialysis: Reduce dose by 50%.

Hepatic impairment: Mild to moderate: Reduce dose by 50%.

#### INTERACTIONS:

Increased risk of serotonin syndrome w/ TCA, SSRI, SNRI, lithium, sibutramine, tramadol. May increase serum levels w/ CYP3A4 inhibitors (e.g. ketoconazole, atazanavir, clarithromycin). May increase serum levels of haloperidol. May decrease serum levels of indinavir. May increase bleeding risk w/ aspirin, NSAIDs, warfarin and other anticoagulants.

Potentially Fatal: Increased risk of serotonin syndrome w/ MAOIs, linezolid and methylene blue.

#### PRECAUTIONS:

History of MI or unstable cardiac disease, seizure; hypomania or mania, increased intraocular pressure or at risk of acute narrow-angle glaucoma, at risk of bleeding. Renal and hepatic impairment. Gradual dose reduction is recommended rather than abrupt withdrawal. Pregnancy and lactation. Patient CounsellingMay impair ability to drive or operate machinery. Monitoring Parameters Monitor BP and heart rate regularly, cholesterol, mental status for depression. Closely observe for clinical worsening, suicidality and unusual changes in behaviour. Monitor for emergence of serotonin syndrome.

# CONTRAINDICATIONS:

Concomitant use w/ MAOIs or w/in 14 days of discontinuing the MAOI. Use w/ linezolid or IV methylene blue. ADVERSE EFFECTS:

Changes in behaviour, suicidal ideation, agitation, tremor, nervousness, anxiety, insomnia, confusions, abnormal dreams, HTN, nausea, headache, asthenia, somnolence, dizziness, dry mouth, vomiting, constipation, diarrhoea, dyspepsia, abdominal pain, anorexia, sexual dysfunction, urinary frequency, visual disturbances, mydriasis, vasodilatation, paraesthesia, hypertonia, chills or fever, palpitations, wt gain or loss, arthralgia, myalgia, tinnitus, pruritus, dyspnoea, yawning, rashes, sweating, increased serum cholesterol, may impair platelet aggregation.

# 278. VIBACT CAP (PROBIOTIC)

### SALINET ACTIONS:

cap: streptococcus faecalis T-110 JPC 30 million cells, clostridium butyricum TO-A 2 million cells, bacillus mesentericus TO-A JPC 1 million cells, lactobacillus 50 million cells.

Live microorganisms which confer a health benefit on the host are called probiotics. Although, several microorganisms are used in probiotics products, but commonly used probiotics are strains of Lactic acid bacteria eg. Lactobacillus, Bifidobacterium and streptococcus. Probiotics are well absorbed when given orally.

# INDICATIONS:

Gastrointestinal disorders: Antibiotic induced/ associated diarrhoea. Prevention, recurrence and to shorten duration of diarrhoea in children. Acute diarrhoea in young children. Infant diarrhoea. Nosocomial diarrhoea especially in infants and young children. Nosocomial rotavirus gastroenteritis. Clostridium difficile diarrhoea. HIV/AIDS diarrhoea. Enternal feeding associated diarrhoea. Acute infections diarrhoea, eg.

Rotavirusinduceddiarrh oea. Toinprove intestinal immunity. Abdominal cramping, bloating, diarrhoea, and nausea due to lactose intolerance. Inflammatory bowel disease -crohn's disease, ulcerative colitis. Irritable bowel syndrome. Helicobacter pylori infections. Pancreatitis. Pouchitis.

Extraiintestinal disorders: Probiotics also alter systemic immunity and hence also indicated to treat urinary tract infection in women, respiratory tract infections, skin infections (especially eczema in infants and children) and nasal passage infections.

## DOSAGE REGIMEN:

A minimum, of one billion/day live cells of bacterial should be consumed orally.

#### CONTRAINDICATIONS:

Hypersensitivity rarely

#### PRECAUTIONS:

Although seem safe, but available information is limited.

#### DRUG INTERACTION:

not reported yet.

#### SIDE-EFFECTS:

Infections by probiotics are extremely rare

# 279. VITAMIN A Cap 25000 IU

## SALIENT ACTIONS:

Retinol (vitamin A) is an essential cofactor in many biological processes for growth, development and maintenance of epithelial tissues and visual adaptation to darkness.

## INDICATIONS & DOSAGE REGIMENS:

Vitamin A deficiency: Adult: For severe deficiency with corneal changes: 500,000 units daily for 3 days, followed by 50,000 units daily for 2 wk and then 10,000-20,000 units daily for 2 mth as follow-up therapy. For cases with corneal changes: 10,000-25,000 units daily until clinical improvement occurs (usually 1-2 wk). In children with xerophthalmia: 5000 units/kg daily for 5 days or until recovery occurs.

#### CONTRAINDICATIONS:

Hypervitaminosis A; pregnancy (dose exceeding RDA), women planning pregnancy.

#### PRECAUTIONS:

Cholestatic jaundice; fat-malabsorption conditions. Monitor patients closely for toxicity. Liver impairment and children. Pregnancy Category (US FDA) -A, if dose > US RDA -X.

## INTERACTIONS:

Decreased absorption with neomycin. Increased risk of hypervitaminosis A with synthetic retinoids eg, acitretin, isotretinoin and tretinoin. Increased risk of toxicity when used with alcohol.

#### ADVERSE EFFECTS:

Hypervitaminosis A; characterised by fatigue, irritability, anorexia, weight loss, vomiting and other GI disturbances, low-grade fever, hepatosplenomegaly, skin changes, alopoecia, dry hair, cracking and bleeding lips, SC swelling, nocturia, pains in bones and joints.

# 280. VITAMIN B1 1 mg +VITAMIN B2 1mg +VITAMIN B6 0.5 mg+NIACINAMIDE 15 mg+VITAMIN B12 1 mcg Tab.

## SALIENT ACTIONS:

Vitamin B1 acts as coenzyme in carbohydrate metabolism.FAD and FMN are coenzymes for flavoproteins involved in oxidation-reduction reactions.B6 has role in synthesis of non essential amino acids.NAD and NADP involved in many oxidation reduction reactions. Vitamin B12 as a water-soluble, cofactor in the enzyme methionine synthase, which functions to transfer methyl groups for the regeneration of methionine from homocysteine. In anaemia, it increases erythrocyte production by promoting nucleic acid synthesis in the bone marrow and by promoting maturation and division of erythrocytes.

#### INDICATIONS:

Convalscence, adjuvant therapy with antibiotics, supportive therapy for cardiac and diabetic patients, postoperative recuperation

#### DOSAGE REGIMENS:

One tablet daily or as directed by physician

#### CONTRAINDICATIONS:

No

#### PRECAUTIONS:

May interfere with precise diagnosis in patients with folate deficiency.

## INTERACTIONS:

Decreased GI tract absorption with neomycin, aminosalicylic acid, H2-blockers and colchicine.Reduced serum concentrations with oral contraceptives. Reduced effects in anaemia with parenteral chloramphenicol.INH therapy therapy increase pyridoxine excretion. Hydrallazine, cycloserine, penicillamine interfere with pyridoxine utilization

#### ADVERSE EFFECTS:

Anorexia, nausea, vomiting and diarrhoea.

## 281. VIT C CHEWABLE TAB

#### SALIENT ACTIONS:

a water-soluble vitamin, acts as a cofactor and antioxidant. It is essential for tissue repair and formation of collagen and intercellular materials. Additionally, it is involved in conversion of folic acid to folinic acid, synthesis of lipids and proteins, carbohydrate metabolism, iron absorption and storage, and cellular respiration.

## INDICATIONS & DOSAGE REGIMENS:

SCURVY-500MG BD

#### INTERACTIONS:

Induced tissue desaturation w/ aspirin, nicotine, Fe, phenytoin, tetracycline estrogen from OCs, and some appetite suppressants and anticonvulsant drugs. Reduced absorption and decreased urinary excretion w/ aspirin. Reduced serum levels w/ OCs. May cause unexpected renal tubular reabsorption of acidic drugs and decreased reabsorption of basic drugs. May reduce response to oral anticoagulants. May decrease plasma concentration of fluphenazine. May worsen Fe toxicity to the heart w/ desferrioxamine.

#### PRECAUTIONS:

Patient w/ hyperoxaluria, G6PD deficiency, DM, haemochromatosis. Renal impairment (e.g. renal failure, renal calculi). Pregnancy and lactation.

#### CONTRAINDICATIONS:N/A

#### ADVERSE EFFECTS:

GI disturbances (e.g. diarrhoea, nausea, vomiting, abdominal cramps, transient colic, flatulent distention), heartburn, fatigue, flushing, headache, insomnia, sleepiness; hyperoxaluria, renal Ca oxalate calculi formation; temporary faintness/dizziness (IV); transient mild soreness at the site of inj (IM/SC).

#### 282. VITAMIN D3 2000 IU CAP

## SALIENT ACTIONS:

Vit D may have anti-osteoporotic, immunomodulatory, anticarcinogenic, antipsoriatic, antioxidant & mood-modulatory activities. Along with parathyroid hormone & calcitonin, regulate serum calcium conc. Onset: Slow.

Duration: Relatively prolonged duration of action.

Absorption: Well absorbed from the GI tract. Presence of bile is essential for adequate intestinal absorption.

Hence absorption may be decreased in patients with decreased fat absorption.

Distribution: Bound to a specific α-globulin. Can be stored in adipose & muscle tissue for long periods of time.

Slowly released from storage sites & skin where it is formed in the presence of sunlight or uv light. May distribute into breast milk.

Metabolism: Hydroxylated in the liver by the enzyme vitamin D 25-hydroxylase to form 25-

hydroxycholecalciferol (calcifediol). Further hydroxylated in the kidneys by the enzyme vitamin D1-

hydroxylase to form the active metabolites 1,25-dihydroxycholecalciferol (calcitriol). Further metabolism also occurs in the kidneys, including the formation of the 1,24,25-trihydroxy derivatives.

Excretion: Mainly in the bile & faeces with only small amounts appearing in urine.

#### INDICATIONS & DOSAGE REGIMENS:

Oral

Nutritional deficiency

Adult: 10 mcg (400 units) daily. May also be given via IM inj.

Oral

Deficiency due to malabsorption states or liver diseases

Adult: Up to 1 mg (40 000 units) daily. May also be given via IM inj.

Oral

Hypocalcaemia caused by hypoparathyroidism

Adult: Up to 5 mg (200 000 units) daily. May also be given via IM inj.

#### INTERACTIONS:

Increased risk of hypercalcaemia if given with thiazide diuretics, calcium or phosphate. Antiepileptics (e.g. carbamazepine, phenobarbitone, phenytoin & primidone) may increase vitamin D requirements. Rifampicin & Isoniazid may reduce efficacy of vitamin D. Corticosteroids may counteract the effect of vitamin D. Digoxin or any cardiac glycoside. Reduced absorption when taken with cholestyramine, colestipol, mineral oil, orlistat. Ketoconazole.

#### PRECAUTIONS:

Excessive intake may lead to development of hyperphosphataemia or hypercalcaemia. Infants, renal impairment

or calculi, heart disease. Monitor plasma phosphate & calcium level. Pregnancy, lactation.

#### CONTRAINDICATIONS:

Hypercalcaemia. Evidence of vitamin D toxicity

#### ADVERSE EFFECTS:

Hyperphosphataemia or hypercalcaemia (in excessive intake). Associated effects of hypercalcaemia include hypercalciuria, ectopic calcification, & renal & CV damage

# 283. VITAMIN E 400MG CAP

#### SALIENT ACTIONS:

Vitamin E is a general term used to refer to a large number of natural or synthetic compounds. Tocopherols are the most common compounds, of which alpha tocopherols are the most active and widely distributed in nature. Alpha tocopherols occur naturally in the d optical isomer form and is more active than the synthetic racemic dl form. d-α-tocopheryl acetate is the acetate ester of natural source d-α-tocopherol. Other naturally occurring tocopherols e.g. beta, gamma, and delta tocopherols are not used clinically. Tocotrienols are another group of compounds with vitamin E activity. Vitamin E, a fat soluble vitamin, reacts with free radicals and protects RBCs against haemolysis and polysaturated fatty acids in membranes against free radical attack. Absorption: 20-80% (oral). Absorption depends on the presence of bile and on normal pancreatic function; decrease with increasing dose.

Distribution: Enters blood via the chylomicrons in the lymph; bound to β-lipoproteins. Widely distributed to all tissues. Stored in adipose tissue. Enters breast milk but crosses the placenta poorly.

Metabolism: Hepatic; converted to glucuronides of tocopheronic acid and its γ-lactone.

Excretion: Excreted mainly via bile into faeces and some into urine.

# INDICATIONS & DOSAGE REGIMENS:

Oral

Vitamin E deficiency

Adult: 40-50 mg of d-α tocopherol daily.

Child: Neonate: 10 mg/kg once daily; 1 mth-18 yr: 2-10 mg/kg/day, up to 20 mg/kg.

Oral

Supplementation in cystic fibrosis

Adult: 100-200 mg daily of dl-α-tocoferil acetate or 67-135 mg daily of d-α-tocopherol.

Child: As  $\alpha$ - tocopheryl acetate: 1 mth-1 yr 50 mg once daily; 1-12 yr 100 mg once daily; 12-18 yr 200 mg once daily. Dose to be adjusted as needed.

Oral

Abetalipoproteinaemia

Adult: 50-100 mg/kg daily of dl-α-tocoferil acetate or about 33-67 mg/kg daily of d-α-tocopherol.

Child: Neonate: 100 mg/kg once daily; 1 mth-18 yr: 50-100 mg/kg once daily.

## INTERACTIONS:

Colestyramine, colestipol, and orlistat may interfere with vitamin E absorption. High doses of vitamin E potentiates the anticoagulant action of warfarin. Large doses of vitamin E may impair response to iron supplementation.

PRECAUTIONS:N/A

CONTRAINDICATIONS: N/A

#### ADVERSE EFFECTS:

Hypertension; myopathy; thrombophloebitis; fatigue, weakness, nausea, headache, dizziness, blurred vision, flatulence, diarrhoea, abdominal pain. Topical: Contact dermatitis.

# 284. VITAMINE E 400 IU + WHEAT GERM OIL 50mg + OMEGA 3 FATTY ACIDS 30 mg Cap SALIENT ACTIONS:

Vitamin E is a fat-soluble vitamin that exists in eight different forms. It has an antioxidant effect - prevents the formation of peroxides that damage cellular and subcellular membranes and protects RBCs against haemolysis and polysaturated fatty acids in membranes against free radical attack. Protects against oxidation of vitamin A. Inhibits the synthesis of cholesterol. It is involved in the biosynthesis of heme and proteins, cell proliferation, tissue respiration, and other critical processes of tissue metabolism, prevents increased permeability and capillary fragility. Vitamin E deficiency is usually characterized by neurological problems due to poor nerve conduction. Symptoms include infertility, neuromuscular impairment, menstrual problems, miscarriage and uterine degradation.

# INDICATIONS & DOSAGE REGIMENS:

Vitamin E deficiency: Adult: 40-50 mg of d-α tocopherol daily. Child: Neonate: 10 mg/kg once daily; 1 mth-18 yr: 2-10 mg/kg/day, up to 20 mg/kg.

Supplementation in cystic fibrosis: Adult: 100-200 mg daily of dl- $\alpha$ -tocoferil acetate or 67-135 mg daily of d- $\alpha$ -tocopherol. Child: As  $\alpha$ - tocopheryl acetate: 1 mth-1 yr 50 mg once daily; 1-12 yr 100 mg once daily; 12-18 yr 200 mg once daily. Dose to be adjusted as needed.

Abetalipoproteinaemia: Adult: 50-100 mg/kg daily of dl- $\alpha$ -tocoferil acetate or about 33-67 mg/kg daily of d- $\alpha$ -tocopherol. Child: Neonate: 100 mg/kg once daily; 1 mth-18 yr: 50-100 mg/kg once daily.

Should be taken with food.

# CONTRAINDICATIONS:

None reported

# PRECAUTIONS:

Pregnancy

#### INTERACTIONS:

Colestyramine, colestipol, and orlistat may interfere with vitamin E absorption. High doses of vitamin E potentiate the anticoagulant action of warfarin. Large doses of vitamin E may impair response to iron supplementation.

## ADVERSE EFFECTS:

Hypertension; myopathy; thrombophloebitis; fatigue, weakness, nausea, headache, dizziness, blurred vision, flatulence, diarrhoea, abdominal pain.

# 285. VOGLIBOSE 0.3MG TAB

# SALIENT ACTIONS:

VogliboseBelongs to the class of alpha glucosidase inhibitors. Used in the treatment of diabetes.

# INDICATIONS & DOSAGE REGIMENS:

Oral

Diabetes mellitus

Adult: 200-300 meg tid.

Elderly: Initiate at lower doses.

## INTERACTIONS:

May enhance effects of other antidiabetics including insulin.

#### PRECAUTIONS:

History of laparotomy or ileus. Roemheld's syndrome, stenosis, severe hepatic or renal impairment. Child <18 yr; elderly. Monitor LFT. Treat hypoglycaemic episodes with glucose (not with sucrose).

#### CONTRAINDICATIONS:

Inflammatory bowel disease; GI obstruction or patients predisposed to it; conditions which may deteriorate as a result of increased gas formation eg, hernia; severe ketosis; diabetic coma or pre-coma; severe infection; hypersensitivity; pregnancy; lactation. Not to be used as monotherapy in IDDM.

# ADVERSE EFFECTS:

Flatulence: abdominal distension; diarrhoea; pain; skin reactions; hypoglycemia; increased LFT. Potentially Fatal: Hepatotoxicity.

444)WHITE PETROLEUM JELLY

Used in the topical treatment of fungal infection

# 286. WARFARIN Tab 5 mg

#### SALIENT ACTIONS:

Warfarin inhibits synthesis of vit K-dependent coagulation factors VII, IX, X and II and anticoagulant protein C and its cofactor protein S. No effects on established thrombus but further extension of the clot can be prevented. Secondary embolic phenomena are avoided.

## INDICATIONS & DOSAGE REGIMENS:

Treatment and prophylaxis of venous thromboembolism: Adult: Initially, 5 mg daily. Rapid anti-coagulation: Initially, 10 mg daily for 2 days. Adjust subsequent doses based on PT/INR. Usual maintenance dose: 2-10 mg daily.

## CONTRAINDICATIONS:

Hypersensitivity; haemorrhagic tendencies or blood dyscrasia; recent surgery; peptic ulcer, hypertension; bacteria! endocarditis; cerebrovascular disorders; psychosis; senility; aneurysms; pericarditis; pericardial

effusion; eclampsia; pre-eclampsia; threatened abortion; alcoholism; renal and hepatic impairment; pregnancy. **PRECAUTIONS:** 

Pregnancy Category (US FDA) – X. Elderly, lactation, alcoholics. Heparin induced thrombocytopenia, DVT, infectious disease, disturbances of intestinal flora, surgery or trauma, indwelling catheters, hypertension, Vit C, Vit K, protein C or S deficiency. Purple toes syndrome (due to cholesterol microembolisation) may occur between 3-10 wk after start of therapy. Discontinue therapy if necrosis develops. Periodic determination of PT/INR. Patient to report any signs of bleeding. An INR <2 represents insufficient anticoagulation while INR>4 represents higher risk of bleeding.

#### INTERACTIONS:

Potentially Fatal: Acute alcoholism, allopurinol, NSAIDs, anabolic steroids, amiodarone, propafenone, quinidine, chloramphenicol, ciprofloxacin, co-trimoxazole, erythromycin, metronidazole, ofloxacin, sulfonamides, azithromycin, clarithromycin, norfloxacin, tetracyclines, SSRI, fluconazole, itraconazole, miconazole, ketoconazole, proguanil, cisapride, ifosfamide, disulfiram, piracetam, zafirlukast, interferon-α, isoniazid, tramadol, glucagon, doxycycline, propylthiouracil, danazol, flutamide, tamoxifen, clofibrate, simvastatin, cimetidine, sulfinpyrazone enhance anticoagulant effect of warfarin.rifampicin, carbamazepine, phenobarbital, barbiturates, bosentan, nafcillin, azathioprine, menthol, primidone, griseofulvin and aminoglutethimide, oral contraceptives containing oestrogens, corticosteroids, sucralfate, vit K as well as chronic alcoholism reduce anticoagulant effect.Cholestyramine reduces anticoagulant effect; avoid admin of warfarin 1 hr before or 4-6 hr after .Food Interaction - Avoid major changes in dietary intake of Vit K (green vegetables eg broccoli, spinach).Increased anticoagulant effects with alfalfa, celery, capsicum, clove, omega 3 triglycerides, fenugreek, and ginger.Reduced anticoagulant effect with St John's wort, coenzyme Q10. Lab Interference May cause false decrease in serum theophylline concentrations with the Schack and Waxler ultraviolet method.

#### ADVERSE EFFECTS:

Overdosage: Haemorrhage. Others-Hypersensitivity, rash, alopecia, diarrhoea, drop in haematocrit, purple toes syndrome, skin necrosis, jaundice, nausea, vomiting, hepatic dysfunction, pancreatitis, increased LFT. Potentially Fatal: Haemorrhage (narrow therapeutic index).

# 287. XANTINOL NICOTINATE 150MG TAB

#### SALIENT ACTIONS:

Belongs to the class of purine derivative agents. Used as peripheral vasodilators.

# INDICATIONS & DOSAGE REGIMENS:

Ora

Cerebrovascular disorders, Peripheral vascular disease

Adult: 3 g daily.

# INTERACTIONS:

N/A

# PRECAUTIONS:

Mitral stenosis.

#### CONTRAINDICATIONS:

Severe haemorrhage, pregnancy, recent MI, recent cerebrovascular accidents, severely compromised cardiac function, hypersensitivity.

## ADVERSE EFFECTS:

Flushing, generalized itching, rash, abdominal pain, hypoglycemia, hypotension.

# 288. ZIDOVUDINE Tab 360 mg

#### SALIENT ACTIONS:

Zidovudine is a thymidine analogue, nucleotide reverse transcriptase inhibitor. It is phosphorylated in the body to its active form zidovudine triphosphate & interferes in DNA synthesis of retroviruses by inhibiting DNA replication. it inhibits the enzyme reverse transcriptase. Human DNA polymerase is inhibited only at a conc 100 times more than that required to inhibit viral reverse transcriptase.

#### INDICATIONS & DOSAGE REGIMENS:

HIV infection: Adult: 600 mg daily in divided doses, in combination with other antiretrovirals. Child: 6 wk - 12 yr: 160 mg/m2 every 8 hr. Max: 200 mg every 8 hr. May be used in combination with other anti-retrovirals. Renal impairment: Haemodialysis or peritoneal dialysis: 100 mg, 6-8 hrly.

Prophylaxis of maternal-foetal HIV transmission: Adult: 100 mg 5 times daily or 200 mg tid or 300 mg bid. Start treatment after 14th wk of gestation until the start of labour. Renal impairment: Haemodialysis or peritoneal dialysis: 100 mg, 6-8 hrly.

Prophylaxis of HIV infection in neonates: Child: Neonates: 2 mg/kg every 6 hr for 1st 6 wk of life, starting within 12 hr after birth.

#### CONTRAINDICATIONS:

Lactation.

#### PRECAUTIONS:

Pregnancy. Anaemia or myelosuppression, renal and hepatic impairment, elderly, Monitor patients with risk factors for liver disease. Reduce dose if neutrophil or haemoglobin count is low. Monitor serum CK concentration every 3 mth in patients who have received >6 mth of treatment. Patients to contact doctor if they experience muscle weakness, shortness of breath, symptoms of hepatitis or pancreatitis.

#### INTERACTIONS:

Decreased zidovudine concentration with tipranavir.Increased risk of peripheral neuropathy with bortezomib. Increased haematological toxicity with IV pentamidine, lamivudine, dapsone, vancomycin flucytosine, amphotericin, ganciclovir, interferon alfa, cyclophosphamide and other bone marrow suppressive or cytotoxic agents& Rifampicin.Increased risk of zidovudine toxicity with atovaquone, chloramphenicol, fluconazole, valproate & probenecid.Decreased absorption with clarithromycin, minimise interactions by admin at least 2 hours apart. Increased bioavailability of zidovudine with nimodipine. Increased incidences of headache with benzodiazepines. Possible increase in zidovudine concentration with methadone. *Potentially Fatal:* Avoid stavudine (due to inhibition of activation of stavudine), didanosine, ribavirin (antagonize effect of zidovudine), zalcitabine (inferior virological activity and a higher rate of side effects) with zidovudine. Increased risk of toxicity (e.g. hepatic decompensation, neutropenia) in patients with interferon alfa with or without ribavirin. *Lab Interference* - Maternal zidovudine treatment may cause wrong results in screening tests for inborn errors of metabolism due to high urinary thymine concentrations in neonates.

#### ADVERSE EFFECTS:

Nausea, severe headache, myalgia, insomnia, vomiting, anorexia, diarrhoea, asthenia, dizziness, taste perversion, convulsions, myopathy, nail, skin and oral mucosa pigmentation, raised LFT, pancreatitis, fat redistribution. *Potentially Fatal:* Lactic acidosis, severe hepatomegaly with steatosis, hepatotoxicity. Blood dyscrasias, e.g. serious anaemia (may require transfusion), neutropenia, leucopenia.

#### 289. ZOLPIDEM TARTRATE TAB

#### SALIENT ACTIONS:

Zolpidem is an imidazopyridine derivative that acts by binding to the benzodiazepine (BZD) receptors of the GABA receptor complex resulting in neuronal hyperpolarisation, action potential inhibition, increased in chloride conductance and decreased in neuronal excitability. It has strong sedative action but only minimal anxiolytic, myorelaxant and anticonvulsant properties due to its selectivity for the BZ<sub>1</sub>-receptor over the BZ<sub>2</sub>-receptor. Zolpidem has a rapid onset but short duration of hypnotic action.

Onset: Immediate release: 30 min.

Duration: Immediate release: 6-8 hr.

Absorption: Rapidly absorbed from GI tract. Food reduces both the rate and extent of GI absorption. Absolute bioavailability: Approx 70%. Time to peak plasma concentration: Immediate release: 1.6 hr; extended release: 1.5 hr.

Distribution: Distributed into breast milk. Volume of distribution: 0.54 kg/L. Plasma protein binding: Approx 92%.

Metabolism: Undergoes first pass metabolism, metabolised primarily by CYP3A4 isoenzyme.

Excretion: Via urine (48-67%) and faeces (29-42%) as inactive metabolites. Elimination half-life: Approx 2.5 hr.

#### INDICATIONS & DOSAGE REGIMENS:

Oral

Short-term management of insomnia

Adult: As immediate release tab: 5-10 mg immediately before bedtime. Max: 10 mg/day. As extended release tab: 6.25-12.5 mg immediately before bedtime. Max: 12.5 mg/day. Max duration of treatment: 4 wk including tapering.

Elderly: As immediate release tab: 5 mg immediately before bedtime. As extended release tab: 6.25 mg immediately before bedtime. Max duration of treatment: 4 wk including tapering.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: As immediate release tab: 5 mg immediately before bedtime. As extended release tab: 6.25 mg immediately before bedtime. Max duration of treatment: 4 wk including tapering. Severe: Contraindicated.

#### INTERACTIONS:

Flumazenil reverses the sedative/hypnotic effect of zolpidem. Increased depressant effects w/ CNS depressants (e.g. sedatives, antihistamines, alcohol). Additive effect on decreased alertness and psychomotor performance w/ imipramine and chlorpromazine. Increased plasma concentration w/ itraconazole, ketoconazole and other CYP3A4 inhibitors. May decrease plasma concentration w/ CYP3A4 inducers (e.g. carbamazepine). Reduced hypnotic effect w/ rifampicin.

Potentially Fatal: Increased risk of prolonged sedation and respiratory depression w/ ritonavir.

#### PRECAUTIONS:

Obstructive sleep apnoea, myasthenia gravis, compromised respiratory function. Patients exhibiting symptoms of depression. History of drug or alcohol abuse. Avoid abrupt withdrawal and rapid dose reduction after prolonged therapy. Re-evaluate if insomnia fail to remit after 7-10 days as this may indicate the presence of underlying psychiatric and/or medical condition. Pregnancy, lactation, childn <18 yr. Patient Counseling Patients should be warned about performing activities involving mental alertness or physical coordination after drug intake.

#### CONTRAINDICATIONS:

Severe hepatic impairment.

#### ADVERSE EFFECTS:

Atypical thinking and behaviour, hallucination, nightmare, somnolence, somnambulism, headache, nausea, vomiting, dizziness, vertigo, drowsiness, asthenia, ataxia, rebound insomnia, amnesia, GI disturbances, upper and lower respiratory tract infection, fatigue, visual disturbances, increased ALT serum concentrations, abnormal LFT.

Potentially Fatal: Hepatitis, anaphylactic reactions, angioedema, sleep-driving (driving while not fully awake after drug intake, w/ no recollection of the event).

#### 290. ZOLPIDEN 10MG TAB

#### SALIENT ACTIONS:

Zolpidem is an imidazopyridine derivative that acts by binding to the benzodiazepine (BZD) receptors of the GABA receptor complex resulting in neuronal hyperpolarisation, action potential inhibition, increased in chloride conductance and decreased in neuronal excitability. It has strong sedative action but only minimal anxiolytic, myorelaxant and anticonvulsant properties due to its selectivity for the BZ<sub>1</sub>-receptor over the BZ<sub>2</sub>-receptor. Zolpidem has a rapid onset but short duration of hypnotic action.

Onset: Immediate release: 30 min.

Duration: Immediate release: 6-8 hr.

Absorption: Rapidly absorbed from GI tract. Food reduces both the rate and extent of GI absorption. Absolute bioavailability: Approx 70%. Time to peak plasma concentration: Immediate release: 1.6 hr; extended release: 1.5 hr.

Distribution: Distributed into breast milk. Volume of distribution: 0.54 kg/L. Plasma protein binding: Approx 92%.

Metabolism: Undergoes first pass metabolism, metabolised primarily by CYP3A4 isoenzyme.

Excretion: Via urine (48-67%) and faeces (29-42%) as inactive metabolites. Elimination half-life: Approx 2.5 hr.

#### INDICATIONS & DOSAGE REGIMENS:

Oral

Short-term management of insomnia

Adult: As immediate release tab: 5-10 mg immediately before bedtime. Max: 10 mg/day. As extended release tab: 6.25-12.5 mg immediately before bedtime. Max: 12.5 mg/day. Max duration of treatment: 4 wk including tapering.

Elderly: As immediate release tab: 5 mg immediately before bedtime. As extended release tab: 6.25 mg immediately before bedtime. Max duration of treatment: 4 wk including tapering.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: As immediate release tab: 5 mg immediately before bedtime. As extended release tab: 6.25 mg immediately before bedtime. Max duration of treatment: 4 wk including tapering. Severe: Contraindicated.

#### INTERACTIONS:

Flumazenil reverses the sedative/hypnotic effect of zolpidem. Increased depressant effects w/ CNS depressants (e.g. sedatives, antihistamines, alcohol). Additive effect on decreased alertness and psychomotor performance w/ imipramine and chlorpromazine. Increased plasma concentration w/ itraconazole, ketoconazole and other CYP3A4 inhibitors. May decrease plasma concentration w/ CYP3A4 inducers (e.g. carbamazepine). Reduced hypnotic effect w/ rifampicin.

Potentially Fatal: Increased risk of prolonged sedation and respiratory depression w/ ritonavir.

#### PRECAUTIONS:

Obstructive sleep apnoea, myasthenia gravis, compromised respiratory function. Patients exhibiting symptoms of depression. History of drug or alcohol abuse. Avoid abrupt withdrawal and rapid dose reduction after prolonged therapy. Re-evaluate if insomnia fail to remit after 7-10 days as this may indicate the presence of underlying psychiatric and/or medical condition. Pregnancy, lactation, childn <18 yr. Patient Counseling Patients should be warned about performing activities involving mental alertness or physical coordination after drug intake.

#### CONTRAINDICATIONS:

Severe hepatic impairment.

#### ADVERSE EFFECTS:

Atypical thinking and behaviour, hallucination, nightmare, somnolence, somnambulism, headache, nausea, vomiting, dizziness, vertigo, drowsiness, asthenia, ataxia, rebound insomnia, amnesia, GI disturbances, upper and lower respiratory tract infection, fatigue, visual disturbances, increased ALT serum concentrations, abnormal LFT.

Potentially Fatal: Hepatitis, anaphylactic reactions, angioedema, sleep-driving (driving while not fully awake after drug intake, w/ no recollection of the event).

# SYRUPS/ LIQUIDS

#### SYRUPS/LIQUIDS

#### 1. ALBENDAZOLE I.P. 400 MG SUSP

#### SALIENT ACTIONS::

Albendazole sulfoxide (active metabolite), causes selective degeneration of cytoplasmic microtubules in intestinal and tegmental cells of intestinal helminths and larvae; glycogen is depleted, glucose uptake and cholinesterase secretion are impaired and desecratory substances accumulate intracellulary. ATP production decreases, causing energy depletion, immobilisation and worm death.

Indication: Echinococcosis, Neurocysticercosis.

#### DOSAGE REGIMEN:

Echinococcosis

Adult: <60 kg: 15 mg/kg daily in 2 divided doses. Max: 800 mg/day. ≥60 kg: 400 mg bid. Admin dose for three 28-day cycles w/ a 14-day drug-free interval in between each cycle.

Child: Same as adult dose.

Neurocysticercosis

Adult: <60 kg: 15 mg/kg daily in 2 divided doses (max: 800 mg/day) for 8-30 days. ≥60 kg: 400 mg bid for 8-30 days.

Child: Same as adult dose.

#### CONTRAINDICATIONS:

Pregnancy, chiid < 1 year.

#### PRECAUTIONS:

Patient w/ retinal lesions. Patient treated for neurocysticercosis should receive appropriate steroid and anticonvulsant therapy as required. Pregnancy and lactation. Monitoring Parameters Monitor faecal specimens for ova and parasites for 3 week after treatment; LFTs and CBC w/ differential; ophthalmic exam: patients w/ neurocysticercosis.

#### INTERACTIONS:

Increased serum concentrations w/ dexamethasone, praziquantel and cimetidine. Decreased serum concentrations w/ aminoquinoline (antimalarials), carbamazepine, phenobarbital, and phenytoin.

#### ADVERSE EFFECTS:

Headache, increased intracranial pressure, dizziness, fever, vertigo, meningeal signs, alopecia, abdominal pain, nausea and vomiting, hypersensitivity reactions including rash and urticaria, elevations of hepatic enzymes, hepatitis, acute liver failure, erythema multiforme, Stevens-Johnson syndrome, acute renal failure. Potentially Fatal: Bone marrow suppression leading to pancytopenia, aplastic anaemia, agranulocytosis and leucopenia

### 2. ANTACID-MAGNESIUM HYDROXIDE 200 mg+ DRIED ALUMINIUM HYDROXIDE 200 mg+ ACTIVATED DIMETHICONE 25 mg Syrup 170 ml bottle

#### SALIENT ACTIONS & INDICATIONS:

Antacids, Antireflux Agents & Antiulcerant Alumunium hydroxide acts on the HCl in the stomach by neutralization, forming aluminium chloride salt and water.

#### DOSAGE REGIMENS:

Adult: Up to 1 g daily. Dose is adjusted to the individual patient's requirement. Up to 10 g/day may be given in divided doses with meals. Max Dosage: 10 g daily in divided doses.

#### CONTRAINDICATIONS:

Hypersensitivity to aluminium salts

#### PRECAUTIONS:

Chronic renal impairment; CHF; oedema; cirrhosis and low Na diets; patients with recent GI haemorrhage. Administer 2-3 hrs before/after another medication to minimise drug interactions. Pregnancy and lactation.

#### INTERACTIONS:

Enhanced absorption with citrates or ascorbic acid. Decreases absorption of allopurinol, tetracyclines, quinolones, cephalosporins, biphosphonate derivatives, corticosteroids, cyclosporin, delavirdine, Fe salts, imidazole antifungals, isoniazid,

#### ADVERSE DRUG REACTIONS:

Constipation; intestinal obstruction (with large doses); phosphate depletion may occur with prolonged admin or large doses

# 3. ASCORBIC ACID 40 mg+ NICOTINAMIDE 10 mg + TOCOPHERYL 3 mg+ ZINC 3 mg + THIAMINE HYDROCHLORIDE 1 mg+ RIBOFLAVIN 1 mg + VIT A 1000 IU + CHOLECALCIFEROL 250 IU + ENERGY 1.4 calories + CARBOHYDRATE 320 mg +FAT 605 mg 15 ml drops.

#### SALIENT ACTIONS:

It is a combination of vitamins, mineral, and energy source. Ascorbic acid is a potent reducing agent & essential for collagen synthesis. Tocopheryl act as antioxidant & terminate free radicals. Zinc is essential trace element & part of many enzymes

#### INDICATIONS:

Vit A :prophylaxis,acne,vit C anemia's , dental infection , antioxidents , growth retardation , zinc:acne vulgaris , skin ulcers , alopecia , delayed wound healing , riboflavin :prophylaxis, adjunct t/t of ht, dm, thiamine, :alcoholics, prophylaxis, neuritis, neurological & cardiovascular disorder,

#### DOSAGE REGIMENS:

As per physicians direction

#### CONTRAINDICATIONS:

Hypersensitivity

#### PRECAUTIONS:

Over dose toxic effect

#### INTERACTIONS:

Vit A cholestyramine reduce vit A absorption ,OCP increase Vit A level, Vit C :increase serum level of oestrogen, Zinc :decrease GI absorption of fluroquinolones &iron ,Penicillin reduce its absorption

#### ADVERSE EFFECTS:

Hypervitaminosis, nausea, vomiting, itching, erythema, dermatitis

#### 4. AZITHROMYCIN 100 MG/5ML SUSP.

#### SALIENT ACTIONS:

Azithromycin blocks transpeptidation by binding to 50s ribosomal subunit of susceptible organisms and disrupting RNA-dependent protein synthesis at the chain elongation step.

#### INDICATIONS & DOSAGE REGIMENS:

Skin and soft tissue infections. Respiratory tract infections

Child: >6 mth: 10 mg/kg; 15-25 kg: 200 mg; 26-35 kg: 300 mg; 36-45 kg: 400 mg. Doses to be taken once daily for 3 days.

Prophylaxisof disseminated Mycobacterium avium complex (MAC) infections: Child: >6 mth: 10 mg/kg once daily for 3 days.

#### CONTRAINDICATIONS:

Hypersensitivity.

#### PRECAUTIONS:

Impaired liver and renal function; pregnancy and lactation; children.

#### INTERACTIONS:

Antacids containing aluminium and magnesium salts reduce rate of absorption. Increased risk of ergot toxicity, Potentially Fatal: Increased serum concentrations of digoxin and ciclosporin.

#### ADVERSE DRUG REACTIONS:

Mild to moderate nausea, vomiting, abdominal pain, dyspepsia, flatulence, diarrhoea, cramping; angioedema, cholestatic jaundice; dizziness, headache, vertigo, somnolence; transient elevations of liver enzyme values.

#### 5. BUCLIZINE HCL IP 6MG SYP

#### SALIENT ACTIONS:

Buclizine is a piperazine antihistamine with antimuscarinic and moderate sedative properties. It is used mainly for its antiemetic action and in the treatment of migraine in combination with analgesics.

#### INDICATIONS & DOSAGE:

Oral

Migraine

Child: 10-14 yr: 6.25 mg at the start of the symptoms. >14 yr: follow adult dose.

#### CONTRAINDICATIONS:

Hypersensitivity; neonates.

#### PRECAUTIONS:

Driving or operating machinery; open-angle glaucoma; urinary retention; prostatic hyperplasia, pyloroduodenal obstruction, epilepsy; renal and hepatic impairment; pregnancy.

#### INTERACTIONS:

Potentially Fatal: Effect of alcohol, sedatives and other CNS depressants potentiated.

#### ADVERSE REACTIONS:

Drowsiness, dizziness, incoordination; blurred vision; urinary retention; vomiting; rash; dry mouth; headache, nausea, epigastric pain, wt gain and diarrhoea.

### 6. CALCIUM PHOSPHATE 500 mg + VIT D3 + VIT B12 0.5 mcg Syrup 100 ml bottle SALIENT ACTIONS:

Calcium is an essential constituent of bones & play big role in homoeostasis, it is necessary for cardiac function, muscle contraction, coagulation of blood, cell membrane integrity,. B12 is essential for DNA synthesis, Vit D3 effective in renal disease.

#### INDICATIONS:

Calicium & vit D def. states ,pregnancy , lactation , rickets , post menopausal , chronic renal failure, Vit B12 :prophylaxis & treatment of deficiency, Vit D3 :nutritional & malabsorption ,rickets

#### CONTRAINDICATIONS:

Hypophosphatemia, renal calculi, ,hypersensitivity, Vit D3 is contraindicated in hyperphosphatetemia

#### PRECAUTIONS:

End stage renal disease

#### INTERACTIONS:

Hypercalcemis with thiazide diuretics, decrease GI absorption of iron & tetracyclines, reduce bioavailability of nortloxacin

#### 7. CEFIXIME SYRUP

#### SALIENT ACTIONS:

Cefixime binds to one or more of the penicillin-binding proteins (PBPs) which inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell wall, thus inhibiting biosynthesis and arresting cell wall assembly resulting in bacterial cell death.

#### INDICATIONS & DOSAGE REGIMENS:

- 1. Susceptible infections: Adult: 200-400 mg/day as a single dose or in 2 divided doses. Child: 8 mg/kg/day as a single dose or in 2 divided doses
- 2. Uncomplicated gonorrhea: Adult: 400 mg as a single dose.

#### CONTRAINDICATIONS:

Hypersensitivity to cephalosporin.

#### PRECAUTIONS:

History of allergy to penicillins; pregnancy, lactation; renal failure; GI disease.

#### INTERACTIONS:

Increased concentrations with probenecid, may increase prothrombin time with anticoagulants.

#### ADVERSE DRUG REACTIONS:

Diarrhoea, nausea, vomiting, abdominal pain; headache, dizziness, thrombocytopenia, eosinophilia, Pseudomembranous colitis.

#### 8. CEFPODOXIME 100MG SYRUP

#### SALIENT ACTIONS:

Cefpodoxime binds to 1 or more of the penicillin-binding proteins (PBPs) which inhibit the final transpeptidation step of peptidoglycan synthesis in bacterial cell wall, thus inhibiting biosynthesis and arresting cell wall assembly resulting in bacterial cell death.

#### INDICATIONS & DOSAGE:

Oral

Respiratory tract infections

Adult: 100-200 mg 12 hrly.

Child: ≥15 days 4 mg/kg 12 hrly. Max: 200 mg daily.

Renal impairment: Patients on haemodialysis: Dose should be given after each dialysis session.

CrCl (ml/min) Dosage Recommendation

<10	Increase dosing intervals to 48 hrly.
10-39	Increase dosing intervals to 24 hrly.

Reconstitution: Reconstitute powd for oral susp at the time of dispensing by adding the amount of water specified on the container to provide a susp containing 50 mg or 100 mg per 5 mL. Add water in 2 equal parts and shake the bottle vigorously after each addition.

Oral

Urinary tract infections

Adult: 100-200 mg 12 hrly.

Child: ≥15 days 4 mg/kg 12 hrly. Max: 200 mg daily.

Renal impairment: Patients on haemodialysis: Dose should be given after each dialysis session.

CrCl (ml/min) Dosage Recommendation	
<10	Increase dosing intervals to 48 hrly.
10-39	Increase dosing intervals to 24 hrly.

Reconstitution: Reconstitute powd for oral susp at the time of dispensing by adding the amount of water specified on the container to provide a susp containing 50 mg or 100 mg per 5 mL. Add water in 2 equal parts and shake the bottle vigorously after each addition.

Oral

Skin and soft tissue infections Adult: 200-400 mg 12 hrly.

Child: ≥15 days 4 mg/kg 12 hrly. Max: 200 mg daily.

Renal impairment: Patients on haemodialysis: Dose should be given after each dialysis session.

CrCl (ml/min)	Dosage Recommendation
<10	Increase dosing intervals to 48 hrly.
10-39	Increase dosing intervals to 24 hrly.

Reconstitution: Reconstitute powd for oral susp at the time of dispensing by adding the amount of water specified on the container to provide a susp containing 50 mg or 100 mg per 5 mL. Add water in 2 equal parts and shake the bottle vigorously after each addition.

Oral

Acute otitis media

Child: ≥15 days 4 mg/kg 12 hrly. Max: 200 mg daily.

Renal impairment: Patients on haemodialysis: Dose should be given after each dialysis session.

CrCl (ml/min) Dosage Recommendation	
<10	Increase dosing intervals to 48 hrly.
10-39	Increase dosing intervals to 24 hrly.

Reconstitution: Reconstitute powd for oral susp at the time of dispensing by adding the amount of water specified on the container to provide a susp containing 50 mg or 100 mg per 5 mL. Add water in 2 equal parts and shake the bottle vigorously after each addition.

Oral

Uncomplicated gonorrhoea

Adult: 200 mg as a single dose.

Renal impairment: Patients on haemodialysis: Dose should be given after each dialysis session.

CrCl (ml/min)	Dosage Recommendation	
	Increase dosing intervals to 48 hrly.	
10-39	Increase dosing intervals to 24 hrly.	

Reconstitution: Reconstitute powd for oral susp at the time of dispensing by adding the amount of water specified on the container to provide a susp containing 50 mg or 100 mg per 5 mL. Add water in 2 equal parts and shake the bottle vigorously after each addition.

#### CONTRAINDICATIONS:

Hypersensitivity to cefpodoxime or other cephalosporins.

#### PRECAUTIONS:

Patient w/ history of penicillin allergy. Renal impairment. Childn. Pregnancy and lactation.

Monitoring Parameters Monitor renal function; observe for signs and symptoms of anaphylaxis during 1st dose.

#### INTERACTIONS:

Antacids or H2-blockers may decrease the absorption of cefpodoxime. Reduced renal excretion w/ probenecid

#### ADVERSE REACTIONS:

Diarrhoea, nausea, abdominal pain, vomiting, diaper and skin rash, headache, vag infection. Anxiety, chest pain, cough, decreased appetite, dizziness, dysgeusia, epistaxis, eye pruritus, fatigue, fever, flatulence, flushing, fungal skin infection, hypotension, insomnia, malaise, nightmares, pruritus, purpuric nephritis, tinnitus, weakness, xerostomia, vulvovaginal candidiasis.

Potentially Fatal: Anaphylaxis, Clostridium difficile-associated diarrhoea and colitis.

### 9. CHLORPHENIRAMINE MALEATE 4 mg +CODEINE PHOSPHATE 10 mg Syrup 50 ml bottle SALIENT ACTIONS:

Helps control allergic coughs and mucosal congestion. The mild anticholinergic action of chlorpheniramine maleate may aid in reducing rhinorrhea, and its mild sedative action may also be beneficial to patients whose excessive coughing has caused them to lose sleep. Codeine phosphate is an antitussive that is well recognized not only because of its efficiency and rapidity of action but also because of its relative safety in clinical use. Thus, irritating, nonproductive cough is suppressed by codeine.

#### INDICATIONS & DOSAGE REGIMENS:

Coughs due to colds as well as coughs and congestive symptoms associated with upper respiratory tract infections such as tracheobronchitis or laryngobronchitis, croup, pharyngitis, allergic bronchitis, and infectious bronchitis, when accompanied by disturbing and fatiguing cough

#### PRECAUTIONS:

Use with caution in patients with hypertension, heart disease, asthma, hyperthyroidism, increased intraocular pressure, diabetes mellitus and prostatic hypertrophy

#### INTERACTIONS:

Antihistamines may enhance the effects of tricyclic antidepressants, barbiturates, alcohol and other CNS depressants. MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines

#### ADVERSE DRUG REACTIONS:

Antihistamines may cause sedation, dizziness, diplopia, vomiting, diarrhea, dry mouth, headache, nervousness, nausea, anorexia, heartburn, weakness, polyuria and dysuria and, rarely, excitability in children. Urinary retention may occur in patients with prostatic hypertrophy

### 10. CHLORPHENIRAMINE 2.5 mg + AMMONIUM CHLORIDE 125 mg + SODIUM CITRATE 55 mg Syrup, 100 ml bottle

#### SALIENT ACTIONS:

Chlorpheniramine maleate is an antihistaminic

#### INDICATIONS & DOSAGE REGIMENS:

For relief of coughs and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold. Adults and Children 12 years of age and older: 1 teaspoonful (5 mL) every 4 to 6 hours, not to exceed 6 teaspoonfuls in 24 hours. Children 6 to under 12 years of age: 1/2 teaspoonful (2.5 mL) every 4 to 6 hours, not to exceed 3 teaspoonfuls in 24 hours.

#### CONTRAINDICATIONS:

Patients with hypersensitivity or idiosyncrasy to any of its ingredient ,patients with severe hypertension, severe coronary artery disease and patients on monoamine oxidase (MAO) inhibitor therapy. Antihistamines are contraindicated in patients with narrow angle glaucoma, urinary retention, peptic ulcer and during an asthma attack. Not recommended for use in children under 6 years of age.

#### PRECAUTIONS:

Use with caution in patients with hypertension, heart disease, asthma, hyperthyroidism, increased intraocular pressure, diabetes mellitus and prostatic hypertrophy

#### INTERACTIONS:

Antihistamines may enhance the effects of tricyclic antidepressants, barbiturates, alcohol and other CNS depressants. MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines.

#### ADVERSE DRUG REACTIONS:

Antihistamines may cause sedation, dizziness, diplopia, vomiting, diarrhea, dry mouth, headache, nervousness, nausea, anorexia, heartburn, weakness, polyuria and dysuria and, rarely, excitability in children. Urinary retention may occur in patients with prostatic hypertrophy.

#### 11. COLISTIN SULPHATE 12.5MG SUSP

#### SALIENT ACTIONS:

Colistin is a polymyxin antibiotic which is active against aerobic gram-ve bacteria including most enterobacteria except Proteus, Providentia and Serratia. Susceptible organisms include P. aeruginosa, Legionella spp, H. influenzae, Acinetobacter, V. cholera, Salmonella, Shigella and Pasteurella. It acts as a cationic detergent that causes leaking of intracellular substances and cell death by damaging the bacterial cytoplasmic membrane.

#### INDICATIONS & DOSAGE:

Oral

Bowel sterilisation

Adult: As colistin sulfate: 1.5-3 MIU tid.

Child: As colistin sulfate: <15 kg: Not suitable; 15-30 kg: 0.75-1.5 MIU tid.

Oral

Gastrointestinal infections

Adult: As colistin sulfate: 1.5-3 MIU tid.

Child: As colistin sulfate: <15 kg: Not suitable; 15-30 kg: 0.75-1.5 MIU tid.

CONTRAINDICATIONS:

Hypersensitivity. Myasthenia gravis.

#### PRECAUTIONS:

Patients w/ renal impairment, porphyria. Pregnancy and lactation. Patient Counselling Due to neurologic disturbances that may occur, if affected, do not drive or operate machinery. Monitoring Parameters Monitor serum creatinine and BUN regularly while on treatment.

#### INTERACTIONS:

Potentiates action of curariform muscle relaxants. Increased nephrotoxicity w/ aminoglycosides, amphotericin B, capreomycin, vancomycin.

#### ADVERSE REACTIONS:

Superinfection; renal damage; visual disturbances; GI disturbances, dizziness, nausea, vomiting; confusion, peripheral neuropathy; respiratory insufficiency and muscle weakness.

Potentially Fatal: Severe colitis.

### 12. DICYCLOMINE HYDROCHLORIDE 10 mg +ACTIVATED DIMETHICONE 40 mg Pediatric drop SALIENT ACTIONS:

Smooth muscle relaxant ,action exerted by inhibition of parasympathetic innervations &reduction of secretion of motility of stomach & intestine .

#### INDICATIONS:

GI spasm, irritable bowel syndrome, hyper peristalsis, peptic ulcer, fltulence, diarrhea.

#### DOSAGE REGIMENS:

Adult :20 mg 2-3 times daily. Children :2.5-5 ml 2-3 times daily.

#### **CONTRAINDICATIONS:**

Infant under 6 month, closed angle glaucoma

#### PRECAUTIONS:

Urinary retentation, prostatic enlargement, tachycardia, cardiac insuffiency, paralytic ileus, ulcerative colitis pyloric stenosis.

#### INTERACTIONS:

enhance effect of antichlinergic,

Hydrochlorthiade decreased excretion

#### ADVERSE EFFECTS:

Dry mouth ,thrist,dizziness ,atonic constipation.

#### 13. DIGESTIVE ENZYME LIQUID

#### SALIENT ACTIONS:

Digestive enzymes improves the patient's condition by Breaking the larger proteins into smaller one, Improving nutrition absorption and utilization.

#### INDICATIONS & DOSAGE:

Aid in digestion & as an adjunct in the treatment of digestive enzyme deficiency.

#### CONTRAINDICATIONS:

Crohn's disease, Formation of fibrous tissue in the colon, Gout, High amount of uric acid in the blood,

Hypersensitivity, Inadequate absorption of nutrients due to short bowel

#### PRECAUTIONS:

Pregnancy, Children.

#### INTERACTIONS:

NA

#### ADVERSE REACTIONS:

GI irritation.

### 14. DIPHENHYDRAMINEHCL 14.08 mg + AMMONIUM CHLORIDE 0.138 gm + SODIUM CITRATE 57.03 mg +MENTHOL 1.14 mg Svrup, 100 ml bottle

#### SALIENT ACTIONS:

Expectorant and Antihistaminic. Diphenhydramine Hydrochloride, which has central sedative, local anaesthetic, spasmolytic and anti-cholinergic (diminishes upper respiratory tract secretions) properties, in addition to its main antihistaminic actions. high ammonium chloride content provides an effective expectorant action reducing the viscosity of the mucous, which can then act as a demulcent, thereby protecting inflamed and irritated surfaces and inducing a productive cough which is less exhausting and less painful to the patient.

#### INDICATIONS:

Control of dry, unproductive cough, and in the alleviation of nasal and bronchial congestion.

#### DOSAGE REGIMENS:

Adults: Two 5 mL medicine measures.

Children: 12 years: One and a half 5 mL medicine measures. 7 years: One 5 mL medicine measure.

1 year: Half a 5 mL medicine measure

#### CONTRA-INDICATIONS:

The drug is contra-indicated in epileptics

#### PRECAUTIONS:

Lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents. Patients undergoing treatment with this drug should not take charge of vehicles, other means of transport, or machinery where loss of attention may lead to accidents.

#### ADVERSE EFFECTS:

Drowsiness, dizziness and dry mouth

#### 15. DISODIUM HYDROGEN CITRATE Syrup 1.35 gm, 100 ml bottle

#### SALIENT ACTIONS & INDICATIONS:

Is a sodium acid salt of citric acid (sodium citrate). It is used as an antioxidant in food as well as to improve the effects of other antioxidants. It is also used as an acidity regulator and sequestrant.

Typical products include gelatin, jam, sweets, ice cream, carbonated beverages, milk powder, wine, and processed cheeses.

#### PRECAUTIONS:

Hypoventilatory states hypocalcemia, alkalosis, renal disease, neonates.

#### INTERACTIONS:

May increase T ½ of basic drugs like quinidine, amphetamines, ephedrine & pseudoephedrine. Reduces nephrotoxicity caused by methrotrexate. Enhances elimination of salicylates & barbiturates. Additive effect with na retention caused bu corticosteroids. Potentiates renal excretion of tetracyclines. Hypochloraemia alkalosis may occur if used in conjuction with pottasium-depleting dieurities.

#### ADVERSE EFFECTS:

Stomach cramps & flatulance. Overdosage or too rapid adin can cause metabolic alkalosis (especially in renal impairment)

#### 16. FERROUS ASCORBATE SYRUP

#### SALIENT ACTIONS:

This medication is an iron supplement used to treat or prevent low blood levels of iron (e.g., for anemia or during pregnancy). Ascorbic acid (vitamin C) improves the absorption of iron from the stomach

#### INDICATIONS:

This medication is an iron supplement used to treat or prevent low blood levels of iron (e.g., for anemia or during pregnancy). Ascorbic acid (vitamin C) improves the absorption of iron from the stomach.

#### DOSAGE REGIMENS:

#### Usual Adult Dose for Iron Deficiency Anemia

Initial dose: 360 mg/day ferrous fumarate (120 mg/day elemental iron) for 3 months

-Give in divided doses (1 to 3 times daily)

#### Usual Adult Dose for Anemia Associated with Chronic Renal Failure

Initial dose: 600 mg/day ferrous fumarate (200 mg/day elemental iron) orally in divided doses (1 to 3 times daily)

#### Comments:

-If goals are not met with oral iron after 1 to 3 months, consider IV iron supplementation.

-Smaller daily doses may be better tolerated.

#### CONTRAINDICATIONS:

Ferrous ascorbate is contraindicated in patients with **haemolytic** anemia, hemochromatosis, hemosiderosis and other iron overload disorders. Hematinic may aggravate regional enteritis, peptic ulcer and ulcerative colitis. Ferrous ascorbate is contraindicated in patients with supplemental iron hypersensitivity.

#### PRECAUTIONS:

-Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6.

-Keep out of reach of children.

#### INTERACTIONS:

It can decrease the absorption of other drugs such as bisphosphonates (for example, alendronate), levodopa, penicillamine, quinolone antibiotics (for

example, ciprofloxacin, levofloxacin), thyroidmedications (for example, levothyroxine),

and tetracycline antibiotics (for example, doxycycline, minocycline). Therefore, separate your doses of these medications as far as possible from your doses of this product.

#### ADVERSE EFFECTS:

Constipation, diarrhea, or upset stomach may occur. These effects are usually temporary and may disappear as your body adjusts to this medication.

#### 17. FEXOFENADINE HCL( SUSP 100ML)

#### SALIENT ACTIONS:

Fexofenadine is an antihistamine that reduces the effects of natural chemical histamine in the body. Histamine can produce symptoms of sneezing, itching, watery eyes, and runny nose.

#### INDICATIONS:

Allergic rhinitis (seasonal). Chronic idiopathic urticaria.

#### **DOSAGE REGIMENS:**

10mL every 12 hours; max 20mL/24hrs.

Children:

<2yrs: not recommended. ≥2yrs: 5mL every 12 hours; max 10mL/24hrs.</p>

#### CONTRAINDICATIONS:

concomitant aluminum- or magnesium-containing antacids.

#### PRECAUTIONS:

Pregnancy (Cat.C). Nursing mothers.

#### INTERACTIONS:

Avoid concomitant aluminum- or magnesium-containing antacids.

#### ADVERSE EFFECTS:

Adults: Headache, back pain, viral infection, GI upset, sinusitis, dizziness, drowsiness.

Children: cough, fever, pain, otitis media, upper respiratory tract infection.

#### 18. HYDROXYZINE HCL 10MG /5ML SYRUP

#### SALIENT ACTIONS:

#### INDICATIONS:

Allergic pruritus.

#### DOSAGE REGIMENS:

Adult:

25 mg 3-4 times daily.

Children:

<6yrs: 50mg daily. ≥6yrs: 50–100mg daily. Both in divided doses.

#### CONTRAINDICATIONS:

Early pregnancy. Allergy to cetirizine or levocetirizine.

#### PRECAUTIONS:

Elderly. Nursing mothers: not recommended.

#### INTERACTIONS:

Potentiates CNS depression with alcohol, other CNS depressants (eg, narcotics, non-narcotic analgesics, barbiturates); reduce dose of these agents.

#### ADVERSE EFFECTS:

Drowsiness, dry mouth, tremor, convulsions.

#### 19. IBUPROFEN 100MG/5ML ORAL SUSUPENSION

#### SALIENT ACTIONS:

#### INDICATIONS:

Ibuprofen 100 mg / 5 ml Oral Suspension is indicated for its analgesic and anti-inflammatory effects in the treatment of dysmenorrhoea, neuralgia, post-operative pain, rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), ankylosing spondylitis, osteoarthritis and other non-rheumatoid (seronegative) arthropathies.

#### DOSAGE REGIMENS:

#### Adults, the elderly and children over 12 years:

The recommended dose is 200mg-400mg (10-20ml), up to three times a day as required.

Leave at least four hours between doses and do not take more than 1200mg (60ml) in any 24 hour period.

#### Children:

For pain and fever - 20mg/kg/day in divided doses (including OTC use).

Infants 3-6 months

weighing more than 5 kg:

One 2.5 ml dose may be taken 3 times in 24 hours. Do not use for more than 24 hours

Infants 6 months-1 year:

2.5ml three to four times a day.

Children 1-4 years:

5ml three times a day

Children 4-7 years:

7.5ml three times a day

Children 7-12 years:

10ml three times a day.

Post-immunisation fever: 2.5ml (50mg) followed by one further dose of 2.5ml (50mg) six hours later if necessary. No more than 2 doses in 24 hours. If fever is not reduced, consult a doctor.

For Juvenile Rheumatoid Arthritis (prescription only use): Doses up to 30-40mg/kg/day may be taken in three or four divided doses.

Elderly: No special dosage modifications are required unless renal or hepatic function is impaired, in which case dosage should be assessed individually.

Do not give to children under 3 months of age.

For infants aged 3 - 5 months medical advice should be sought if symptoms worsen or not later than 24 hours if symptoms persist.

#### CONTRAINDICATIONS:

Hypersensitivity to ibuprofen or any of the constituents in the product.

Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema or urticaria) in response to aspirin or other non-steroidal anti-inflammatory drugs.

Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding)

History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.

#### PRECAUTIONS:

The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal.

Systemic lupus erythematosus and mixed connective tissue disease – increased risk of aseptic meningitis (see section 4.8 Undesirable effects).

Renal impairment as renal function may further deteriorate

#### INTERACTIONS:

Anticoagulants: NSAIDs may enhance the effects of anticoagulants, such as warfarin.

Antihypertensives and diuretics: NSAIDs may diminish the effect of these drugs. Diuretic can increase risk of nephrotoxicity of NSAIDs.

Corticosteroids: increased risk of gastrointestinal ulceration or bleeding.

Anti-platelets agents and selective serotonin reuptake inhibitors (SSRIs): Increased risk of gastrointestinal bleeding

#### ADVERSE EFFECTS:

Gastrointestinal:

The most commonly-adverse events are gastrointestinal in nature.

Uncommon: Abdominal pain, nausea and dyspepsia.

Rare: Diarrhoea, flatulence, constipation and vomiting.

Hypersensitivity reactions

#### 20. IBUPROFEN 100 mg + PARACETAMOL 125 mg Syrup, 60 ml bottle

#### SALIENT ACTIOS & INDICATIONS:

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). Fever, pain and inflammation associated with musculoskeletal and joint disorders

#### DOSAGE REGIMENS:

Based on per Kg body Wt decided by pediatrician

#### CONTRAINDICATIONS:

Active peptic ulcer, history of hypersensitivity to either component, recent GI bleeding, neonates

#### PRECAUTIONS:

Bronchial asthma, renal or hepatic disorders, bleeding disorders, CV diseases, hypertension, patients on anticoagulants, aspirin/NSAIDs induced allergy, pregnancy & lactation

#### INTERACTIONS:

Ibuprofen antagonises the effects of furosemide & thiazides. Pethidine & propanthelene reduce absorption of paracetamol. Aspirin displaces ibuprofen from binding sites. NSAIDs blunt the effects of antihypertensives. *Potentially Fatal:* Increased risk of GI ulceration & bleeding with anticoagulants. Paracetamol increases the risk of liver damage in chronic alcoholics. Ibuprofen increases the risk of methotrexate toxicity & lithium toxicity ADVERSE DRUG REACTIONS:

Dyspepsia, heart burn, GI bleeding, rash, asthmatic attacks, thrombocytopenia, drug induced ulcer, drowsiness, hepatic necrosis, renal papillary necrosis, vision disturbances & disorientation; rarely nausea & vomiting can occur. *Potentially Fatal:* Hematemesis, agranulocytosis, severe allergic reaction

#### 21. IRON HYDROXIDE POLYMALTOSE Syrup 200 ml bottle

#### INDICATIONS & DOSAGE REGIMENS:

Iron-deficiency anaemia. 200 mg elemental iron divided in three doses. 30 mg elemental iron per day for prophylaxis

#### CONTRAINDICATIONS:

Hypersensitivity or intolerance to iron and overloading of iron in the body. Anaemia not caused by iron deficiency. Disturbances in iron utilisation, thalassemia. Patients receiving repeated blood transfusion, decompensated liver cirrhosis. Pregnancy (1st trimester)

#### PRECAUTIONS:

Avoid concomitant parenteral and oral iron admin, oral iron therapy should start at least 1 wk after last iron inj. Parenteral: Pregnancy (2nd and 3rd trimester), allergies, hepatic and liver insufficiency, low iron binding capacity and or folic acid deficiency.

#### ADVERSE EFFECTS:

Gl irritation, epigastric pain, stomach cramping, constipation, nausea, vomiting, diarrhoea, dark stools, heart burn, discoloured urine, teeth staining.

#### INTERACTIONS:

Concurrent use with psychotropic drugs may worsen constipation. Increased systemic side effects with concomitant ACE inhibitors and parenteral iron admin

#### 22. IRON PREPRATION (VITCOFOL SUSP)

#### SALIENT ACTIONS:

iron (III) hydroxide polymaltose complex 50 mg, folic acid 0.5 mg/5 mL.

#### INDICATIONS:

Recommended in the treatment of iron deficiency anemia.

#### DOSAGE REGIMENS:

Child 2-12 vrs: 5 ml od

#### CONTRAINDICATIONS:

N/A

#### PRECAUTIONS:

N/A

#### INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

- Itching
- Dark or green stools
- Constipation
- Diarrhea
- · Loss of appetite
- Nausea

#### 23. IVERMECTIN 12MG SUSPENTION

#### SALIENT ACTIONS:

Ivermectin binds selectively and with high affinity to glutamate-gated chloride ion channels in invertebrate muscle and nerve cells of the microfilaria. This binding causes an increase in the permeability of the cell membrane to chloride ions and results in hyperpolarization of the cell, leading to paralysis and death of the parasite.

#### INDICATIONS & DOSAGE REGIMENS:

dult: PO Onchocerciasis ≥15 kg: 150 mcg/kg as a single dose 6-12 mthly until adult worms die. Strongyloidiasis 200 mcg/kg as a single dose for 1-2 days. Filariasis Mansonella streptocerca Single dose of 150 mcg/kg; Mansonella ozzardi Single dose of 200 mcg/kg. Ascariasis Ascaris lumbricoidesSingle dose of 150-200 mcg/kg. Gnathostomiasis Gnathostoma spinigerum: 200 mcg/kg once daily for 2 days. Scabies Sarcoptes scabiei 200 mcg/kg as a single dose, repeat dose in 2 wk.

#### CONTRAINDICATIONS:

Hypersensitivity. Pregnancy and lactation. Childn <15 kg body weight.

#### PRECAUTIONS:

Concurrent Loa loa infection, impaired blood-brain barrier function due to infection.

#### INTERACTIONS:

Bioavailability may be increased by alcohol, levamisole.

#### ADVERSE EFFECTS:

Diarrhoea, nausea, vomiting, dizziness, pruritus, urticaria, rash, arthralgia, fever, myalgia, asthenia, postural hypotension, tachycardia, oedema, lymphadenopathy, sore throat, cough, headache, somnolence, transient eosinophilia, raised liver enzyme values.

#### 24. KETOCONAZOLE SYRUP

#### SALIENT ACTIONS: antifungal

#### INDICATIONS:

Indicated for the treatment of the following systemic fungal infections in patients who have failed or who are intolerant to other therapies: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis

#### DOSAGE REGIMENS:

Adult: PO Fungal infections 200 mg once daily, up to 400 mg once daily if needed

#### CONTRAINDICATIONS:

Hypersensitivity; preexisting liver disease. Concurrent use w/ CYP3A4 substrates e.g. HMG-CoA reductase inhibitors (e.g. lovastatin, simvastatin), midazolam, triazolam, cisapride, dofetilide, eplerenone, nisoldipine, pimozide, quinidine, terfenadine, astemizole, ergot alkaloids (e.g. ergotamine, dihydriergotamine).

#### PRECAUTIONS:

Predisposition to adrenocortical insufficiency. Admin w/ acidic drink in patients w/ achlorhydria. Pregnancy. Iactation. Monitoring Parameters Assess liver status prior to therapy and monitor serum ALT during treatment. Discontinue if there is persistent or worsening of liver enzyme elevation. Monitor adrenal function in patients w/ adrenal insufficiency or w/ borderline adrenal function and in patients under prolonged periods of stress (e.g. major surgery, intensive care).

#### INTERACTIONS:

Reduced absorption w/ antimuscarinics, antacids, H<sub>2</sub>-blockers, PPIs, sucralfate. Reduced plasma concentrations w/ rifampicin, isoniazid, efavirenz, nevirapine, phenytoin. May also reduce concentrations of isoniazid and rifampicin. May reduce efficacy of oral contraceptives. May increase serum levels of CYP3A4 substrates e.g. digoxin, oral anticoagulants, sildenafil, tacrolimus.

Potentially Fatal: May potentiate and prolong sedative and hypnotic effects of midazolam and triazolam. Increased plasma levels and prolonged QT intervals of astemizole, cisapride, dofetilide, pimozide, quinidine and terfenadine which may lead to torsade de pointes. Increased risk of myopathy w/ HMG-CoA reductase inhibitors (e.g. lovastatin, simvastatin). Markedly increased plasma levels of nisoldipine. Increased risk of hyperkalaemia and hypotension w/ eplerenone. Increased risk of vasospasm potentially leading to cerebral ischaemia w/ ergot alkaloids (e.g. ergotamine, dihydroergotamine).

#### ADVERSE EFFECTS:

Adrenal insufficiency; GI disturbances (e.g. abdominal pain, nausea, vomiting); rash, irritation, dermatitis, burning sensation, pruritus, urticaria, angioedema, anaphylaxis; alopecia, headache, dizziness, somnolence, fever and chills; thrombocytopenia, paraesthesia; menstrual irregularities, oligospermia, adrenal cortex supression, gynaecomastia, impotence; raised intracranial pressure; photophobia, photosensitivity; asymptomatic, transient elevations in LFTs.

Potentially Fatal: Hepatotoxicity.

### 25. LACTULOSE Syrup 10 gm / 15 ml, 100 ml bottle INDICATIONS & DOSAGE REGIMENS:

Constipation: Adult: Initially, 10-20 g (15-30 ml) daily as a single dose or in 2 divided doses; gradually adjust according to patient's response. Max dose: 45 ml (or up to 40 g of the reconstituted oral powder formulation)/day. Child: As 3.35 mg/5 ml solution: 1 mth to 1 yr: 2.5 ml; 1-5 yr: 5 ml; 5-10 yr: 10 ml; 10-18 yr: 15 ml. All doses to be given bid.

**Hepatic encephalopathy:** *Adult:* 60-100 g (90-150 ml) daily in 3 divided doses; adjust to produce 2 or 3 soft stools each day. *Rectal:* Mix 200 g (300 ml) with 700 ml water or 0.9% sodium chloride as a retention enema. Retain enema for 30-60 minutes; repeat every 4-6 hr until oral medication can be administered

#### PRECAUTIONS:

Monitor electrolyte imbalance.

#### INTERACTIONS:

Prevent release of mesalazine in the colon. Decreased effect with oral neomycin, antacids.

#### ADVERSE DRUG REACTIONS:

Diarrhoea (dose-related), nausea, vomiting, hypokalaemia, bloating and abdominal cramps. *Potentially Fatal:* Dehydration and hypernatraemia on aggressive treatment.

#### 26. LEVETIRACETAM 100MG SOLUTION

#### SALIENT ACTIONS:

The exact mechanism by which levetiracetam acts to treat epilepsy is unknown. However, the drug binds to a synaptic vesicle glycoprotein, <u>SV2A</u>, <sup>[26]</sup> and inhibits presynaptic calcium channels <sup>[27]</sup> reducing neurotransmitter release and acting as a neuromodulator. This is believed to impede impulse conduction across synapses.

#### INDICATIONS:

- 1) Partial Onset Seizures
- 2) Myoclonic Seizures in Patients with Juvenile Myoclonic Epilepsy
- 3) Primary Generalized Tonic-Clonic Seizures

#### DOSAGE REGIMENS:

#### Dosing for Partial Onset Seizures:

#### Adults 16 Years and Older

Initiate treatment with a daily dose of 1000 mg/day, given as twice-daily dosing (500 mg twice daily). Additional dosing increments may be given (1000 mg/day additional every 2 weeks) to a maximum, recommended daily dose of 3000 mg. There is no evidence that doses greater than 3000 mg/day confer additional benefit.

#### **Pediatric Patients**

#### I Month to < 6 Months

Initiate treatment with a daily dose of 14 mg/kg in 2 divided doses (7 mg/kg twice daily). Increase the daily dose every 2 weeks by increments of 14 mg/kg to the recommended daily dose of 42 mg/kg (21 mg/kg twice

daily). In the clinical trial, the mean daily dose was 35 mg/kg in this age group. The effectiveness of lower doses has not been studied.

6 Months to < 4 Years:

Initiate treatment with a daily dose of 20 mg/kg in 2 divided doses (10 mg/kg twice daily). Increase the daily dose in 2 weeks by an increment of 20 mg/kg to the recommended daily dose of 50 mg/kg (25 mg/kg twice daily). If a patient cannot tolerate a daily dose of 50 mg/kg, the daily dose may be reduced. In the clinical trial, the mean daily dose was 47 mg/kg in this age group.

4 Years to < 16 Years

Initiate treatment with a daily dose of 20 mg/kg in 2 divided doses (10 mg/kg twice daily). Increase the daily dose every 2 weeks by increments of 20 mg/kg to the recommended daily dose of 60 mg/kg (30 mg/kg twice daily). If a patient cannot tolerate a daily dose of 60 mg/kg, the daily dose may be reduced. In the clinical trial, the mean daily dose was 44 mg/kg. The maximum daily dose was 3000 mg/day.

For Levetiracetam tablet dosing in pediatric patients weighing 20 to 40 kg, initiate treatment with a daily dose of 500 mg given as twice daily dosing (250 mg twice daily). Increase the daily dose every 2 weeks by increments of 500 mg to a maximum recommended daily dose of 1500 mg (750 mg twice daily).

For Levetiracetam tablet dosing in pediatric patients weighing more than 40 kg, initiate treatment with a daily dose of 1000 mg/day given as twice daily dosing (500 mg twice daily). Increase the daily dose every 2 weeks by increments of 1000 mg/day to a maximum recommended daily dose of 3000 mg (1500 mg twice daily).

Levetiracetam Oral Solution Weight-Based Dosing Calculation For Pediatric Patients

The following calculation should be used to determine the appropriate daily dose of oral solution for pediatric patients:

Total daily dose (mL/day) = Daily dose (mg/kg/day) x patient weight (kg)

100 mg/mL

Dosing for Myoclonic Seizures in Patients 12 Years of Age and Older with Juvenile Myoclonic Epilepsy Initiate treatment with a dose of 1000 mg/day, given as twice-daily dosing (500 mg twice daily). Increase the dosage by 1000 mg/day every 2 weeks to the recommended daily dose of 3000 mg. The effectiveness of doses lower than 3000 mg/day has not been studied.

Dosing for Primary Generalized Tonic-Clonic Seizures

Adults 16 Years and Older

Initiate treatment with a dose of 1000 mg/day, given as twice-daily dosing (500 mg twice daily). Increase dosage by 1000 mg/day every 2 weeks to the recommended daily dose of 3000 mg. The effectiveness of doses lower than 3000 mg/day has not been adequately studied.

Pediatric Patients Ages 6 to <16 Years

Initiate treatment with a daily dose of 20 mg/kg in 2 divided doses (10 mg/kg twice daily). Increase the daily dose every 2 weeks by increments of 20 mg/kg to the recommended daily dose of 60 mg/kg (30 mg/kg twice daily). The effectiveness of doses lower than 60 mg/kg/day has not been adequately studied. Patients with body weight ≤20 kg should be dosed with oral solution. Patients with body weight above 20 kg can be dosed with either tablets or oral solution .Only whole tablets should be administered.

Dosage Adjustments in Adult Patients with Renal Impairment

Levetiracetam dosing must be individualized according to the patient's renal function status. Recommended dosage adjustments for adults are shown in Table 1. In order to calculate the dose recommended for patients with renal impairment, creatinine clearance adjusted for body surface area must be calculated. To do this an estimate of the patient's creatinine clearance (CLcr) in mL/min must first be calculated using the following formula:

[140-age (years)] x weight (kg) (x 0.85 for female patients) CLcr = 72 x serum creatinine (mg/dL) Then CLer is adjusted for body surface area (BSA) as follows: BSA subject (m 2)

CONTRAINDICATIONS:

Levetiracetam tablets are contraindicated in patients with a hypersensitivity to Levetiracetam. Reactions have included anaphylaxis and angioedema.

PRECAUTIONS AND ADVERSE EFFECTS:

#### Behavioral Abnormalities and Psychotic Symptoms

Levetiracetam may cause behavioral abnormalities and psychotic symptoms. Patients treated with Levetiracetam should be monitored for psychiatric signs and symptoms.

#### Suicidal Behavior and Ideation

Antiepileptic drugs (AEDs), including Levetiracetam, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

#### Somnolence and Fatigue

Levetiracetam may cause somnolence and fatigue. Patients should be monitored for these signs and symptoms Anaphylaxis and Angioedema

Levetiracetam can cause anaphylaxis or angioedema after the first dose or at any time during treatment.

#### Serious Dermatological Reactions

Serious dermatological reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in both pediatric and adult pat Coordination Difficulties Levetiracetam may cause coordination difficulties.

#### Withdrawal Seizures

Antiepileptic drugs, including Levetiracetam, should be withdrawn gradually to minimize the potential of increased seizure frequency.

#### Hematologic Abnormalities

Levetiracetam can cause hematologic abnormalities. Hematologic abnormalities occurred in clinical trials and included decreases in red blood cell (RBC) counts, hemoglobin, and hematocrit, and increases in eosinophil counts. Decreased white blood cell (WBC) and neutrophil counts also occurred in clinical trials.

#### **Blood Pressure Increases**

#### INTERACTIONS:

No significant pharmacokinetic interactions were observed between levetiracetam or its major metabolite and concomitant medications via human liver cytochrome P450 isoforms, epoxide hydrolase, UDP-glucuronidation enzymes, P-glycoprotein, or renal tubular secretion.

#### 27. LEVOCETRIZINE DIHYDROCHLORIDE SYRUP

#### SALIENT ACTIONS:

Levocetirizine is an active isomer of cetirizine which selectively competes w/ histamine for  $H_1$ -receptor sites on effector cells in the GI tract, blood vessels and resp tract.

#### INDICATIONS:

#### Seasonal allergic rhinitis

Chronic idiopathic urticaria

#### DOSAGE REGIMENS:

2.5-5 mg once daily in the evening.

#### CONTRAINDICATIONS:

End-stage renal disease (CrCl <10 mL/min) or undergoing haemodialysis. Childn (6 mth to 11 yr) w/ renal impairment.

#### PRECAUTIONS:

Epileptic patients and patients at risk of convulsions. Renal impairment. Pregnancy and lactation. *Patient Counselling* May impair ability to drive or operate machinery. *Monitoring Parameters* Monitor CrCl prior to treatment for dosage adjustment.

#### INTERACTIONS:

Possible additive adverse CNS effects w/ CNS depressants (e.g. sedatives, tranquilizers).

#### ADVERSE EFFECTS:

Somnolence, dizziness, fatigue, dry mouth, pharyngitis, pyrexia, cough, epistaxis, nasopharyngitis, diarrhoea, vomiting, constipation, otitis media, dysuria, urinary retention, blurred vision, angioedema, paraesthesia, dystonia, oculogyric crisis, myoclonus, extrapyramidal symptoms.

### 28. LIGNOCAINE HCL ORAL TOPICAL SOLUTION

#### SALIENT ACTIONS:

Lidocaine is an amide type local anaesthetic. It stabilises the neuronal membrane and inhibits sodium ion thovements, which are necessary for conduction of impulses. In the heart, lidocaine reduces phase 4

depolarization and automaticity. Duration of action potential and effective refractory period are also reduced. INDICATION & DOSAGEREGIMENS:

**Surface anaesthesia:**For pain: 300 mg (15 ml) of 2% solution rinsed and ejected for mouth and throat pain; or gargled and swallowed if necessary for pharyngeal pain. Not to be used more frequently than every 3 hr. Max. (topical oral solution): 2.4 g/day. Before bronchoscopy, bronchography, laryngoscopy, oesophagoscopy, endotracheal intubation, and biopsy in the mouth and throat: 40-300 mg (1-7.5 ml) of 4% solution. For dentistry and otorhinolaryngology procedures: 10-50 mg of 10% solution sprayed to mucous membrane. *Adult:* As 2% gel: Female: 60-100 mg inserted into the urethra several minutes before examination. Male: 100-200 mg before catheterisation and 600 mg before sounding or cystoscopy.

CONTRAINDICATIONS: contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type or to other components of the solution.

#### PRECAUTIONS:

When topical anesthetics are used in the mouth or throat, the patient should be aware that the production of topical anesthesia may impair swallowing and thus enhance the danger of aspiration. For this reason, food should not be ingested for 60 minutes following use of local anesthetic preparations in the mouth or throat area. This is particularly important in children because of their frequency of eating.

Numbness of the tongue or buccal mucosa may increase the danger of biting trauma. For this reason food and/or chewing gum should not be used while the mouth or throat area is anesthetized.

PATIENTS SHOULD BE INSTRUCTED TO STRICTLY ADHERE TO DOSING INSTRUCTIONS, AND TO KEEP THE SUPPLY OF MEDICATION OUT OF THE REACH OF CHILDREN.

#### ADVERSE DRUG REACTIONS:

Dizziness, paraesthesia, drowsiness, confusion, respiratory depression and convulsions. *Potentially Fatal:* Hypotension and bradycardia leading to cardiac arrest; anaphylaxis.

#### 29. MEBENDAZOLE SUSP 100 MG

#### SALIENT ACTIONS:

Mebendazole is thought to work by selectively inhibiting the synthesis of microtubules in parasitic worms, and by destroying extant cytoplasmic microtubules in their intestinal cells, thereby blocking the uptake of glucose and other nutrients, resulting in the gradual immobilization and eventual death of the helminths

#### INDICATIONS:

Mebendazole is a highly effective, broad-spectrum <u>antihelmintic</u> indicated for the treatment of <u>nematode</u> infestations, including roundworm, hookworm, whipworm, threadworm, pinworm, and the intestinal form of <u>trichinosis</u> prior to its spread into the tissues beyond the digestive tract. Other drugs are used to treat worm infections outside the digestive tract, as mebendazole is poorly absorbed into the bloodstream. Mebendazole is used alone in those with mild to moderate infestations.

It is also used rarely in the treatment of hydatid disease. Evidence for effectiveness for this disease, however, is poor. Mebendazole and other benzimidazole antithelmetics are active against both larval and adult stages of nematodes, and in the cases of roundworm and whipworm, kill the eggs, as well. Paralysis and death of the parasites occurs slowly, and elimination in the feces may require several days.

#### DOSAGE REGIMENS:

#### Usual Adult Dose for Angiostrongylosis

100 mg orally twice a day for 5 days.

#### Usual Adult Dose for Ascariasis

100 mg orally twice a day for 3 days. If biliary obstruction is also present, piperazine citrate 150 mg/kg initially, followed by 65 mg/kg every 12 hours for 6 doses by nasogastric tube is also recommended.

#### Usual Adult Dose for Capillariasis

200 mg orally twice a day for 20 days. Relapses may be treated with prolonged courses of therapy.

#### Usual Adult Dose for Trichostrongylosis

100 mg orally twice a day for 3 days.

#### **Usual Adult Dose for Filariasis**

100 mg orally one time. This dose should be repeated in 2 weeks. All family members and close contacts should also be examined.

Mansonella perstans infection - 100 mg twice daily for 30 days.

#### Usual Adult Dose for Hookworm Infection (Necator or Ancylostoma)

100 mg orally twice a day for 3 days.

Usual Adult Dose for Whipworm Infection (Trichuris trichiura)

100 mg orally twice a day for 3 days.

#### Usual Adult Dose for Pinworm Infection (Enterobius vermicularis)

100 mg orally one time. This dose should be repeated in 2 weeks. All family members and close contacts should also be examined.

#### Usual Adult Dose for Trichinosis

200 to 400 mg orally three times a day for 3 days, then 400 to 500 mg three times a day for 10 days.

Concomitant steroid therapy may be administered if patient is symptomatic.

#### Usual Adult Dose for Visceral Larva Migrans (Toxicariasis)

100 to 200 mg orally twice daily for 5 days. Coadministration of anti-inflammatory agents might be considered.

#### Usual Adult Dose for Echinococcus Infection

Case Series (n=769)

Hepatic Cystic infection - Larval (tissue stage): 40 to 50 mg/kg per day, administered in three divided doses, in conjunction with percutaneous aspiration-injection-reaspiration (PAIR) drainage, 1 week before and 4 weeks after PAIR drainage.

#### Usual Adult Dose for Hydatid Disease

Case Series (n=769)

Hepatic Cystic infection - Larval (tissue stage): 40 to 50 mg/kg per day, administered in three divided doses, in conjunction with percutaneous aspiration-injection-reaspiration (PAIR) drainage, 1 week before and 4 weeks after PAIR drainage.

#### Usual Adult Dose for Dracunculiasis

400 to 800 mg per day for 6 days.

#### Usual Pediatric Dose for Angiostrongylosis

Greater than or equal to 2 years: 100 mg orally twice a day for 5 days.

#### Usual Pediatric Dose for Ascariasis

Greater than or equal to 2 years: 100 mg orally twice a day for 3 days. If biliary obstruction is also present, piperazine citrate 150 mg/kg initially, followed by 65 mg/kg every 12 hours for 6 doses by nasogastric tube is also recommended.

#### Usual Pediatric Dose for Capillariasis

Greater than or equal to 2 years: 200 mg orally twice a day for 20 days. Relapses may be treated with prolonged courses of therapy.

#### **Usual Pediatric Dose for Filariasis**

Greater than or equal to 2 years: 100 mg orally one time. This dose should be repeated in 2 weeks. All family members and close contacts should also be examined.

Mansonella perstans infection - 100 mg twice daily for 30 days.

#### Usual Pediatric Dose for Hookworm Infection (Necator or Ancylostoma)

Greater than or equal to 2 years: 100 mg orally twice a day for 3 days.

Usual Pediatric Dose for Whipworm Infection (Trichuris trichiura)

Greater than or equal to 2 years: 100 mg orally twice a day for 3 days.

#### Usual Pediatric Dose for Pinworm Infection (Enterobius vermicularis)

Greater than or equal to 2 years: 100 mg orally one time. This dose should be repeated in 2 weeks. All family members and close contacts should also be examined.

#### **Usual Pediatric Dose for Trichinosis**

Greater than or equal to 2 years: 200 to 400 mg orally three times daily for 3 days, then 400 to 500 mg three times daily for 10 days. Steroids may be administered if patient is symptomatic.

#### Trichinella nativa infection:

1 to 14 years: 200 mg orally three times daily for the first 3 days, then 400 mg orally three times daily for another 11 days. Concomitant steroid therapy may be administered if patient is symptomatic.

#### Usual Pediatric Dose for Visceral Larva Migrans (Toxicariasis)

Greater than or equal to 2 years: 100 to 200 mg orally twice daily for 5 days. Coadministration of antiinflammatory agents might be considered.

#### PRECAUTIONS:

Neutropenia and agranulocytosis have been rarely reported with prolonged administration of mebendazole and at dosages substantially above those recommended.

The manufacturer recommends periodic assessment of organ system functions, including hematopoietic and hepatic, during prolonged mebendazole therapy.

There is no evidence that mebendazole, even at high doses, is effective for hydatid disease. The safety of mebendazole in children younger than 2 years has not been established.

#### ADVERSE EFFECTS:

Rare

Black, tarry stools

chills

convulsions

cough or hoarseness

dark urine

fever with or without chills

general feeling of tiredness or weakness

hives or welts, itching, or skin rash

large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or sex organs

light-colored stools

lower back or side pain

nausea and vomiting

painful or difficult urination

pale skin

redness of the skin

sore throat

sores, ulcers, or white spots on the lips or in the mouth

unusual bleeding or bruising

unusual tiredness or weakness

upper right abdominal or stomach pain

yellow eyes and skin

Blistering, peeling, or loosening of the skin

diarrhea

difficulty with swallowing

dizziness

fast heartbeat

joint or muscle pain

red skin lesions, often with a purple center

red, irritated eyes

tightness in the chest

Incidence not known

Bloated

excess air or gas in the stomach or intestines

full feeling

hair loss or thinning of the hair

loss of appetite

passing gas

weight loss

#### INTERACTIONS:

Carbamazepine and phenytoin lower serum levels of mebendazole. Cimetidine does not appreciably raise serum mebendazole (in contrast to the similar drug albendazole), consistent with its poor systemic absorption. [14][15]

Stevens-Johnson syndrome and the more severe toxic epidermal necrolysis can occur when mebendazole is combined with high doses of metronidazole

### 30. NORFLOXACIN 100 mg + METRONIDAZOLE 120 mg per 5 ml Suspension, 30 ml bottle SALIENT ACTIONS:

Amoebicidal, bactericidal, and trichomonicidal. It is a nitroimidazole, active against various anaerobic bacteria and protozoa. It enters the cells of microorganisms that contain nitroreductase, where its nitro group is reduced. Unstable intermediate compounds are formed which bind to DNA and inhibit synthesis, causing cell death. Norfloxacin inhibits the action of DNA gyrase in DNA replication, transcription, repair, recombination and transposition

#### INDICATIONS & DOSAGE REGIMENS:

Diarrhoea caused by E.coli, samonella and shigella.

As directed by pediatrician based on per Kg body Wt

#### PRECAUTIONS:

Pregnancy, lactation renal/hepatic impairment. H/O convulsions. Ensure adequate hydration, urinary output. Patients predisposed to seizures

#### INTERACTIONS:

Acute psychoses when metronidazole co-administered with disulfiram. It has additive/synergistic effect with other antimicrobials. Blood levels increased by cimetidine. Antacids reduce absorption of norfloxacin from GIT. *Potentially Fatal:* Disulfiram-like reaction when metronidazole is administered with alcohol. Enhances action of coumarin anticoagulants. Norfloxacin raises theophylline and cyclosporin levels. Effects of warfarin are potentiated. Probenecid reduces urinary excretion of norfloxacin

#### ADVERSE DRUG REACTIONS:

Peripheral neuropathies. GI disturbances, rash, urticaria, pruritus, superinfection (candida), metallic taste, headache, dizziness, transient leucopaenia, paraesthesias, tongue, glossitis, pseudomembranous colitis (rare). reduced serum levels of cholesterol, and triglycerides, nausea, vomiting, heart burn, constipation/diarrhoea, headache, dizziness, depression, insomnia, dry mouth, fever, arthralgia and anaemia, elevated liver enzymes, urea and creatinine. *Potentially fatal:* seizures, eosinophilia, neutropaenia, thrombocytopaenia

### 31. OFLOXACIN(OFLOX REDIUSE 100 SUSP 60ML) SALIENT ACTIONS:

Ofloxacin is a fluoroquinolone which inhibits bacterial topoisomerase IV and DNA gyrase enzymes required for DNA replication, transcription, repair, transposition and recombination. It has antibacterial activity against a wide range of gm-ve and gm-+ve microorganisms.

Absorption: Rapidly and well absorbed from the GI tract. Bioavailability: Approx 100% (oral). Time to peak plasma concentration: 1-2 hr.

**Distribution:** Widely distributed into body fluids, including CSF; appears in the bile; good tissue penetration; crosses the placenta and enters breast milk. Volume of distribution: 2.4-3.5 L/kg. Plasma protein binding: Approx 25%

#### INDICATIONS & DOSAGE REGIMENS:

Intravenous

#### Complicated urinary tract infections

Adult: 200 mg daily by infusion over at least 30 min. Max: 400 mg bid infused over at least 1 hr.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation
20-50	Reduce dose by half 24 hrly following usual initial dose.
<20 and patients on haemodialysis or peritoneal dialysis	100 mg 24 hrly following usual initial dose.

Hepatic impairment: Severe: Reduce dose. Max: 400 mg daily.

Incompatibility: Heparin.

Intravenous

#### Lower respiratory tract infections

Adult: 200 mg bid by infusion over at least 30 min. Max: 400 mg bid infused over at least 1 hr.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation
20-50	Reduce dose by half 24 hrly following usual initial dose.
<20 and patients on haemodialysis or peritoneal dialysis	100 mg 24 hrly following usual initial dose.

Hepatic impairment: Severe: Reduce dose. Max: 400 mg daily.

Incompatibility: Heparin.

Intravenous

Septicaemia

Adult: 200 mg bid by infusion over at least 30 min. Max: 400 mg bid infused over at least 1 hr.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation
20-50	Reduce dose by half 24 hrly following usual initial dose.
<20 and patients on haemodialysis or peritoneal dialysis	100 mg 24 hrly following usual initial dose.

Hepatic impairment: Severe: Reduce dose. Max: 400 mg daily.

Incompatibility: Heparin.

Intravenous

Skin and soft tissue infections

Adult: 400 mg bid infused over at least 1 hr.

Renal impairment:

CrCl (ml/min)	Dosage Recommendation	
20-50	Reduce dose by half 24 hrly following usual initial dose.	
<20 and patients on haemodialysis or peritoneal dialysis	100 mg 24 hrly following usual initial dose	

Hepatic impairment: Severe: Reduce dose. Max: 400 mg daily.

Incompatibility: Heparin. CONTRAINDICATIONS:

Hypersensitivity to ofloxacin or to other quinclones.

#### PRECAUTIONS:

Patient w/ known or suspected CNS disorders (e.g. severe cerebral arteriosclerosis, epilepsy, other seizure disorders), or other factors that predispose to seizures or lower the seizure threshold. Patient w/ history of QT interval prolongation, psychiatric illness and tendinitis; uncorrected electrolyte disorders (e.g. hypokalaemia), latent or actual defects in G6PD activity. Kidney, heart or lung transplant recipients. May exacerbate myasthenia gravis symptoms. Hepatic and renal impairment. Pregnancy and lactation. Patient Counselling This drug may cause somnolence, dizziness and visual disturbances, if affected, do not drive or operate machinery. Avoid excessive exposure to direct sunlight or artificial UV light (e.g. sunlamps, solariums). Rest and refrain from exercise at the 1st sign of tendinitis or tendon rupture (e.g. pain, swelling). Monitoring Parameters Renal, hepatic and haematologic systems should be evaluated periodically during prolonged therapy.

INTERACTIONS:

Concomitant use of class IA (e.g. quinidine, procainamide) or class III (e.g. amiodarone, sotalol) antiarrhythmic agents may increase risk of QT interval prolongation. Decreased serum and urine concentrations w/ antacids containing Mg, Al or Ca. Additive antibacterial activity w/ aminoglycosides (e.g. amikacin, tobramycin). Corticosteroids may increase risk of severe tendon disorders. Increased risk of CNS stimulation (e.g. seizures) w/ NSAIDs. Higher and prolonged serum theophylline concentrations and increased risk of theophylline-related adverse effects.

#### ADVERSE DRUG REACTIONS:

GI disturbances (e.g. nausea, vomiting, abdominal pain, discomfort or cramps, diarrhoea, fiatulence, constipation), tendinitis, tendon rupture, CNS effects (e.g. headache, insomnia, dizziness), peripheral neuropathy, rash, pruritus, external genital pruritus, vaginal discharge, mild increases in serum AST and/or ALT, eosinophilia, leucopenia, anaemia, ocular discomfort and irritation, cough, resp arrest, rhinorrhea, thirst, wt loss. Rarely, photosensitivity reactions.

Potentially Fatal: Hypersensitivity reactions, Clostridium difficile-associated diarrhoea and colitis, fatal vasculitis.

#### 32. ONDANSETRON HCL 2MG/5ML, 30ML SYRUP

#### SALIENT ACTIONS:

Antiemetics / Supportive Care Therapy. Belongs to the class of serotonin (5HT3) antagonists. Used for the prevention of nausea and vomiting

#### **INDICATION & DOSAGE REGIMENS:**

Oral

rophylaxis of postoperative nausea and vomiting

Adult: 16 mg taken 1 hr prior to anaesth; or 8 mg taken 1 hr prior to anaesth followed by 2 more doses of 8 mg 8 hrly.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Moderate or severe: Max: 8 mg/day.

Oral

Nausea and vomiting associated with cancer chemotherapy

Adult: 24 mg as a single dose, 30 min prior to the start of single-day chemotherapy.

Child: 4-11 yr 4 mg 30 min prior to chemotherapy; repeat dose at 4 and 8 hr after initial dose, then 4 mg tid for 1-2 days after completion of chemotherapy.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Moderate or severe: Max: 8 mg/day.

Oral

Nausea and vomiting associated with cancer chemotherapy or radiotherapy

Adult: Less emetogenic chemotherapy and/or radiotherapy: 8 mg 2 hr prior to treatment followed by 8 mg 8-12 hr later.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Moderate or severe: Max: 8 mg/day.

Oral

Prevent delayed emesis following chemotherapy

Adult: 8 mg bid, for up to 5 days after the end of a course of chemotherapy.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Moderate or severe: Max: 8 mg/day.

Oral

Prophylaxis of chemotherapy-induced nausea and vomiting

Adult: Moderate emetogenic cancer chemotherapy: Initially, 8 mg 30 min prior to chemotherapy; repeat dose 8 hr after initial dose, then 8 mg 12 hrly for 1-2 days after completion of chemotherapy. Highly emetogenic cancer chemotherapy: 24 mg as a single dose 30 min prior to chemotherapy.

Child: Moderate emetogenic cancer chemotherapy: 4-11 yr Initially, 4 mg 30 min prior to chemotherapy; repeat dose at 4 and 8 hr after the initial dose, then 4 mg 8 hrly for 1-2 days after completion of chemotherapy.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Moderate or severe: Max: 8 mg/day.

Oral

Prophylaxis of nausea and vomiting associated with radiation therapy

Adult: Usual dose: 8 mg tid. Undergoing total body irradiation: 8 mg 1-2 hr prior to each fraction of therapy daily. Undergoing single high-dose fraction radiation therapy to the abdomen: 8 mg 1-2 hr prior to radiation, repeat dose 8 hrly for 1-2 days after completion of therapy. Undergoing daily fractioned radiation to the abdomen: 8 mg 1-2 hr prior to radiation, then 8 hrly; repeat therapy daily.

Elderly: No dosage adjustment needed.

Renal impairment: No dosage adjustment needed.

Hepatic impairment: Moderate or severe; Max: 8 mg/day.

CONTRAINDICATIONS:

Use with apomorphine (profound hypotension).

PRECAUTIONS:

May cause QT prolongation; caution when used in cardiac diseases, patients who are on medications that can prolong QT or patients with electrolyte abnormalities. Severe hepatic impairment. May mask progressive ileus and/or gastric distension. Pregnancy, lactation

INTERACTIONS:

Refampicin and other CYP3A4 inducers reduce levels/effects of ondansetron.

Ferentially Fatal: Concurrent use may increase the hypotensive effect of apomorphine; avoid concurrent use.

ADVERSE DRUG REACTIONS:

leadache, malaise/fatigue, constipation; drowsiness, fever, dizziness, anxiety, cold sensation; pruritus, rash;

diarrhoea; gynaecological disorder, urinary retention; elevated transaminase; local inj site reaction (pain, redness, burning); paresthesia; hypoxia. Rarely: Anaphylaxis, angina, bronchospasm, ECG changes, extrapyramidal symptoms, grand mal seizure, hypokalaemia, tachycardia, vascular occlusive events.

#### 33. ORS LIQUID

#### SALIENT ACTIONS:

Oral rehydration therapy (ORT) is a type of fluid replacement used to prevent and treat dehydration, especially that due to diarrhea

orproteing that due to that thea	
Reduced osmolarity ORS	mmol/litre
Sodium chloride	2.6
Sodium	75
Glucose, anhydrous	13.5
Chloride	65
Potassium chloride	1.5
Glucose, anhydrous	75
Trisodium citrate	13
Potassium	20
Dehydrate	
Citrate	2.9
Total Osmolarity	10
DIDLOCATIONS	245

### INDICATIONS & DOSAGE REGIMENS:

ORT is less invasive than the other strategies for fluid replacement, specifically intravenous (IV) fluid replacement. Mild to moderate dehydration in children seen in an emergency department is best treated with ORT. Persons taking ORT should eat within 6 hours and return to their full diet within 24-48 hours. Oral rehydration therapy may also be used as a treatment for the symptoms of dehydration and rehydration in burns in resource-limited settings

Dose calculated on the basis of body surface area depending on patients requirement for maintenance & replacement of losses .2-3 litres/day. Children >5 yr 400ml - 1600 ml /day. <5 yrs; 2-3 liters over 24 hrs CONTRAINDICATIONS:

ORT should be discontinued and fluids replaced intravenously when vomiting is protracted despite proper administration of ORT, signs of dehydration worsen despite giving ORT, the person is unable to drink due to a decreased level of consciousness, or there is evidence of intestinal blockage or ileus. ORT might also be contraindicated in people who are in hemodynamic shock due to impaired airway protective reflexes Short-term your ring is not a contraindication to receiving oral rehydration therapy. In persons who are vomiting, drinking oral rehydration solution at a slow and continuous pace will help the vomiting to resolve ADVERSE EFFECTS:

Side effects may include vomiting, high blood sodium, or high blood potassium

### 34. PARACETAMOL(CALPOL PEAD DROP 15ML)

#### SALIENT ACTIONS:

Belong to the class of NSAIDs and act by non selectively inhibiting the COX-1 and COX-2 Ezymes. It has analgesic and antipyretic action and no anti-inflammatory action.

### INDICATIONS & DOSAGE REGIMENS:

Mild to moderate pain and fever

Post-immunization pyrexia

For children aged 0-2 years (100mg/mL Suspension Infant Drops)

- Oral administration only
- Dose may be based on weight or age: use weight if you know it, otherwise use age.

Give every 4-6 hours.

Do not give more than 4 doses in any 24-hour period.

#### CONTRAINDICATIONS:

Gastro-duodenal ulcer, chronic alcoholic.

#### PRECAUTIONS:

Pregnancy Category (US FDA) - B. Renal or hepatic impairment; alcohol-dependent patients; G6PD deficiency

#### INTERACTIONS:

Reduced absorption of cholestyramine within 1 hr of admin. Accelerated absorption with metoclopramide.

Decreased effect with barbiturates, carbamazepine, hydantoins, rifampicin and sulfinpyrazone. Paracetamol may increase effect of warfarin.

Potentially Fatal: Paracetamol increases the risk of liver damage in chronic alcoholics. Increased risk of toxicity with other hepatotoxic drugs or drugs which induce microsomal enzymes e.g. barbiturates, carbamazepine, hydantoins, rifampicin and sulfinpyrazone.

#### ADVERSE EFFECTS:

Nausea, allergic reactions, skin rashes, acute renal tubular necrosis.

Potentially Fatal: Very rare, blood dyscrasias (e.g. thrombocytopenia, leucopenia, neutropenia, agranulocytosis); liver damage.

#### 35. PARAFFIN 3.75 ml +MILK OF MAGNESIA 11.25 ml, Syrup 170 ml bottle

#### INDICATIONS:

Constipation

#### CONTRAINDICATIONS:

Abdominal pain, nausea, vomiting, child<3

#### PRECAUTIONS:

Patient with difficulty in swallowing or impair neurodevelopement

#### INTERACTIONS:

May impair fat soluble vit

#### ADVERSE EFFECTS:

Magnesium may be systemically absorbed following administration of magnesium hydroxide. In patients with normal renal function, increased magnesium elimination in the urine occurs and no significant changes in serum magnesium levels would be expected. However, magnesium may accumulate in patients with renal insufficiency General side effects have included signs and symptoms of hypermagnesemia. These have included hypotension, nausea, vomiting, EKG changes, respiratory depression, mental depression and coma

#### 36. PERFLURO-N-OCTANE LIQUID

#### SALIENT ACTIONS:

Perfluorooctane, also known as octadecafluorooctane, is a <u>fluorocarbon</u> liquid—a perfluorinated derivative of the hydrocarbon octane.

#### INDICATIONS & DOSAGE REGIMENS:

- Heat transfer agent
- Dielectric fluid
- Tamponade in eye surgery

#### 37. PHENOBARBITONE SYRUP

#### SALIENT ACTIONS:

Phenobarbital is a long-acting barbiturate. It depresses the sensory cortex, reduces motor activity, changes cerebellar function and produces drowsiness, sedation and hypnosis. Its anticonvulsant property is exhibited at high doses.

#### INDICATIONS & DOSAGE REGIMENS:

Oral

#### Sedation

Adult: 30-120 mg daily in 2-3 divided doses.

Child: 6 mg/kg daily or 180 mg/m<sup>2</sup> daily in 3 divided doses.

Elderly: Reduce dose.

Renal impairment: Reduce dose. Severe: Contraindicated. Flepatic impairment: Reduce dose. Severe: Contraindicated.

Oral

#### Status epilepticus

A dult: 100-300 mg daily at bedtime. Child: 3-5 mg/kg or 125 mg/m<sup>2</sup> daily.

Elderly: Reduce dose.

Renal impairment: Reduce dose. Severe: Contraindicated.

Hepatic impairment: Reduce dose. Severe: Contraindicated.

Oral

Emergency management of acute seizures

Adult: 100-300 mg daily at bedtime. Child: 3-5 mg/kg or 125 mg/m<sup>2</sup> daily.

Elderly: Reduce dose.

Renal impairment: Reduce dose. Severe: Contraindicated. Hepatic impairment: Reduce dose. Severe: Contraindicated.

Oral

As a hypnotic

Adult: 100-320 mg. Do not admin for >2 wk for the treatment of insomnia.

Elderly: Reduce dose.

Renal impairment: Reduce dose. Severe: Contraindicated. Hepatic impairment: Reduce dose. Severe: Contraindicated. Oral

Preoperative sedation

Child: 1-3 mg/kg pre-op.

Renal impairment: Reduce dose. Severe: Contraindicated. Hepatic impairment: Reduce dose. Severe: Contraindicated.

CONTRAINDICATIONS:

Severe resp depression, acute intermittent porphyria. Severe renal and hepatic impairment. Intra-arterial and SC admin.

#### PRECAUTIONS:

Patient w/ history or sedative/hypnotic addiction; resp disease, depression or suicidal tendencies, hypoadrenalism. Avoid abrupt withdrawal. Mild to moderate renal and hepatic impairment. Elderly or debilitated patient, childn. Pregnancy and lactation. *Patient Counselling* May impair ability to drive or operate machinery. *Monitoring Parameters* Monitor CBC, LFTs, mental status and seizure activity.

DRUG INTERACTIONS:

May reduce plasma levels of oral anticoagulants (e.g. warfarin, dicoumarol, acenocoumarol, phenprocoumon), corticosteroids, griseofulvin, doxycycline, Na valproate and valproic acid. May increase CNS depressant effect w/ phenytoin, antihistamines, sedative/hypnotics, tranquilisers. May prolong the effect w/ MAOIs. May reduce the effect of estradiol, progesterone, estrone and other steroidal hormones.

ADVERSE DRUG REACTIONS:

Bradycardia, syncope, hypotension; anxiety, agitation, ataxia, CNS excitation or depression, confusion, dizziness, drowsiness, hallucinations, hangover effect, headache, hyperkinesias; constipation, nausea, vomiting; agranulocytosis, thrombocytopenia, megaloblastic anaemia; oliguria; pain at inj site, thrombophlebitis (w/ IV use); laryngospasm, resp depression, apnoea (esp w/ rapid IV use), hypoventilation; gangrene (w/ unintentional intra-arterial inj).

Potentially Fatal: Stevens-Johnson syndrome, toxic epidermal necrolysis.

#### 38. PHENYTOIN SUSPENSION

#### SALIENT ACTIONS:

Phenytoin acts as an anticonvulsant by increasing efflux or decreasing influx of sodium ions across cell membranes in the motor cortex during generation of nerve impulses; thus stabilising neuronal membranes and decreasing seizure activity. It acts as an antiarrhythmic by extending the effective refractory period and suppressing ventricular pacemaker automaticity, shortening action potential in the heart.

#### **INDICATIONS & DOSAGE REGIMENS:**

Intravenous

Tonic-clonic status epilepticus

Adult: Adjunctive therapy with a benzodiazepine (e.g. diazepam): 10-15 mg/kg by slow inj or intermittent infusion at a max rate of 50 mg/min. Maintenance: 100 mg IV (or orally) given every 6-8 hr.

Child: Neonates: 20 mg/kg as a loading dose, then 2.5-5 mg/kg bid; 1 mth-12 yr: 18 mg/kg as a loading dose, then 2.5-5 mg/kg bid; >12 yr: 18 mg/kg as a loading dose, then up to 100 mg 3-4 times daily.

CONTRAINDICATIONS:

Pregnancy. IV admin in sinus bradycardia, heart block, or Stokes-Adams syndrome.

#### PRECAUTIONS:

Cardiovascular disease, e.g. sinus bradycardia, heart blocks; DM; hepatic impairment; hypoalbuminemia; porphyria; seizures (may increase frequency of petit mal seizures); debilitated patients; elderly. Caution in IV admin in hypotension, heart failure or MI, monitor BP and ECG during therapy. IV must be given slowly (too rapid admin may cause hypotension, CNS depression, cardiac arrhythmias and impaired heart conduction). Extravasation and intra-arterial admin must be avoided. Do not discontinue abruptly (may increase seizure frequency), unless safety concerns require a more rapid withdrawal. May impair ability to drive or operate machinery.

#### DRUG INTERACTIONS:

Effects with other sedative drugs or ethanol may be potentiated. Enhances toxic effects of paracetamol, lithium. Increased risk of osteomalacia with acetazolamide. Decreased serum levels/effects with acyclovir, antineoplastics, benzodiazeines, ciprofloxacin, CYP2C9 inducers (e.g. carbamazepine), CYP2C19 inducers (e.g. rifampin), folic acid, vigabatrin. Increased serum concentrations with allopurinol, capecitabine, cimetidine, CYP2C9 inhibitors (e.g. fluconazole), CYP2C19 inhibitors (e.g. delavirdine), disulfiram, methylphenidate, metronidazole, omeprazole, SSRI, trazodone, trimethoprim. Increases metabolism of antiarrhythmics, anticonvulsants, antipsychotics, beta-blockers, calcium channel blockers, chloramphenicol, corticosteroids, doxycycline, oestrogens, HMG-CoA reductase inhibitors, methadone, theophylline, TCAs. Decreases levels/effects of clozapine, ciclosporin, tacrolimus, CYP2B6 substrates (e.g. bupropion, selegiline), CYP2C8 substrates (e.g. amiodarone), CYP2C9 substrates (e.g. celecoxib), CYP2C19 substrates (e.g. citalopram), CYP3A4 substrates (e.g. benzodiazepines), digoxin, itraconazole, levodopa, neuromuscular-blocking agents, thyroid hormones, topiramate. Increases levels/effect of dopamine, ticlopidine. Valproic acid may displace phenytoin from binding sites; and affect phenytoin serum concentrations. Transiently increases the hypothrombinaemia response to warfarin initially, followed by an inhibition of the response. Lorentially Fatal: Enhances the hypotensive properties of dopamine and the cardiac depressant properties of lidocaine.

#### ADVERSE DRUG REACTIONS:

Hypersensitivity, lack of appetite, headache, dizziness, tremor, transient nervousness, insomnia, GI disturbances (e.g. nausea, vomiting, constipation), tenderness and hyperplasia of the gums, acne, hirsutism, coarsening of the facial features, rashes, osteomalacia. Phenytoin toxicity as manifested as a syndrome of cerebellar, vestibular, ecular effects, notably nystagmus, diplopia, slurred speech, and ataxia; also with mental confusion, dyskinesias, exacerbations of seizure frequency, hyperglycaemia. Solutions for inj may cause local irritation or phlebitis. Prolonged use may produce subtle effects on mental function and cognition, especially in children. Potentially Fatal: Toxic epidermal necrolysis, Stevens-Johnson syndrome.

#### 39. PIRACETAM(NOOTROPIL 100ML SYP)

#### SALIENT ACTIONS:

Piracetam protects the cerebral cortex against hypoxia. It also inhibits platelet aggregation and reduces blood viscosity.

#### INDICATIONS & DOSAGE REGIMENS:

Oral

#### Adjunct in cortical myoclonus

Adult: 7.2 g daily in 2-3 divided doses, increased by 4.8 g/day every 3-4 days. Max dose: 20 g daily.

#### Renal impairment:

CrCl (ml/min)	Dosage Recommendation
	2/3 usual dose
30-49	1/3 usual dose
20-29	1/6 usual dose
<20	Contra-indicated

Oral

#### As a cognitive enhancer in cerebrocortical insufficiency

Adult: 2.4 g daily, given as 2-3 divided doses. Up to 4.8 g daily may be used in severe cases.

Rena! impairment:

CrCl (r	nl/min) Dosage Recommendation
50-79	2/3 usual dose
30-49	1/3 usual dose

20-29	1/6 usual dose	
<20	Contra-indicated	

#### CONTRAINDICATIONS:

Hepatic and severe renal impairment. Cerebral haemorrhage. Pregnancy and lactation.

#### PRECAUTIONS:

Avoid abrupt withdrawal. Impaired renal function. Cardiac disorders. Haemostatic disorders. Patients who have recently undergone major surgery. Elderly.

#### **DRUG INTERACTIONS:**

May increase prothrombin time in patients who are on warfarin.

#### ADVERSE DRUG REACTIONS:

Hyperkinesia, nervousness, depression, diarrhoea, rashes. CNS stimulation, sleep disturbances, dizziness, excitement, insomnia, somnolence, wt gain.

#### 40. RISPERIDONE LIQUID

Risperidone is an atypical antipsychotic. Its activity is mediated through a combination of dopamine (D2) and serotonin (5-HT2) receptor antagonism. It also exhibits affinity to adrenergic ( $\alpha$ 1 and  $\alpha$ 2) and histamine (H1) receptors. It is less likely to cause extrapyramidal effects than conventional antipsychotics.

#### **Indications and DOSAGE REGIMENS:**

Oral

Schizophrenia

Adult: Initially, 2 mg daily, may increase to 4 mg daily on the 2nd day, adjusted further in increments or decrements of 1-2 mg daily at wkly intervals. Doses may be given in 1-2 divided doses. Maintenance: 4-6 mg daily. Max: 16 mg/day.

Elderly: Initially, 0.5 mg bid gradually increased in increments of 0.5 mg bid. Maintenance: 1-2 mg bid. Renal impairment: Initially, 0.5 mg bid, may increase in steps of 0.5 mg bid, up to 1-2 mg bid. Dose increments above 1.5 mg bid should be made at intervals of at least 1 wk.

Hepatic impairment: Initially, 0.5 mg bid, may increase in steps of 0.5 mg bid, up to 1-2 mg bid. Dose increments above 1.5 mg bid should be made at intervals of at least 1 wk.

Oral

Acute manic episodes of bipolar disorder

Adult: Initially, 2-3 mg once daily. May increase by 1 mg daily at intervals of at least 24 hr. Max: 6 mg daily. Elderly: Initiate with lower doses.

Renal impairment: Initially, 0.5 mg bid, may increase in steps of 0.5 mg bid, up to 1-2 mg bid. Dose increments above 1.5 mg bid should be made at intervals of at least 1 wk.

Hepatic impairment: Initially, 0.5 mg bid, may increase in steps of 0.5 mg bid, up to 1-2 mg bid. Dose increments above 1.5 mg bid should be made at intervals of at least 1 wk.

Intramuscular

Schizophrenia

Adult: Give oral risperidone for a few days to assess tolerability prior to initiating inj. For patients not stabilised on oral risperidone: 25 mg every 2 wk. Patients stabilised on oral risperidone for at least 2 wk in doses ≤4 mg daily: 25 mg every 2 wk. Patients stabilised on oral risperidone for at least 2 wk in doses >4 mg daily: 37.5 mg every 2 wk. Continue oral risperidone for the 1st 3 wk after the 1st inj.

Elderly: Max dose: 25 mg every 2 wk.

#### PRECAUTIONS:

Preexisting CV diseases; discontinue use if signs and symptoms of tardive dyskinesia occur; renal and hepatic impairment, elderly, epilepsy; parkinsonism; pregnancy. May cause drowsiness and orthostatic hypotension. Gradual withdrawal is recommended. Monitor blood glucose in diabetics and patients at risk of developing diabetes.

#### DRUG INTERACTIONS:

May antagonise the effects of levodopa and dopamine agonists. May increase serum levels of clozapine when used together. Increased serum levels of carbamazepine when used concurrently. Carbamazepine may also decrease the serum levels of risperidone. Increased risk of neuroleptic malignant syndrome when used with indinavir and ritonavir.

Potentially Fatal: Risperidone may enhance the hypotensive effect of certain antihypertensives.

#### ADVERSE EFFECTS:

Agitation, anxiety, dizziness, headache, somnolence; orthostatic hypotension; constipation, dyspepsia, nausea,

vomiting, abdominal pain, blurred vision, erectile dysfunction, priapism, rhinitis, rash and allergy, galactorrhoea, gynaecomastia, menstrual disorders, extrapyramidal symptoms (rarely). weight gain, oedema, tardive dyskinesia.

Potentially Fatal: Neuroleptic malignant syndrome may occur rarely; seizures. May cause increased mortality in elderly with dementia-related psychosis

#### 41. SUCRALFATE 1 gm /10 ml, Syrup 200 ml bottle

#### **SALIENT ACTIONS & INDICATIONS:**

Sucralfate Suspension is a gastric protective agent. It works by forming a protective layer on the ulcer to serve as a barrier against acid, bile salts, and enzymes in the stomach

#### **CONTRAINDICATIONS:**

Allergic to any ingredient in Sucralfate Suspension

#### PRECAUTIONS:

Pregnant, planning to become pregnant, or are breast-feeding, taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement, kidney problems or are on dialysis, or have blockage of the intestines, delayed stomach emptying, or difficulty swallowing if receive tube feedingsif have diabetes

#### INTERACTIONS:

Citrate salts or medicines that contain aluminum (eg, certain antacids), specifically in patients with kidney disease, because side effects from aluminum may occur

#### ADVERSE DRUG REACTIONS:

Constipation; dizziness; feeling of a whirling motion, Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, throat, or tongue; unusual hoarseness); symptoms of high blood sugar (eg, confusion; increased thirst, hunger, or urination; severe drowsiness; unusual weakness

### 42. VIT B1 5 mg + VIT B2 $\,$ 2.5 mg +VIT B6 $\,$ 1.5 mg + D- PANTHENOL 5 mg + VIT B12 5 mcg per 5 ml syrup, 120 ml bottle

#### SALIENT ACTIONS:

Vit B1 is act as coenzyme & in thiamine conversion of thiamine pyrophosphate ,play some role in neuromuscular transmission .vit B2 help in oxidation reduction reaction , vit B6 :the coenzyme form pyridoxal 5 phosphate takes part in many biochemical reactions ,nicotinamide help lower high cholesterol in blood vit B12 essential for DNA synthesis .

#### **INDICATIONS:**

Prophylaxis, Malnutrition, nutritional supplement.

#### ADVERSE DRUG REACTIONS:

Flushing, vomiting, diarrhea, pruriyus, skin rash.

## 43. VIT B1 0.75 mg + VIT B2 0.75 mg + VIT B6 1 mg + NICOTINAMIDE 7.5 mg + VIT B12 0.5 mg + L-LYSINE MONOHYDROCHLORUDE 5 mg per 5 ml, 100 ml bottle SALIENT ACTIONS:

Vit B1 is act as coenzyme & in thiamine conversion of thiamine pyrophosphate ,play some role in neuromuscular transmission .vit B2 help in oxidation reduction reaction , vit B6 :the coenzyme form pyridoxal 5 phosphate takes part in many biochemical reactions ,nicotinamide help lower high cholesterol in blood vit B12 essential for DNA synthesis . lysine is essential amino acid

#### INDICATIONS:

Prophylaxis, malnutrition,,nutritional supplement

#### **CONTRAINDICATIONS:**

Hypersensitivity

#### PRECAUTIONS:

VIT B6 / OC pills can ppt B6 deficiency

#### ADVERSE DRUG REACTIONS:

Flushing, vomiting, diarrhea, purities, skin rash, headache, paralytic illness.

#### 44. VITAMIN D3 (CHOLECALCIFEROL) DROPS

#### **SALIENT ACTIONS:**

Vit D may have anti-osteoporotic, immunomodulatory, anticarcinogenic, antipsoriatic, antioxidant & mood-

modulatory activities. Along with parathyroid hormone & calcitonin, regulate serum calcium conc.

Onset: Slow.

Duration: Relatively prolonged duration of action.

Absorption: Well absorbed from the GI tract. Presence of bile is essential for adequate intestinal absorption.

Hence absorption may be decreased in patients with decreased fat absorption.

Distribution: Bound to a specific α-globulin. Can be stored in adipose & muscle tissue for long periods of time.

Slowly released from storage sites & skin where it is formed in the presence of sunlight or uv light. May

distribute into breast milk.

Metabolism: Hydroxylated in the liver by the enzyme vitamin D 25-hydroxylase to form 25-

hydroxycholecalciferol (calcifediol). Further hydroxylated in the kidneys by the enzyme vitamin D1-

hydroxylase to form the active metabolites 1,25-dihydroxycholecalciferol (calcitriol). Further metabolism also occurs in the kidneys, including the formation of the 1,24,25-trihydroxy derivatives.

Excretion: Mainly in the bile & faeces with only small amounts appearing in urine.

#### INDICATIONS & DOSAGE REGIMENS:

Oral

Nutritional deficiency

Adult: 10 mcg (400 units) daily. May also be given via IM inj.

Deficiency due to malabsorption states or liver diseases

Adult: Up to 1 mg (40 000 units) daily. May also be given via IM inj.

Oral

Hypocalcaemia caused by hypoparathyroidism

Adult: Up to 5 mg (200 000 units) daily. May also be given via IM inj.

#### INTERACTIONS:

Increased risk of hypercalcaemia if given with thiazide diuretics, calcium or phosphate. Antiepileptics (e.g. carbamazepine, phenobarbitone, phenytoin & primidone) may increase vitamin D requirements. Rifampicin & isoniazid may reduce efficacy of vitamin D. Corticosteroids may counteract the effect of vitamin D. Digoxin or any cardiac glycoside. Reduced absorption when taken with cholestyramine, colestipol, mineral oil, orlistat. Ketoconazole.

#### PRECAUTIONS:

Excessive intake may lead to development of hyperphosphataemia or hypercalcaemia. Infants, renal impairment or calculi, heart disease. Monitor plasma phosphate & calcium level. Pregnancy, lactation.

#### CONTRAINDICATIONS:

Hypercalcaemia. Evidence of vitamin D toxicity

#### ADVERSE EFFECTS:

Hyperphosphataemia or hypercalcaemia (in excessive intake). Associated effects of hypercalcaemia include hypercalciuria, ectopic calcification, & renal & CV damage.

#### 45. TERBUTALINE SULPHATE 1.25 mg +GAUIPHENESIN 50 mg +BROMHEXIN 2 mg +MENTHOL 0.5% per 5 ml syrup, 60 ml bottle

#### SALIENT ACTIONS:

Adrenergic stimulant

#### INDICATIONS:

bronchospasm, nocturnal asthma, bronchial asthma, asthma during exercise, chronic bronchitis bronchietasis DOSAGE REGIMENS:

1-2 tsf Bd/tds

#### CONTRAINDICATIONS:

Hypersensitivity

#### ADVERSE EFFECTS:

Headache, nervousness allergic reaction

#### **46. TRYPAN BLUE 0.06%**

Used along with sodium chloride

#### SALIENT ACTIONS:

Sodium chloride is the major extracellular cation. It is important in electrolyte and fluid balance, osmotic pressure control and water distribution as it restores sodium ions. It is used as a source of electrolytes and water for hydration, treatment of metabolic acidosis, priming solution in haemodialysis and treatment of hyperosmolar diabetes. It is also used as diluents for infusion of compatible drug additives.

Absorption: Well-absorbed from the GI tract.

Excretion: Mainly in the urine, with small amounts excreted in the sweat, faeces, tears and saliva.

#### INDICATIONS & DOSAGE REGIMENS:

Oral

Chronic salt-losing conditions

Adult: As modified-release preparation: 2.4-4.8 g (40-80 mmol sodium) daily accompanied by suitable fluid intake. Up to 12 g daily may be necessary in severe cases.

Renal impairment: Dosage adjustment may be necessary.

Oral

Prophylaxis of muscle cramps during routine haemodialysis

Adult: As modified-release preparation: 6-10 g every dialysis session.

Oral

Oral hygiene

Adult: Used as mouthwash.

Nasal

Nasal congestion

Adult: 0.9% used as nasal drops or spray.

Child: 0.9% used as nasal drops.

Intravenous

Replacement of fluid and electrolytes

Adult: As 0.9%, 3% or 5% solution: Dosage depends on age, wt, clinical condition and laboratory determinations of the patient. Dose to be administered via a large vein, with care taken to prevent infiltration. Intravenous

Hypernatraemia

Adult: As 0.9% solution: Dosage depends on age, wt, clinical condition and laboratory determinations of the patient. Dose to be administered via a large vein, with care taken to prevent infiltration.

Irrigation

Irrigation of the bladder, eye, general skin and wound cleansing

Adult: 0.9% solution is used.

#### INTERACTIONS:

May affect serum concentrations of lithium.

#### PRECAUTIONS:

Hypertension, heart failure, peripheral or pulmonary oedema, impaired renal function, liver cirrhosis, preeclampsia. Maintain adequate water intake. Pregnancy. Inj of 3 or 5% sodium chloride solution should be given via a large vein at a rate not exceeding 100 ml/hr. Monitor fluid balance, serum electrolytes and acid base balance espcially during prolonged treatment. Caution when used in patients who are receiving corticosteroids or corticotropin.

#### CONTRAINDICATIONS:

Conditions whereby admin of sodium chloride would be detrimental. Not to be used to induce emesis. Sustained release tablets: GI disorders associated with strictures or diverticula.

#### ADVERSE EFFECTS:

Hypernatraemia; thirst, reduced salivation and lachrymation, fever, tachycardia, hypertension, headache, dizziness, restlessness, irritability and weakness.

Potentially Fatal: Intra-amniotic inj of hypertonic solutions: Disseminated intravascular coagulation, renal necrosis, cervical and uterine lesions, pulmonary embolism, pneumonia and death.

### 47. ZINC ACETATE EQ TO ELEMENTAL ZINC 20 mg, Syrup 60 ml bottle INDICATIONS :

Diarrhoea

Certain liver disease (Wilson's disease). This inherited disease causes the liver to hold onto too much copper, resulting in liver damage and other serious problems. This medication causes the intestines to make more of a certain substance (a protein) that prevents the body from absorbing too much copper from food, thereby preventing further damage.

#### DOSAGE REGIMENS:

10-20 mg per day for diarroea

3 times daily Take each dose at least 1 hour before or 2 hours after all food or beverages (except water). Swallow the capsule whole.

#### PRECAUTIONS:

Allergic to drug content .Pregnant & lactating women

#### ADVERSE EFFECTS:

Upset stomach may occur. Serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

#### 48. ZINC DRY POWDER FOR SUSPENSION

#### SALIENT ACTIONS:

Zinc sulfate can also be used orally or systemically as a zinc supplement.

#### **INDICATIONS & DOSAGE REGIMENS:**

Oral

Zinc deficiency

Adult: 50 mg of elemental zinc tid.

#### INTERACTIONS:

Reduced absorption of both zinc and oral iron supplements, penicillamine and tetracyclines when admin concomitantly. Phosphorus-containing preparations reduce zinc absorption. Zn sulfate reduces absorption of copper and flouroquinolones e.g. ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin. Reduced zinc absorption with calcium co-admin. Reduced bisphosphonates absorption with concurrent zinc admin.

#### PRECAUTIONS:

Oral/IV: Monitor CBC and serum cholesterol to detect early signs of copper deficiency, especially if prolonged high dose use of zinc. Topical: Consult medical advice if relief not seen within 3 days.

#### CONTRAINDICATIONS:

N/A

#### ADVERSE EFFECTS:

Abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation, gastritis. Prolonged use may cause copper deficiency (e.g. sideroblastic anaemia, neutropenia)

# **POWDER**

#### POWDER

#### 1. L ARGININE 3MG SACHET

#### SALIENT ACTIONS:

L-arginine is a chemical building block called "an amino acid." It is obtained from the diet and is necessary for the body to make proteins. L-arginine is converted in the body into a chemical called nitric oxide. Nitric oxide causes blood vessels to open wider for improved blood flow. L-arginine also stimulates the release of growth hormone, insulin, and other substances in the body.

#### INDICATIONS:

L-arginine is used for heart and blood vessel conditions including congestive heart failure (CHF), chest pain, high blood pressure, and coronary artery disease. L-arginine is also used for recurrent pain in the legs due to blocked arteries (intermittent claudication), decreased mental capacity in the elderly (senile dementia), erectile dysfunction (ED), and male infertility.

#### DOSAGE REGIMENS:

3-6g.

#### CONTRAINDICATIONS:

Excess Body Acid, high amount of potassium in the blood, Sickle Cell Anemia, heart attack within the last 30 days, Renal Tubular Acidosis, kidney disease with reduction in kidney function

#### PRECAUTIONS &INTERACTIONS:

L-arginine has unpredictable effects on insulin and cholesterol-lowering agents. L-arginine may increase the effects of isosorbide mononitrate and other nitric oxide donors, such as glyceryl trinitrate and sodium nitroprusside.

#### ADVERSE EFFECTS:

L-arginine has few reported adverse reactions. Nausea and diarrhea have been reported infrequently. Bitter taste may occur with higher doses. Due to its ability to dilate blood vessels, low blood pressure may occur. Intravenous preparations containing L-arginine hydrochloride have a high chloride content that may increase the risk for metabolic acidosis in patients with electrolyte imbalances. Low potassium and high serum urea nitrogen levels may occur in patients with kidney and/or liver impairment.

#### 2. NUTRITIONAL PRODUCT(CERELAC RICE)

#### SALIENT ACTIONS:

#### BIFIDUS BL probiotics

helps to fight against harmful bacteria, thereby maintaining a healthy digestive system.

#### DHA

An important building block for brain and eye development (for children up to 3 years of age).

#### Iron

Each serving contains more than 50% of daily iron intake. Iron is an important component of red blood cells which carry oxygen to all parts of the body to help the body's production of energy.

#### Vitamin C

Helps your baby's body to absorb iron from food.

- Made with Baby Grade ingredients, nutrition and quality
- No added preservatives

#### Ingredients

Rice, Skimmed Milk Powder (Cow's Milk), Sugar, Vegetable Oils (Palm Olein, Rapeseed Oil, Coconut Oil, Sunflower Oil), Minerals (Calcium Carbonate, Sodium Phosphate, Ferrous Fumarate, Zinc Sulphate, Potassium Iodide), Maltodextrin, Fish Oil Powder, Vitamins (C, E, Niacin, Calcium Pantothenate, B1, A, B6, B2, Folic Acid, D3, Biotin, B12), Corn Starch, Taurine, Vanillin, Bifidobacterium Lactis Culture. Contains permitted flavouring. All additives are of plant or synthetic origin. May contain traces: Soya and Gluten.

Average Composition	Per 100g	
Energy	414kcal	
Fat	9.0g	
Comprising of		
Monosaturated Fatty Acids	2.5g	
Polysaturated Fatty Acids	1.2mg	
Saturated Fatty Acids	3.5mg	
Trans Fatty Acids	0.1g	

Average Composition	Per 100g	
DHA	8.0g	
Linoleic Acid	1.2g	
Alpha-Linolenic acid	120mg	
Protein	12g	
Carbohydrate	71g	
Dietary Fibre	0.7g	
Sodium	250mg	
Calcium	420mg	
Vitamin A	330µg RE	
Vitamin D	5.0μg D	
Vitamin E	4.1mg TE	
Vitamin C	65mg	
Vitamin B1	0.4mg	
Vitamin B2	0.4mg	
Niacin	4.2mg	
Vitamin B6	0.3mg	
Folic Acid	26µg	
Vitamin B12	0.8µg	
Iron	10mg	
Iodine	47μg	
Zine	2.5mg	

### 3. ORS (NaCl 2.6 mg + KCl 1.5 mg + Na CITRATE 2.9 gm +DEXTROSE 13.5 gm ) powder SALIENT ACTIONS:

Reduced osmolarityORS packets. The reduced osmolarity solution not only decreased stool output, but also resulted in less vomiting and fewer unscheduled intraveneous therapy cases.

#### INDICATIONS:

Electrolyte imbalance in patient with gastroenteritis, vomiting, diarrhea

#### DOSAGE REGIMENS:

Dose calculated on the basis of body surface area depending on patients requirement for maintenance & replacement of losses ,2-3 litres/day . Children >5 yr 400ml - 1600 ml /day. <5 yrs ; 2-3 liters over 24 hrs

#### LACTIC ACID BACILLUS(POWDER)

#### SALIENT ACTIONS:

lactic acid producing organisms, combinations; It works by lowering the pH of intestines and producing Lactic acid in the intestines. This makes the digestive tract inhabitable for pathogens and other harmful microorganisms. Belongs to the class of antidiarrheal microorganisms

#### INDICATIONS:

Constipation, Diarrhea, Antibiotic associated diarrhea, Gastrointestinal disorders, Gastro-intestinal disorders, Pseudomembranous colitis

#### **DOSAGE REGIMENS:**

N/A

#### CONTRAINDICATIONS:

N/A

#### PRECAUTIONS:

N/A

#### INTERACTIONS:

- Alcohol
- Antibiotic drugs
- Azathioprine
- Barbiturates
- Basiliximab
- Cyclosporine

- Diphenylhydantoin
- Methotrexate
- Nitrofurantoin

#### ADVERSE EFFECTS:

- Gas
- Bloating
- Gastro-intestenal Infection

#### 4. POLYETHYLENE GLYCOL POWDER

#### **SALIENT ACTIONS:**

A white powder for reconstitution. Is an osmotic agent for the treatment of constipation.

#### INDICATIONS & DOSAGE REGIMENS:

It is used to treat hard stools (constipation).

The usual dose is 17 grams (about 1 heaping tablespoon) of powder per day in 4-8 ounces of water, juice, soda, coffee, or tea. Each bottle of Polyethylene Glycol 3350, NF Powder for Oral Solution is supplied with a dosing cup marked to contain 17 grams of laxative powder when filled to the indicated line.

Two to 4 days (48 to 96 hours) may be required to produce a bowel movement

#### CONTRAINDICATIONS:

contraindicated in patients with known or suspected bowel obstruction and patients known to be allergic to polyethylene glycol.

#### PRECAUTIONS:

Patients presenting with complaints of constipation should have a thorough medical history and physical examination to detect associated metabolic, endocrine and neurogenic conditions, and medications. A diagnostic evaluation should include a structural examination of the colon. Patients should be educated about good defecatory and eating habits (such as high fiber diets) and lifestyle changes (adequate dietary fiber and fluid intake, regular exercise) which may produce more regular bowel habits.

#### INTERACTIONS:

No specific drug interactions have been demonstrated.

#### ADVERSE EFFECTS:

Nausea, abdominal bloating, cramping and flatulence may occur. High doses may produce diarrhea and excessive stool frequency, particularly in elderly nursing home patients.

Patients taking other medications containing polyethylene glycol have occasionally developed urticaria suggestive of an allergic reaction.

#### POTASSIUM PERMANGANATE POWDER

Potassium permanaganate, a strong oxidising agent with disinfectant, deodorising and astringent properties. Even though it is bactericidal in vitro, its clinical use is limited as it is rapidly reduced in the presence of body fluids

#### INDICATIONS:

Wet dressings to assist healing of suppurating superficial wounds, tropical ulcers, tinea pedis infection, pemphigus, impetigo.

#### AVAILABILITY:

SOLUTION 1:10,000 (0.01% solution).

#### DOSAGE REGIMEN:

Suppurating superficial wounds and tropical ulcers: wet dressings of 1:10,000 (0.01%) solution, changed 2 or 3 times daily; tropical ulcers also require treatment for 2 to 4 weeks with procaine benzylpenicillin. Tinea pedis: soak severe weeping lesions in 1:10,000 (0.01%) solution every 8 h. Pemphigus: soak compresses in 1:10,000 (0.01%) solution and apply every 4 h. Impetigo: superficial crusts should be gently separated with a 1:10,000 (0.01%) solution.

#### CONTRAINDICATIONS:

Avoid occlusive dressings; interactions (Appendix 6d).

#### PRECAUTIONS:

Irritant to mucous membranes; redness of skin.

#### ADVERSE EFFECTS:

Local irritation; skin and fabrics stained brown.

#### 5. PROTEIN POWDER (B PROTEIN CHOC POWDER)

B-Protein A NUTRITIONAL SUPPLEMENT

#### INGREDIENTS:

Whey protein concentrate, skimmed milk powder, sucrose. Soya protein isolate, Maltodextrin, Malt extract, Natural cocoa powder, Vitamins & minerals

These nutrients ensure the continuous supply of Amino acids for the formation of haemoglobin, production of enzymes, and maintaining tissues. This B-Protin supplement maintains good health, boosts energy level and enhances the immunity system. So is indicated in case of General Weakness, Fatigue, Convalescence, Hospitalised and Immuno-compromised patients.

B-Protin nutritional powder also contains:

28 essential vitamins and minerals.

5 Antioxidants.

Cholesterol and Gluten free.

#### ADVERSE EFFECTS:

Rarely acute and severe allergic reactions can occure with protein powders

#### 6. RACECADOTRIL SACHET

#### SALINET ACTIONS:

Racecadotril increases the availability of endogenous opioids (enkephalins) by inhibiting the membrane-bound enkephalinase. The enkephalins in turn mediate their effect through  $\delta$  receptor activation that induces a selective increase in Cl absorption by inhibiting adenylate cyclase.

#### INDICATIONS AND DOSAGE REGIMENS:

Oral

Acute diarrhoea

Adult: 100 mg tid. Continue treatment until 2 normal stools are recorded. Max duration: 7 days.

Child: 3 mth to 17 yr <9 kg: 10 mg tid; 9 to <13 kg: 20 mg tid; 13-27 kg: 30 mg tid; >27 kg: 60 mg tid.

Continue treatment until 2 normal stools are recorded. Max duration: 7 days.

#### PRECAUTIONS:

Presence of bloody or purulent stools and fever. Renal or hepatic impairment. Childn. Pregnancy and lactation ADVERSE EFFECTS:

Headache, tonsillitis, rash, erythema multiforme or nodosum; tongue, face, lip or eyelid oedema; angioedema, urticaria, prurigo, pruritus.

# TOPICAL PREPARATION

# CREAMS / OINTMENT

#### TOPICAL PREPARATION

#### CREAMS / OINTMENT

#### 1. ADAPALENE 0.1% W/W + PRESERVATIVE GEL

#### SALIENT ACTIONS:

Adapalene normalizes the differentiation of follicular epithelial cells resulting in decreased microcomedone formation. It binds to specific retinoic acid nuclear receptors.

#### INDICATIONS:

Acne vulgaris

#### DOSAGE REGIMEN:

Adult: As 0.1% sol/cream/gel or 0.3% gel: Apply thinly onto affected areas once daily at night after cleansing. **CONTRAINDICATIONS**:

#### NIA

NA

#### PRECAUTIONS:

Not intended for application to broken, sunburnt or eczematous skin. Pregnancy and lactation Patient Counselling Avoid exposure to excessive sunlight and UV irradiation.

#### INTERACTIONS:

Additive irritant effects with peeling agents, astringents, abrasive cleaners, strong drying agents or irritant products (e.g. aromatic and alcoholic agents).

#### ADVERSE ACTIONS:

Mild skin irritation, scaling, erythema, dryness, stinging and burning, pruritus, rash, eczema, acne flare, dermatitis, skin discoloration, sunburn.

#### 2. AZELAIC ACID GEL 20%W/W

#### SALIENT ACTIONS:

Azelaic acid is a naturally-occurring aliphatic dicarboxylic acid that inhibits the growth of Propionibacterium acnes and reduces keratinisation, thus restricts the development of comedones.

#### INDICATIONS & DOSAGE:

Acne vulgaris

Adult: As 20% cream: Apply thinly into the affected areas bid (morning and evening) after cleansing. Improvement may be detectable w/n 4 wk. Duration of treatment: Up to 6 mth.

Child: ≥12 yr Same as adult dose.

Topical/Cutaneous

Rosacea

Adult: Apply thinly into the affected areas bid (morning and evening). Improvement occurs in 4-8 wk. Child: ≥12 yr Same as adult dose.

Special Populations: Acne vulgaris: Patients w/ sensitive skin: As 20% cream: Apply once daily (in the evening) for 1 wk then apply bid thereafter.

#### CONTRAINDICATIONS:

Hypersensitivity

#### PRECAUTIONS:

Patient w/ sensitive skin. Not intended for application to broken, sunburnt or eczematous skin. Avoid use of occlusive dressing or wrappings. Pregnancy and lactation. Monitoring Parameters Monitor for hypopigmentation in patients w/ dark complexion.

INTERACTIONS: food interactions - Avoid spicy foods, alcoholic beverages and hot drinks that might provoke erythema, flushing and blushing during treatment of rosacea.

#### ADVERSE REACTIONS:

Burning, erythema, stinging, pruritus, dryness and scaling, peeling, irritation, dermatitis, hypopigmentation, rash, and photosensitivity. Rarely, exacerbation of asthma.

# 3. BECLOMETHASONE DISPROPIONATE 0.025%W/W, 20 gm cream SALIENT ACTIONS:

It is a corticosteroid anhydrous or contains one molecule of water of hydration . A white to cream ,white odorless powder. It beneifit by virtue of its anti-inflammatory Immunosuppressive ,vasoconstrictor & antiproliferative actions. Intesity of action depends on extent of absorption to deeper layers ,thus lipophilicity of compound determine potency to great extent .

#### INDICATIONS & DOSAGE REGIMENS:

Eczema Psoriasis, contact dermatitis, Lichen simplex &planus, Anal &vulval pruiritus, otitis externa, seborrhoeic dermatitis.

Apply topically ,comes in combination with clotrimazole, neomycin .

#### CONTRAINDICATIONS:

Scabies, acne, perioral dermatitis, furunculosis of skin, chickenpox, herpes, untreated fungal infection or bacterial infection, post vaccination skin eruptions

#### PRECAUTIONS:

Sudden withdrawal can produce rebound exacerbation of the condition , Avoid eyes. Use on face or children should be limited to  $5~\mathrm{days}$  .

#### INTERACTION:

Even After topical use ,particularly under a occlusive dressing or when skin is broken ,corticosteroid may be absorbed lead to systemic side effect and drug interactions Use of barbiturate , carbamazepine , Phenytoin , Primidone or rifampicin increased metabolism and reduce effect of steroids .

#### ADVERSE EFFECTS:

Skin atrophy, Vellus growth of hair, Thinning of epidermis Telengiectasia, striae, Delayed wound healing Fungal &bacterial infection, Long term use suppress adrenal pituitary

#### 4. BENZOCAINE GEL

#### **SALIENT ACTIONS:**

Benzocaine, an ester local anaesthetic, blocks the initiation and conduction of nerve impulses by decreasing the neuronal membrane's permeability to Na ions, which results in inhibition of depolarization w/ resultant blockade of conduction.

#### INDICATIONS & DOSAGE:

Surface anaesthesia of mouth and throat

Adult: As gel up to 20%: Apply to affected area up to 4 times daily.

Topical/Cutaneous

Topical analgesia and anaesthesia

Adult: As gel: Apply 3-4 times daily.

#### CONTRAINDICATIONS:

Epiglottis (oral spray), methaemoglobinaemia

#### PRECAUTIONS:

Patient w/ asthma, bronchitis, emphysema, heart disease; smokers. Childn. Pregnancy and lactation.

Monitoring Parameters: Monitor for signs and symptoms of methaemoglobinaemia.

#### INTERACTIONS:

May antagonise the therapeutic effect of sulfonamides. Anticholinesterases may inhibit the metabolism benzocaine.

#### ADVERSE REACTIONS:

Localised burning or erythema, stinging sensation, contact dermatitis, rash, urticaria, methaemoglobinaemia, oedema, tenderness.

#### 5. BENZOYL PEROXIDE 2.5 % W/W, 20 gm gel

#### SALIENT ACTIONS:

Used almost exclusively for Acne, gradually liberates oxygen which kills bacteria, specially anaerobic /microaerophilic. As the powder form can be explosive so mainly made in cream base or gel base.

#### INDICATIONS:

Acne vulgaris & Acne rosecea

#### **DOSAGE REGIMENS:**

Apply &leave on skin for 15 mts the first evening .Increase length of exposure by 15mts each evening until application tolerated for 2 hrs .

#### **CONTRAINDICATIONS:**

Hypersensitivity, Ulcerated lesion on face

#### PRECAUTIONS:

Avoid contact with eye ;eye lids or mucous membrane ,burning and stinging sensation is often felt initially .It can bleach hair & coloured fabrics, Paediatrics: contraindicated, Prgnancy & lactation :safe ,Elderly : use with caution

#### INTERACTIONS:

As it is metabolized in skin to benzoic acid and excreated through urine very less chance of interaction .If used with other Acne drug like Retin –A can lead to increase hypersensitivity to skin .

#### ADVERSE EFFECTS:

Excessive dryness of skin ,irritation, Skin peel Marked scaling of skin, Erythema, Edema, Contact sensitization Increased risk of skin carcinogenicity?

#### 6. BETAMETHASONE CREAM

#### SALIENT ACTIONS:

Betamethasone is a corticosteroid w/ mainly glucocorticoid activity. It induces phospholipase  $A_2$ inhibitory lipase (lipocortins) and sequentially inhibits the release of arachidonic acid, thereby depressing the formation, release, and activity of prostaglandins, leukotrienes, and other inflammatory mediators.

#### INDICATIONS & DOSAGE:

Corticosteroid-responsive dermatoses

Adult: As 0.05% betamethasone dipropionate oint, cream, gel, or lotion: Apply to affected area 1-2 times daily for up to 2 wk. As 0.025 or 0.1% betamethasone valerate cream, oint, or lotion: Apply thinly into affected area 1-3 times daily for up to 4 wk or until improvement occurs. As 0.1% betamethasone valerate soln: Rub gently into affected area bid. As 0.12% betamethasone valerate foam: Massage gently into scalp bid.

Topical/Cutaneous

Mild to moderate plaque psoriasis

Adult: As 0.05% betamethasone dipropionate spray: Apply to affected area bid for up to 4 wk.

#### CONTRAINDICATIONS:

Untreated infections (systemic and topical). Idiopathic thrombocytopenic purpura (IM).

#### PRECAUTIONS:

Patient w/ history of severe affective disorder esp steroid psychosis, osteoporosis, CHF or HTN, recent MI, DM, history of TB, glaucoma, corticosteroid-induced myopathy, epilepsy, peptic ulceration, hypothyroidism, myasthenia gravis; psoriasis (topical). Renal and hepatic impairment. Childn. Pregnancy and lactation. Patient Counselling Avoid abrupt withdrawal. Avoid exposure to chickenpox or measles.

Monitoring Parameters Monitor for hypothalamic-pituitary-adrenal (HPA) axis suppression, esp in childn.

#### INTERACTIONS:

Increased plasma concentration when used w/ CYP3A4 inhibitors (e.g. ritonavir, itraconazole), and OCs. Decreased therapeutic effect when concurrently used w/ rifampicin, rifabutin, carbamazepine, phenobarbitone, phenytoin, primidone, aminoglutethimide and ephedrine. May antagonise the effect of hypoglycaemic agents, antihypertensives, neuromuscular blockers (e.g. vecuronium), and diuretics. Increased risk of hypokalaemia w/ acetazolamide, loop/thiazide diuretics, carbenoxolone, theophylline, cardiac glycosides. May inhibit the growth promoting effects of somatropin. Increased risk of tendon rupture w/ concurrent use of fluoroquinolones. May increase the metabolism of quetiapine and tretinoin. Increased risk of GI bleeding when used w/ NSAIDs. May enhance the efficacy of coumarin anticoagulants.

#### 7. CALCITRIOL (Ointment)

#### SALIENT ACTIONS:

Calcitriol promotes Ca absorption in the intestines and retention at the kidneys thus increasing serum Ca levels. It also increases renal tubule phosphate resorption, consequently decreasing serum phosphatase levels, PTH levels and bone resorption.

#### INDICATIONS & DOSAGE:

Topical/Cutaneous

Mild to moderate plaque psoriasis

Adult: As 3 mcg/g oint: Apply to affected areas bid, in the morning and in the evening before retiring and after washing. It is recommended that not more than 35% of body surface be exposed to daily treatment. Max: 30 g daily. Max duration: 6 wk.

#### CONTRAINDICATIONS:

Diseases associated w/ hypercalcaemia, evidence of metastatic calcification and vit D toxicity.

#### PRECAUTIONS:

Patient w/ malabsorption syndrome. Renal or hepatic impairment. Pregnancy and lactation. Patient Counselling Maintain adequate fluid intake. Avoid uncontrolled intake of additional Ca-containing preparations. Monitoring Parameters Periodically monitor serum Ca, Mg, phosphorus and alkaline phosphatase and 24-hr urinary Ca and

phosphorus. During initial phase, determine serum Ca and phosphorus at least twice wkly.

#### INTERACTIONS:

Increased risk of hypercalcaemia w/ thiazide diuretics. Hypercalcaemia in patients on digitalis may precipitate cardiac arrhythmias. Mg-containing drugs (e.g. antacids) may cause hypermagnesaemia in patients undergoing chronic renal dialysis. Bile acid sequestrants including colestyramine and sevelamer may impair intestinal absorption of calcitriol. CYP450 enzyme-inducing anticonvulsants (e.g. carbamazepine, phenobarbital, phenytoin) may reduce effects of vit D. Corticosteroids w/ glucocorticoid activity may counteract the effects of calcitriol in bone and mineral metabolism.

#### ADVERSE REACTIONS:

Weakness, headache, somnolence, nausea, vomiting, dry mouth, constipation, muscle and bone pain, metallic taste, anorexia, abdominal pain and epigastric discomfort; polyuria, polydipsia, wt loss, nocturia, conjunctivitis (calcific), pancreatitis, photophobia, rhinorrhoea, pruritus; hyperthermia, decreased libido; elevated BUN, albuminuria; hypercholesterolaemia, elevated AST and ALT, ectopic calcification, HTN, cardiac arrhythmias, nephrocalcinosis, sensory disturbance, dehydration, apathy, occasional mild pain on inj site. Rarely, overt psychosis.

# 8. CALENDULA OFFICINALIS CRM OINTMENT SALIENT ACTIONS:

Calendula officinalis is an aromatic annual plant, which is rich in oxygenated monoterpenes and sesquiterpenes. Calendula extract contains significant essential oil concentrations, flavonoids (especially quercetrin-3-O-glycoside) and a variety of triterpene alcohols. Calendula also contains phenol acids, tannins, carotenoids, saponosides, coumarins and polysaccharides (mucilage). Its most common cosmeceutical properties include repithelization and wound healing. Calendula extract also has demonstrable and clinically significant moisturizing activity in dry, irritated or delicate skin as well as an anti-irritant, anti-inflammatory and immunomodulatory actions.

#### INDICATION & DOSAGE:

Topical

acne, reducing inflammation, controlling bleeding, and soothing irritated tissue. [11][12] Limited evidence indicates *Calendula* cream or ointment is effective in treating radiation dermatitis.

#### CONTRAINDICATIONS:

hypersensitivity

#### PRECAUTIONS:

Limited evidence is available to guide usage in pregnancy.

#### **INTERACTIONS:**

NA

#### ADVERSE REACTIONS:

Allergic reactions, contact sensitization, and one case of anaphylaxis have been reported

#### 9. CLINDAMYCIN PHOSPHATE 1% GEL

#### SALIENT ACTIONS:

Clindamycin inhibits protein synthesis by reversibly binding to the 50S ribosomal subunit, thus blocking the transpeptidation or translocation reactions of susceptible organisms resulting to stunted cell growth.

#### INDICATIONS & DOSAGE:

Topical/Cutaneous

Acne

Adult: As 1% preparation: Apply a thin layer onto affected area bid.

Vaginal

Bacterial vaginosis

Adult: As pessary or 2% cream: 100 mg at bedtime for 3-7 days.

#### **CONTRAINDICATIONS:**

Hypersensitivity to clindamycin or lincomycin.

#### PRECAUTIONS:

Patient w/ history of GI disease particularly colitis, atopic individuals. Not intended for the treatment of CNS infections. Severe renal and/or hepatic impairment. Pregnancy and lactation. Monitoring ParametersMonitor CBC, liver and renal function during prolonged therapy.

#### INTERACTIONS:

May enhance the action of neuromuscular blocking agents (e.g. atracurium). May antagonise the effects of parasympathomimetics. May competitively inhibit the effects of macrolides, ketolides, streptogramins, linezolid and chloramphenicol. Increased coagulation tests (prothrombin time/INR) and/or bleeding w/ vit K antagonists (e.g. warfarin, acenocoumarol, fluindione).

#### ADVERSE REACTIONS:

Nausea, vomiting, abdominal pain or cramps, taste disturbances, oesophagitis, oesophageal ulceration, rashes, urticaria, erythema multiforme, Stevens-Johnson syndrome, drug rash w/ eosinophilia and systemic symptoms (DRESS), exfoliative and vesiculobullous dermatitis, leucopenia, agranulocytosis, eosinophilia, thrombocytopenia, polyarthritis, renal dysfunction (e.g. azotemia, oliguria, proteinuria), local irritation, skin dryness, contact dermatitis, cervicitis, vaginitis, vag candidiasis, vulvovaginal irritation, sterile abscess and thrombophlebitis.

Potentially Fatal: Clostridium difficile-associated diarrhoea (CDAD) or pseudomembranous colitis, toxic epidermal necrolysis (TEN).

#### in LFTs.

#### 10. CLOBETASONE BUTYRATE 0.05%W/W + CHLOROCRESOL 0.1% W/W, 15 gm cream SALIENT ACTIONS:

Clobetasone butyrate is a glucorticosteroid ,used mainly in treatment of various skin disease . It is usually used as cream or ointment containing 0.05%.

#### INDICATIONS:

Eczema psoriasis, contact dermatitis, lichen simplex &planus, anal &vulval pruiritus, otitis externa, seborrhoeic dermatitis

#### DOSAGE REGIMENS:

As directed by physician

#### **CONTRAINDICATIONS:**

Scabies, acne, perioral dermatitis, furunculosis of skin, chickenpox, herpes, untreated fungal infection or bacterial infection, post vaccination skin eruptions

#### PRECAUTIONS:

Sudden withdrawal can produce rebound exacerbation of the condition, Avoid eyes. Use on face or children should be limited to 5 days.

#### **INTERACTIONS:**

Even After topical use ,particularly under a occlusive dressing or when skin is broken ,corticosteroid may be absorbed lead to systemic side effect and drug interactions. Use of barbiturate, carbamazepine, Phenytoin, Primidone or rifampicin increased metabolism and reduce effect of steroids.

#### ADVERSE EFFECTS:

Skin atrophy, Vellus growth of hair, Thinning of epidermis Telengiectasia, striae, Delayed wound healing Fungal &bacterial infection, Long term use suppress adrenal pituitary

#### 11. CLOBETASOLE PROPIONATE 0.05%, cream

#### SALIENT ACTIONS:

It is a glucorticosteroid ,used mainly in treatment of various skin disease. It is usually used as cream or ointment containing 0.05%. It comes in combination with antimicrobial drugs like Gentamycin , Miconazole etc . INDICATIONS:

Secondary bacterial and/or candidal infection is present, when using occlusive dressing such as Psoriasis, recalcitrant eczema, Lichen planus, DLE, Other condition that do not respond to other less active steroids

#### DOSAGE REGIMNS:

Used topically

#### CONTRAINDICATIONS:

Rosacea, Acne vulgaris, Perioral dermatitis, Primary cutaneous viral infection (herpes simplex, chickenpox) PRECAUTIONS:

HPA axis suppression, Cushing syndrome, Hyperglycemia, Glycosuria, Not recommended in under 12 yrs age. INTERACTIONS:

Use of barbiturate, carbamazepine, Phenytoin, Primidone or rifampicin increased metabolism and reduce effect of steroids

#### ADVERSE EFFECTS:

Burning &stinging sensation, Itching, atrophy of skin, Cracking &fissuring of skin, Erythema, Folliculitis Telengiectasia

#### 12. CLOTRIMAZOLE 1.0% W/W, 15 gm cream

#### SALIENT ACTIONS:

It is a synthetic Imidazole broad-spectrum antifungal with antimicrobial activity. It binds to phospholipids in the cell membrane altering cell wall permeability causing a loss in essential intracellular elements.

#### INDICATIONS:

Superficial candidiasis, Candida vulvo vaginits, Pityriasis versicolor, Dermatophytosis, Dusting powder for athlete feet, Ring worm infection of skin folds, Dosages :cream or solution to be applied 2-3 times daily for 3-4 weeks

#### **CONTRAINDICATIONS:**

Hypersensitivity. Not for ophthalmic use.

#### PRECAUTIONS:

Intravaginal prepration may damage latex contraceptive so additional contraceptive measures are necessary Pregnancy Category (US FDA) - B. Avoid contact with eyes upon topical application. Childn <3 yrs. Pregnancy, lactation

#### **INTERACTIONS:**

Antagonise with polyene antibiotics

#### ADVERSE EFFECTS:

Local irritation, erythema, stinging, burning sensation, itching, contact allergic dermatitis

#### 13. CLOTRIMAZOLE 1.0% W/W +BECLOMETHASONE DISPROPIONATE 0.025%W/W, 15 gm cream

#### SALIENT ACTIONS:

Clotrimazole is a broad-spectrum antifungal which binds to phospholipids in the cell membrane altering cell wall permeability causing a loss in essential intracellular elements. Beclomethasone is corticosteroid with antiinflammatory property.

#### INDICATIONS:

Superficial candidiasis ,candida vulvo vaginits, pityriasis versicolor, dermatophytosis, dusting powder for athlete feet, ring worm infection of skin folds

#### DOSAGE REGIMENS:

Cream or solution to be applied 2-3 times daily for 3-4 weeks

#### CONTRAINDICATIONS:

Not for ophthalmic use.

#### PRECAUTIONS:

Intravaginal prepration may damage latex contraceptive so additional contraceptive measures are necessary

#### INTERACTIONS:

Antagonise with polyene antibiotics

#### ADVERSE EFFECTS:

Local irritation, Burning sensation, Itching, Contact allergic dermatitis

#### 14. DESONIDE 0.05% W/W CREAM

#### SALIENT ACTIONS:

Desonide is a synthetic corticosteroid that induces phospholipase A2 inhibitory proteins (lipocortins) and sequentially inhibits release of arachidonic acid, hence depresses the formation, release, and activity of chemical inflammatory mediators.

#### INDICATIONS & DOSAGE:

Topical/Cutaneous

Corticosteroid-responsive dermatoses

Adult: As 0.05% cream, oint, or lotion: Apply sparingly onto the affected areas 2-4 times daily until optimal response is achieved. Max duration of therapy: 8 wk.

Child: ≥2 yr Same as adult dose.

Topical/Cutaneous

Atopic dermatitis

Adult: As 0.05% foam or gel: Apply to affected area(s) bid. Max duration of therapy: 4 wk.

Child:  $\geq 3$  mth Same as adult dose.

#### PRECAUTIONS:

Childn. Pregnancy and lactation. Patient Counselling Avoid use w/ occlusive dressing. Desonide foam is flammable, do not smoke during or immediately after application. Monitoring Parameters Monitor for hypothalamic-pituitary-adrenal (HPA) axis suppression thru ACTH stimulation test, plasma cortisol test and urinary free cortisol test; signs and symptoms of bacterial or fungal infection.

#### INTERACTIONS:

Enhanced effect w/ other topical corticosteroids.

#### ADVERSE REACTIONS:

Pruritus, pain, folliculitis, rash, peripheral oedema, pustular rash, sweating, erythema, irritation, burning, itching, dryness, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, skin maceration/atrophy, secondary infection, striae and miliaria. Adrenal suppression, manifestations of Cushing syndrome, hyperglycaemia or glycosuria, facial swelling, withdrawal syndrome, growth retardation in childn (systemic).

#### 15. DINOPROSTONE 0.5 mg gel

#### SALIENT ACTIONS:

Prostaglandin, agent for cervical ripening, stimulates gravid uterus to contract; also stimulates smooth muscle of gi tract.

#### INDICATIONS & DOSAGE REGIMENS:

Gel -Cervical ripening in pregnant women at or near term with need for labor induction.

Vaginal suppositories-Termination of pregnancy from 12 to 20 wk.

Cervical Ripening-Intravaginal Gel 0.5 mg (contents of one syringe); may repeat dose 6 h later if necessary (max dose 1.5 mg (3 syringes/24 h).Intravaginal Insert 10 mg (1 insert). Releases approximately 0.3 mg/h over 12 h. Remove insert upon onset of active labor or 12 h after insertion. Termination of Pregnancy-Intravaginal 1 suppository (20 mg) high into vagina. Repeat at 3 to 5 h intervals until abortion occurs. Do not give continuously for longer than 2 days.

#### CONTRAINDICATIONS:

Hypersensitivity to prostaglandins; patients in whom oxytocic drugs are contraindicated or when prolonged contractions of uterus are considered inappropriate; ruptured membranes; placenta previa; unexplained vaginal bleeding during current pregnancy; when vaginal delivery is not indicated; acute pelvic inflammatory disease; active cardiac, pulmonary, renal or hepatic disease.

#### INTERACTIONS:

Oxytocic agents-May augment effect of other oxytocic agents. Use with caution in patients with asthma, glaucoma, or raised IOP, hypotension or hypertension, cardiovascular or renal or hepatic function impairment, anemia, jaundice, diabetes, epilepsy, compromised uterus, infected endocervical lesions; acute vaginitis.

#### ADVERSE DRUG REACTIONS:

Cardiovascular-Transient fall in BP; syncope; dizziness; arrhythmias.CNS-Headache; flushing; anxiety; tension; hot flashes; paresthesia; weakness.,Blurred vision; eye pain.Anorexia; nausea; vomiting;

diarrhea.GenitourinaryUterine contractile abnormality; endometritis; uterine rupture; uterine pain; amnionitis; premature rupture of membranes; vaginal pain; warm feeling in vagina.,Bronchospasm; coughing; dyspnea; wheezing.

#### 16. ESTRIOL BP 1 GM CREAM

#### SALIENT ACTIONS:

Estriol (E3) is a steroid, a weak estrogen, and a minor female sex hormone. Estriol is an estrogen, specifically an agonist of the estrogen receptors  $ER\alpha$  and  $ER\beta$ .

#### INDICATIONS:

Estriol is used to mimic the activity of the naturally occurring female sexhormone oestrogen, and it helps to restore the natural balance of this hormone in the body.

It is a hormone known as oestrogen, sometimes known as hormone replacement therapy (HRT).

It is used to treat problems associated with the vagina that are caused by a lack of oestrogen in the body. It is used to relieve symptoms that start to occur when the female body no longer produces certain hormones such as oestrogen. This may occur after the change of life, also known as the menopause, or after surgery to remove the ovaries.

In general this drug is used to treat symptoms associated with a lack of oestrogen in women who have gone through the menopause (change of life) or after surgical removal of the ovaries.

Benefits of being on this drug can include relief from symptoms associated with a lack of oestrogen including dryness and itching of the vagina, uncomfortable or painful sexual intercourse. typical uses of estriol.

- Treatment of symptoms associated with a lack of oestrogen
- · To help wound healing after vaginal surgery

#### DOSAGE REGIMENS:

The recommended adult dose of conjugated estrogens vaginal cream ranges from 0.5 g to 2 g of cream daily. **CONTRAINDICATIONS:** 

It should not be used in: women who have an allergy to estriol, soya or peanuts or to any other ingredients in the medicine, angina (a heartcondition), women who have had a heart attack or blood clot (thrombosis), heart disease, women who have had breast cancer, liver problems, women who have had cancer of other sex organs, unexplained vaginal bleeding, untreated unusual growth of the lining of the womb (endometrial hyperplasia), the rare condition porphyria, pregnancy, breast-feeding.

#### PRECAUTIONS:

Estriol should be used with caution in: women who have or have had unusual growth of the lining of the womb (endometrial hyperplasia), asthma, circulatory diseases, kidney disease, fitting (epilepsy), gallstones, high blood pressure, migraine headache, diabetes, deafness caused by thickened ear tissue, the rare disease systemic lupus erythematosus (SLE), fibroids (growths) in the womb (uterus), endometriosis (tissue that lines the womb grows in other areas outside the womb), patients with high levels of cholesterol in their blood (hypercholesterolaemia), women with relatives who have had blood clots, women with blood clotting problems requiring treatment with warfarin, women using a barrier method of contraception including condoms or a diaphragm, women whose close relatives have had breast cancer or cancer of the lining of the womb, patients who are overweight, women who have had one or more miscarriage, women who are not very active because of major surgery, injury or illness.

#### INTERACTIONS:

- Phenobarbital
- Phenytoin
- Carbamazepine
- Rifampicin
- Rifabutin
- Nevirapine
- Efavirenz
- Ritonavir
- Nelfinavir
- BosentanLamotrigine

#### ADVERSE EFFECTS:

- Undiagnosed abnormal genital bleeding.
- · Known, suspected, or history of cancer of the breast.
- · Known or suspected estrogen-dependent neoplasia.
- Active deep vein thrombosis, pulmonary embolism or history of these conditions.
- Active or recent (e.g., within the past year) arterial thromboembolic disease (e.g., stroke, myocardial infarction).
- Liver dysfunction or disease.
- · Known hypersensitivity to Estradiol or any other ingredients present in Evalon Cream.
- Known or suspected pregnancy.

#### 17. FLUOROURACIL(1% CREAM)

#### SALIENT ACTIONS:

Fluorouracil is an antineoplastic antimetabolite

#### INDICATIONS:

Fluorouracil Cream is indicated for the topical treatment of actinic keratosis lesions of the face, ears, and/or scalp.

#### DOSAGE REGIMENS:

once daily in an amount sufficient to cover the lesions of the face, ears, and/or scalp with a thin film, using the fingertips to gently massage the medication uniformly into the skin. Apply Cream for a period of 4 weeks as tolerated.

#### CONTRAINDICATIONS:

- During pregnancy
- In patients with dihydropyrimidine dehydrogenase (DPD) deficiency

#### PRECAUTIONS:

N/A

#### INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

- Photosensitivity
- · Embryofetal toxicity

#### 18. FLUTICASONE(CREAM)

#### **SALIENT ACTIONS:**

Fluticasone is classed as a **potent** topical corticosteroid. Topical corticosteroids are also referred to as topical steroids. Topical steroids are used in addition to moisturisers (emollients) for treating inflammatory skin conditions such as eczema and dermatitis. A topical steroid is used when patches of eczema or dermatitis flare up. Fluticasone relieves the symptoms of a flare-up by reducing inflammation, itching and redness.

#### INDICATIONS:

This medication is used to treat a variety of skinconditions (such as eczema, psoriasis, rash). Fluticasonereduces swelling (inflammation), itching, and redness.

#### DOSAGE REGIMENS:

Apply a thin film to affected area twice a day

#### CONTRAINDICATIONS:

N/A

#### PRECAUTIONS:

N/A

#### INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

Burning, itching, stinging, or dryness

#### 19. FUSIDIC ACID 20 mg, 5 gm cream

#### SALIENT ACTIONS:

Potent topical antibacterial action inhibit nearly all strains of *staphylococcus aureus*. Topical application of fusidic acid is also effective against streptococci, corynebacteria, neisseria and certain clostridium

#### INDICATIONS:

Eczema and dermatitis with secondary bacterial infections, atopic eczema, primary irritant dermatitis and allergic and seborrhoeic dermatitis where the organisms responsible are known to be or believed to be sensitive to fusidic acid.

#### DOSAGE REGIMENS:

Adults and Children: Uncovered lesions – a small quantity should be applied to the affected area twice daily until a satisfactory response is obtained. A single treatment course should not normally exceed 2 weeks.

#### CONTRAINDICATIONS:

Hypersensitivity. contra-indicated in primary bacterial, viral and fungal skin infections, skin manifestations in relation to tuberculosis or syphilis, perioral dermatitis and rosacea.

#### PRECAUTIONS:

Not be used in or near the eye as causes conjunctival irritation., contact sensitisation and the development of antibiotic resistance.

#### INTERACTIONS:

None known

# 20. FUSIDIC ACID 2 mg + BETAMETHASONE 1.2 mg, 5 gm cream SALIENT ACTIONS:

Topical antibacterial action of fusidic acid with the anti-inflammatory and antipruritic effects of betamethasone. fusidic acid inhibit nearly all strains of *staphylococcus aureus*. Topical application of fusidic acid is also effective against streptococci, corynebacteria, neisseria and certain clostridia

#### INDICATIONS:

Eczema and dermatitis with secondary bacterial infections, atopic eczema, primary irritant dermatitis and allergic and seborrhoeic dermatitis where the organisms responsible are known to be or believed to be sensitive to fusidic acid

#### DOSAGE REGIMENS:

Adults and Children: Uncovered lesions – a small quantity should be applied to the affected area twice daily until a satisfactory response is obtained. A single treatment course should not normally exceed 2 weeks.

#### CONTRAINDICATIONS:

Hypersensitivity to fusidic acid and its salts. As with other topical corticosteroid preparations, primary bacterial, viral and fungal skin infections, skin manifestations in relation to tuberculosis or syphilis, perioral dermatitis and rosacea.

#### PRECAUTIONS

Not be used in or near the eye as sodium fusidate causes conjunctival irritation. Bacterial resistance has been reported to occur with the use of fusidic acid applied topically. As with all topical antibiotics, extended or recurrent application may increase the risk of contact sensitisation and the development of antibiotic resistance. Steroid-antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement since in this situation occult extension of the infection may occur due to the masking of the steroid. Similarly, steroids may also mask hypersensitivity reactions. Not recommended in the following conditions: atrophic skin, cutaneous ulcer, acne vulgaris, fragile skin veins and perianal and genital pruritus. Contact with open wounds and mucous membranes should be avoided. As with all corticosteroids, prolonged use on the face should be avoided. In infants and children, long-term continuous topical therapy with corticosteroids should be avoided. Adrenal suppression can occur even without occlusion.

#### INTERACTIONS:

None known.

# 21. HALOBETASOL PROPIONATE 0.05%W/W 15 GM CREAM SALIENT ACTIONS:

This medication is used to treat a variety of skin conditions (e.g., eczema, dermatitis, allergies, rash). Halobetasol reduces the swelling, itching, and redness that can occur in these types of conditions. This medication is a very strong (super-high potency) corticosteroid.

#### INDICATIONS:

This medication is used to treat a variety of skin conditions (e.g., eczema, dermatitis, allergies, rash).

#### DOSAGE REGIMENS:

Apply a thin layer of the ointment, cream, or lotion to your affected skin once or twice per day **CONTRAINDICATIONS**:

Halobetasol propionate cream is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

#### PRECAUTIONS:

Halobetasol propionate cream should not be used in the treatment of rosacea or perioral dermatitis, and it should not be used on the face, groin, or in the axillae.

#### INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

dry skin, erythema, skin atrophy, leukoderma, vesicles and rash folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, striae and miliaria.

# 22. HEPARIN SODIUM. 50 IU + BENZYL NICOTINATE 2 mg, 20 gm ointment INDICATIONS:

superficial thrombophlebitis (superficial vein inflammation), pain in dilated veins area, pains and cramps in the leg muscles, disturbances of lymph circulation, sporting and traffic injuries(hematomas, contusions, sprains)

disturbed lymph circulation, postoperative and posttraumatic scars, non-joint rheumatism or soft tissue rheumatism

#### DOSAGE REGIMENS:

Heparin Sodium 50 I.U. + Benzyl Nicotinate 3 mg Cream should be applied 2 to 4 times a day to the affected skin surface, in the layer of about 2mm thick and gently rubbed in until absorbed. In case when cream rubbing is to be avoided (for example in thrombophlebitis), it is recommended to put an elastic or occlusive bandage over the applied cream.

#### CONTRAINDICATIONS:

This medicine should not be used if you are allergic to one or any of its ingredients. Please inform your doctor or pharmacist if you have previously experienced such an allergy. If you feel you have experienced an allergic reaction, stop using this medicine and inform your doctor or pharmacist immediately.

#### INTERACTIONS:

Inhibited by Zinc ,antiplatelets may ppt bleeding ,NSAIDS ,Dextrans may increase effect

#### ADVERSE EFFECTS:

Flushing of the skin due to widening of the small blood vessels (erythema), Allergy to one or more of the ingredients (hypersensitivity).

#### 23. HYDROCORTISONE ACETATE 1%(CREAM)

#### **SALIENT ACTIONS:**

Hydrocortisone acetate reduces the swelling, **itching**, and **redness** that can occur in these types of conditions. This medication is a **mild** corticosteroid.

#### INDICATIONS:

- Allergic contact dermatitis
- Irritant contact dermatitis
- Insect bite reactions
- Mild to moderate eczema

#### DOSAGE REGIMENS:

It is generally applied to the affected area as a thin film two to four times daily, depending on the severity of the condition. Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions. If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

#### CONTRAINDICATIONS:

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

#### PRECAUTIONS:

The product should not be used during pregnancy or breast-feeding unless recommended by a health care professional (see section 4.6).

Prolonged use of the product is not recommended (see section 4.2) as continuous application without interruption will result in local atrophy of the skin, striae and superficial vascular dilatation, particularly of the face.

Prolonged use of uninterrupted occlusion or use with extensive occlusive dressings may suppress adrenocortical function.

This product contains ceteostearly alcohol which my cause local skin reactions (e.g. contact dermatitis).

#### INTERACTIONS:

N/A

#### ADVERSE EFFECTS:

- Burning
- Maceration of the skin
- Acneiform eruptions
- Irritation
- Skin atrophy
- Perioral dermatitis
- Folliculitis
- Miliaria

- Hypertrichosis
- Itching
- · Secondary infection
- Hypopigmentation
- Dryness
- Striae
- · Allergic contact dermatitis

#### 24. LIDOCAINE HCL 2.0 % W/V, 30 gm gel

#### SALIENT ACTIONS:

Very commonly used local anaesthetic with a quick onset of action (within 3 minutes) and high degree of penetration, the duration of action is 30 to 60 minutes but addition of adrenaline (1 in 2,00.000) prolongs the action for about 2 hours

#### INDICATIONS:

Surface application .infiltration anaesthesia, intravenous regional anaesthesia, nerve block topically, effusive etc, for rectal vaginal .otological & throat examination, cystoscopy, catheterisation. urethral operations, endotracheal intubation.

#### CONTRAINDICATIONS:

Hypersensitivity, conduction defects

#### INTERACTIONS:

Adrenaline reduces absorption of lidocaine propranolol increase lidocaine levels.

#### ADVERSE EFFECTS:

Bradycardia, hepatic, convulsions,tremor,dizziness, nervousness, nausea, respiratory arrest, cardiovascular collapse and cardiac arrest can occur if drug enters systemic circulation in high concentrations

#### 25. LULICONAZOLE 1%W/W CREAM

#### SALIENT ACTIONS:

Is an <u>imidazole antifungal</u> drug. As a 1% <u>topical</u> cream, It is indicated for the treatment of <u>athlete's foot, jock itch</u>, and <u>ringworm</u> caused by <u>dermatophytes</u> such as <u>Trichophyton rubrum</u>, <u>Microsporum</u> and <u>Epidermophyton floccosum</u>.

#### INDICATIONS & DOSAGE REGIMENS:

#### Usual Adult Dose for Tinea Pedis

Apply a thin layer to the affected area and about 1 inch of the immediate surrounding area(s) once a day for 2 weeks

Use: For the topical treatment of interdigital tinea pedis due to Trichophyton rubrum and Epidermophyton floccosum

Usual Adult Dose for Tinea Corporis

Apply to the affected area and about 1 inch of the immediate surrounding area(s) once a day for 1 week Uses: For the topical treatment of tinea cruris and tinea corporis due to T rubrum and E floccosum Usual Adult Dose for Tinea Cruris.

Apply to the affected area and about 1 inch of the immediate surrounding area(s) once a day for 1 week Uses: For the topical treatment of tinea cruris and tinea corporis due to T rubrum and E floccosum

#### CONTRAINDICATIONS:

None

#### ADVERSE DRUG REACTIONS:

allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue increased inflammation, redness, or pain.

#### 26. MUPIROCIN 2.0% W/W, 5 gm oint

#### SALIENT ACTIONS:

Natural product by Pseudomonas fluorescence. Mupirocin is antibiotic used topically as ointment. It inhibits and kills staphylococci by inhibiting isoleucyl+RNA synthetase.

#### INDICATIONS

Minor skin infections like impetigo, intra nasal application of methicillin resistant S. aureus carriage by patients or health care workers. Staphylococcal folliculitis, furunculosis. Secondary infection like infected dermatosis

#### DOSAGE REGIMENS:

Three times a day up to 10 days.

#### CONTRAINDICATIONS:

Hypersensitivity

#### PRECAUTIONS:

Avoid contact with the eyes. The use over large infected areas like decubitus ulcers or open surgical wounds is not recommended due to emergence of mupirocin resistant strains.use with caution in children &avoid in pregnancy and lactation.Procainamide increases potential for cardiac

#### **DRUG INTERACTIONS:**

Mixing mupirocin ointment with other prep may dilute its content and lead to less effect.

#### ADVERSE EFFECTS:

Irritation, stinging, burning. Itching. erythema, dryness in localized area

#### 27. MICONAZOLE NITRATE 2% W/W CREAM

#### SALIENT ACTIONS:

is an <u>antifungal medication</u> used to treat <u>ring worm</u>, <u>pityriasis versicolor</u>, and <u>yeast infections</u> of the skin or vagina It is applied to the skin or vagina as a cream or ointment.

#### INDICATIONS:

Miconazole is mainly used externally for the treatment of <u>athlete's foot</u>, <u>ringworm</u>, and <u>jock itch</u>. Internal application is used for <u>oral</u> or <u>vaginal thrush</u> (<u>yeast infection</u>). The oral gel may also be used for the lip disorder <u>angular cheilitis</u>.

#### INTERACTIONS:

Interactions are possible with <u>anticoagulants</u>, <u>phenytoin</u>, <u>terbinafine</u>, <u>[citation needed]</u>, some newer <u>atypical</u> <u>antipsychotics</u>, <u>cyclosporin</u>, and some <u>statins</u> used to treat <u>hypercholesterolemia</u>.

#### PRECAUTIONS:

Intravaginal prepration may damage latex contraceptive so additional contraceptive measures are necessary Pregnancy Category (US FDA) – B.Avoid contact with eyes upon topical application. Childn <3 yrs. Pregnancy, lactation

#### ADVERSE EFFECTS:

Local irritation, erythema, stinging, burning sensation, itching, contact allergic dermatitis

#### 28. MOMETASONE FUROATE IP 0.1%W/W CREAM

#### SALIENT ACTIONS:

Mometasone depresses the formation, release and activity of endogenous inflammatory chemical mediators (e.g. kinins, histamine, liposomal enzymes and prostaglandin). It inhibits the margination and subsequent cell migration to the injury site, reverses vascular dilatation and permeability, resulting in decreased access of cells to the area of injury.

#### INDICATIONS & DOSAGE REGIMENS:

#### Corticosteroid-responsive dermatoses

Adult: As 0.1% cream/oint: Apply a thin film to affected area once daily. As 0.1% lotion: Apply a few drops to affected area once daily, massage lightly until it disappears.

Child:  $\geq 2$  yr As 0.1% cream/oint: Apply a thin film to affected area once daily for not more than 3 wk.  $\geq 12$  yr As 0.1% lotion: Same as adult dose.

#### PRECAUTIONS:

Patient w/ heart failure, DM, GI disorders, myasthenia gravis, acute MI, cataracts/glaucoma, thyroid disease; history of seizure disorders; untreated localised infection of the nasal mucosa (e.g. herpes simplex), recent nasal surgery/trauma; patient w/ or at risk of osteoporosis. Patient w/ facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, perianal/genital pruritis, napkin eruptions; bacterial, viral, parasitical and fungal infections; varicella, syphilis or post-vaccine reactions. Avoid abrupt withdrawal when switching from systemic to oral or orally inhaled corticosteroid. Hepatic and renal impairment. Pregnancy and lactation. *Monitoring Parameters* Monitor pulmonary function, signs/symptoms of candidiasis, ocular effects.

#### INTERACTIONS:

Strong CYP3A4 inhibitors (e.g. ketoconazole) may increase systemic exposure of mometasone.

#### ADVERSE EFFECTS:

Hypothalmic-pituitary-adrenal (HPA) axis suppression, immunosuppression, Kaposi sarcoma, oral candidiasis, psychiatric disturbances, headache, allergic rhinitis, pharyngitis, upper resp tract infection, sinusitis,

dysmenorrhoea, musculoskeletal pain, back pain, dyspepsia, myalgia, abdominal pain, nausea.

Potentially Fatal: Paradoxical bronchospasm, anaphylaxis.

#### 29. NADIFLOXACIN 1% CREAM

#### SALIENT ACTION:

Nadifloxacin <u>inhibits</u> the enzyme <u>DNA gyrase</u> that is involved in bacterial DNA synthesis and replication, thus inhibiting the bacterial multiplication. Nadifloxacin in addition to determine a therapeutic antibacterial action, can have a sebostatic and anti-inflammatory action, thus contributing to the improvement of the clinical condition of the patient.

#### INDICATIONS & DOSAGE REGIMENS:

Treatment of acne vulgaris

Treatment of bacterial skin infections

should be applied to the lesions twice daily. In case of acne, it should be applied after washing the face.

#### **CONTRAINDICATIONS:**

contraindicated in those patients with a history of hypersensitivity reactions to any of its components.

#### PRECAUTIONS:

#### General

As a rule, susceptibility testing should be performed prior to the actual use of this drug to estimate nadifloxacin susceptibility. To minimize the chance that resistant microorganisms will develop as a result of therapy, the treatment duration should be the shortest feasible.

This drug is intended for topical (dermal) application only and is not intended for ophthalmologic use. The drug should not be applied to the cornea or conjunctiva.

This drug should be discontinued if the desired therapeutic effect is not achieved at the recommended dose.

#### Pregnancy

The safety of this drug for use during pregnancy has not been established (clinical experience in pregnant women is insufficient).

#### Paediatric use

The safety of this drug in children younger than 14 years has not been studied or established.

#### ADVERSE DRUG REACTIONS:

Mild and transient side effects like itching and erythema may occur at the site of application. Other side effects like flushes, papules, feeling of facial warmth, increased sweating, contact dermatitis, and dryness of the skin may infrequently occur. These local side effects are very rare and occur in less than 5% of the patients.

# 30. POVIDINE IODINE 5% W/W, 15 gm ointment SALIENT ACTIONS:

These are soluble complex of iodine with large molecular organic compounds that serve as earner release free iodine slowly. It is non irritating, non-staining nontoxic, exerts prolonged germicidal action. Povidone-iodine is an iodophore with a powerful broad-spectrum germicidal activity against a wide range of bacteria, viruses, fungi, protozoa and spores.

#### **INDICATIONS:**

Boils, bums, furunculosis, otitis externa, ulcers, surgery scrubbing, monilial/trichomonal/ non-specific vaginitis. Candida albicans

#### **CONTRAINDICATIONS:**

Hypersensitivity; prolonged use in patients with thyroid disorders or on lithium therapy. Premature neonates or neonates weighing <1.5 kg.

#### PRECAUTIONS:

Pregnancy Category (US FDA) – D. Avoid contact with eyes; should not be used under occlusive dressing. Pregnancy, lactation; neonates.If Irritation, redness – discontinue.

#### INTERACTIONS:

Lab Interference May interfere with thyroid function test results and interpretation, when applied over large surface areas.

#### **ADVERSE EFFECTS:**

Hypersensitivity to iodine, goiter, Local irritation and sensitivity (rare). Application to large areas of denuded skin may produce systemic effects due to iodine absorption.

#### 31. SALICYLIC ACID 12 % W/W, 30 gm cream

#### SALIENT ACTIONS:

Salicylic acid has a potent keratolytic action and a slight antiseptic action when applied topically. It softens and destroys the stratum corneum by increasing endogenous hydration which causes the horny layer of the skin to swell, soften, and then desquamate. At high concentrations, salicylic acid has a caustic effect. It also possesses weak antifungal and antibacterial activity

#### **INDICATIONS & DOSAGE REGIMENS:**

Hyperkeratotic and scaling skin conditions: As 2-6% preparation; may be applied up to tid.

Acne: 2-6% preparation; may be applied up to tid.

Warts and calluses: Apply 60% salicylic acid preparation

#### PRECAUTIONS:

Not for prolonged use in high concentrations and on large areas of the body. Impaired peripheral circulation or diabetes. Avoid broken skin, mouth, eyes, mucous membranes and anogenital region

#### ADVERSE DRUG REACTIONS:

Irritation, sensitivity, excessive drying; systemic effects on prolonged use

#### 32. SERTACONAZOLE NITRATE CREAM 2% W/W

#### SALIENT ACTIONS:

Sertaconazole alters fungal cell wall membrane permeability. It inhibits the CYP450-dependent synthesis of ergosterol.

#### INDICATION & DOSAGE:

Topical/Cutaneous

Tinea pedis

Adult: As 2% cream: Apply to affected area bid for 4 wk.

#### CONTRAINDICATION:

Hypersensitivity.

#### PRECAUTION:

Discontinue if irritation or sensitivity develop. Pregnancy and lactation. Monitoring Parameters Reassess diagnosis if no clinical improvement after 2 wk.

#### ADVERSE REACTION:

Contact dermatitis, dry skin, burning skin, application site reaction, skin tenderness, erythema, pruritus, vesiculation, desquamation, hyperpigmentation.

#### 33. SILVER NITRATE GEL 0.2%W/W

#### SALIENT ACTIONS:

Silver nitrate inhibits growth of both gram-positive and gram-negative bacteria by precipitating bacterial protein through the release of liberated silver ions. It also forms an eschar by coagulation of cellular proteins.

#### INDICATION & DOSAGE:

Topical/Cutaneous

Prophylaxis of gonococci ophthalmic neonatorum

Child: Neonate: As a 1% solution: To be applied after cleansing of the neonate's eyes immediately after birth.

Topical/Cutaneous

As an antiseptic agent

Adult: As a 0.5% solution: May be applied to severe burns to reduce risk of infection.

#### CONTRAINDICATION:

Hypersensitivity. Applicator sticks not for ophthalmic use.

#### PRECAUTION:

Prolonged use may result to skin discolouration. Protect surrounding skin and avoid broken skin. Not suitable for application to face, ano-genital region or large areas.

#### ADVERSE REACTION:

Pain in the mouth, sialorrhoea, diarrhoea, vomiting, coma and convulsions. Argyria (chronic use); methaemoglobinaemia; electrolyte disturbances. Short-term mild conjunctivitis in infants which may lead to blindness if use repeatedly or with high concentrations.

#### 34. SODIUM FUSIDATE IP 20MG OINTMENT

#### SALIENT ACTIONS:

Fusidic acid disrupts translocation of peptide subunits and elongating the peptide chain of susceptible bacteria, thus inhibiting protein synthesis.

#### INDICATIONS & DOSAGE REGIMENS:

Topical/Cutaneous

Skin infections

Adult: As a 2% ointment/cream/gel: Apply onto affected area 3-4 times daily until there is improvement. If gauze dressing is used, then frequency of application may be reduced to 1-2 times daily.

Child: As a 2% ointment/cream/gel: Apply onto affected area 3-4 times daily until there is improvement. If gauze dressing is used, then frequency of application may be reduced to 1-2 times daily.

#### INTERACTIONS:

Synergistic action with antistaphylococcal penicillin. Antagonism with ciprofloxacin.

#### PRECAUTIONS:

Fusidic acid: Should be taken with food.

Hepatic disease; monitor liver function. Neonates; pregnancy, lactation.

#### CONTRAINDICATIONS:

Hypersensitivity.

#### ADVERSE EFFECTS:

Topical: Rashes and irritation.

#### 35. TACROLIMUS OINTMENT

#### SALIENT ACTIONS:

Tacrolimus inhibits T-lymphocyte activation, although the exact mechanism of action unclear. Tacrolimus bind to cytosolic receptors known as immunophilins (i.e., cyclophilin and FK binding protein-12 [FKBP-12], respectively), forming complexes that inhibit the production of cytokines via the calcineurin pathway. Inhibition of calcineurin activity inhibits early activation of T-cells (ie.immunosuppresion results).

Absorption: Incomplete and variable. Food decreased rate and extent of tacrolimus absorption.

Distribution: 99% bound to plasma protein, mainly to albumin and alpha-1-acid glycoprotein, and has a high level of association with erythrocytes.

#### INDICATIONS & DOSAGE REGIMENS:

Topical/Cutaneous

Atopic dermatitis

Adult: >15 yr: Apply thinly 0.03% or 0.1% ointment to affected area bid. Rub in gently and completely. For short-term and intermittent use only. If no improvement after 6 wk, re-confirm diagnosis.

Child: 2-15 yr: Apply thinly 0.03% oint to affected area bid. Rub in gently and completely. For short-term and intermittent use only.

#### INTERACTIONS:

Increased nephrotoxicity with ciclosporin, aminoglycosides, amphotericin B, cisplatin, NSAIDs, vancomycin, co-trimoxazole, aciclovir, ganciclovir. Increased risk of hyperkalemia with potassium-sparing diuretics. Increased plasma concentrations and toxicity with azole antifungals, calcium-channel blockers, cimetidine, danazol, HIV-protease inhibitors, macrolide antibacterials and metoclopramide. Antacids, rifampin, rifabutin, casofungin, phenytoin, phenobarbital and carbamazepine decrease tacrolimus plasma concentrations. Concurrent admin of sirolimus and tacrolimus decrease levels of both.

#### PRECAUTIONS:

Monitoring of blood trough serum concentrations to prevent organ rejection and to reduce drug-related toxicity. Topical: Used with caution on the face or neck, large areas of the body (not >50% of the total BSA), or areas of broken skin. Infections at the treatment site should be cleared prior to therapy. Delay use in patients with unknown cause of lymphadenopathy or acute infectious mononucleosis till resolution. Use in patients with Netherton's syndrome is not recommended. Pregnancy.

#### CONTRAINDICATIONS:

Hypersensitivity, lactation.

#### ADVERSE EFFECTS:

Systemic: Tremor, headache, paraesthesias, nausea and diarrhoea, hypertension, blood dyscrasias, leucocytosis, impaired renal function, serum electrolyte disturbances, infectious complications. Mood changes, sleep disturbances, confusion, dizziness, tinnitus, visual disturbances convulsions, alterations in glucose metabolism,

ECG changes, tachycardia, myocardial hypertrophy, constipation, dyspepsia and GI haemorrhage; dyspnoea, asthma, pleural effusions; alopoecia, hirsutism, skin rash and pruritus; myalgia, spasm, leg cramps, peripheral oedema, liver dysfunction and coagulation disorders. Topical: Burning, stinging, soreness, pruritus, skin disorders, headache and flu-like symptoms. Increased incidence of malignancy.

Potentially Fatal: Nephrotoxicity, neurotoxicity and anaphylactic reaction.

### 36. TERBINAFINE HCL CREAM 1%W/W SALIENT ACTIONS:

Terbinafine causes fungal cell death by inhibiting squalene epoxidase, the main enzyme in sterol biosynthesis, resulting in ergosterol deficiency within fungal cell walls. It has fungicidal activity against dermatophytes and some yeast.

Absorption: Absorbed well from the GI tract with 40% bioavailability (oral), minimal absorption (topical); peak plasma concentrations after 2 hr (oral).

Distribution: Distributed into stratum corneum of the skin, nail plate, hair (concentrations higher than plasma) and breastmilk. Protein-binding: Extensive.

Metabolism: Hepatic; converted to inactive metabolites.

Excretion: Via urine; 17-36 hr (plasma elimination half-life); up to 400 hr (terminal elimination half-life) in prolonged therapy.

#### INDICATIONS & DOSAGE REGIMENS:

Topical/Cutaneous

Dermatophytosis

Adult: Apply a 1% cream/solution once or bid. 1-2 wk to treat tinea corporis and tinea cruris; 1-wk course is for tinea pedis; 2-wk course in cutaneous candidiasis and pityriasis versicolor

#### INTERACTIONS:

Possible increase in levels in drugs metabolised by CYP450 2D6. Decreased terbinafine concentration with rifampicin; increased terbinafine concentration with cimetidine.

#### PRECAUTIONS:

Preexisting liver or renal impairment, pregnancy. Perform liver function tests prior to oral therapy.

#### CONTRAINDICATIONS:

Hypersensitivity, active or chronic liver disease, lactation.

#### ADVERSE EFFECTS:

Anorexia, nausea, abdominal pain, taste disturbances, diarrhoea, rash, urticaria.

Potentially Fatal: Liver failure, Stevens-Johnson syndrome, neutropaenia.

#### 37. TRETINOIN 0.05% CREAM USP

#### SALIENT ACTIONS:

Tretinoin, a retinoid, is the acid form of vit A. Topically, it decreases cohesiveness of follicular epithelial cells by stimulating mitosis and turnover. This causes extrusion of existing comedones and preventing formation of new ones. Additionally, it has a thinning effect on the stratum corneum. Systemically, it induces cellular differentiation and decreases proliferation of acute promyelocytic leukemia (APL) cells.

Onset: Acne: ≥2 wk, may take ≥7 wk. Facial wrinkles: Up to 6 mth.

#### INDICATIONS & DOSAGE REGIMENS:

Topical/Cutaneous

Mottled hyperpigmentation, roughness and fine wrinkling of photodamaged skin

Adult: As 0.02 or 0.05% cream: Apply a pea-sized amount onto entire face once daily at night. Therapeutic response may be seen after 6 mth.

#### INTERACTIONS:

Increased risk of pseudotumor cerebri/intracranial HTN w/ tetracyclines. Increased skin irritation w/ topical medications, soaps, cleansers, and other cosmetics w/ high conc of alcohol, astringent, spices/lime, or preparations w/ sulphur, resorcinol, or salicylic acid. Reduced efficacy w/ oxidising agents (e.g. benzoyl peroxide).

Potentially Fatal: Exacerbation of hypervitaminosis A symptoms w/ vit A.

#### PRECAUTIONS:

Topical: Patient w/ eczema, sunburn, history of skin cancer, or those undergoing skin procedures (e.g. depilation, chemical hair treatment and peels, dermabrasion or laser resurfacing). Renal or hepatic impairment. Childn. Pregnancy. Patient Counselling Avoid excessive exposure to sunlight and UV light. This drug may

cause dizziness or severe headache, if affected, do not drive or operate machinery. Monitoring Parameters Monitor for haematologic and coagulation profiles, LFT, serum triglyceride and cholesterol concentration.

#### CONTRAINDICATIONS:

Pregnancy (first trimester) and lactation. Concomitant use w/ vit A.

#### ADVERSE EFFECTS:

Oral: headache, fever, xeroderma, skin/mucous membrane dryness, cheilitis, oedema, nausea, vomiting, bone pain and inflammation, mucositis, alopecia, visual disturbance; increased serum triglycerides, ALT, AST, and creatinine; CV effects (e.g. arrhythmia, flushing, hypotension, HTN, heart failure, cardiac arrest, MI, cardiomegaly, heart murmur, ischaemia, stroke, myocarditis, pericarditis, pulmonary HTN, secondary cardiomyopathy); resp system disorder (e.g. dyspnoea, resp insufficiency, pleural effusion, pneumonia, asthma, pulmonary oedema). Topical: skin irritation, stinging, warmth, erythema, dryness, pruritus, peeling, blistering, crusting, discomfort. Rarely, temporary hypo- and hyperpigmentation, oedema, atrophy, photosensitivity. Potentially Fatal: Retinoic acid syndrome (RAS) w/ or w/o leucocytosis.

# 38. TRIAMCINOLONE ACETONIDE BUCCAL PASTE SALIENT ACTIONS:

Triamcinolone has mainly glucocorticoid activity. It suppresses the migration of polymorphonuclear leukocytes and reduces capillary permeability thereby decreasing inflammation.

#### INDICATIONS & DOSAGE REGIMENS:

Mouth/Throat

Mouth ulceration

Adult: A small amount (about 0.6 cm) of the 0.1% paste is pressed onto the lesion without rubbing until a thin film develops. Apply 2 or 3 times daily, preferably after meals. Re-evaluate if recovery does not occur after 7 days of treatment.

#### INTERACTIONS:

Lowering of plasma salicylates levels. Increased risk of GI bleeding and ulceration with NSAIDs. Antagonised blood glucose-lowering effects of the antidiabetics. Increased risk of hyperkalaemia with amphotericin B,  $\beta$  agonists,  $\beta$ -blockers, potassium-depleting diuretics, theophylline. Increased clearance of the triamcinolone with ciclosporin, carbamazepine, phenytoin, barbiturate, rifampicin. Infections may develop if given with live vaccines.

#### PRECAUTIONS:

Diabetes; hypertension, renal and liver impairment; glaucoma; psychosis; delayed tissue healing; cirrhosis; heart failure; recent MI; hypothyroidism; osteoporosis; peptic ulceration; thromboembolic disorders. Monitor height in children on prolonged therapy. Avoid rapid drug withdrawal. Elderly, children, pregnancy, lactation.

#### CONTRAINDICATIONS:

Untreated systemic fungal, bacterial, viral or parasitic infection, hypersensitivity. Neonates (Parenteral) ADVERSE EFFECTS:

HPA axis supression, intracranial hypertension, Cushing's syndrome, growth retardation in children; osteoporosis, fractures. Peptic ulceration; glaucoma; hyperglycaemia; GI upsets; increased appetite; increased fragility of skin; behavioural changes. Topical: Systemic absorption if applied to large areas, broken skin or under occlusive dressing.

Potentially Fatal: Acute adrenal insufficiency may be precipitated by infection or trauma in patients on long-term corticosteroid therapy or rapid withdrawal.

# 39. WHITE PETROLLIUM JELLY 40 mg pack / 500 mg tin SALIENT ACTIONS:

Petroleum jelly is a semi-solid mixture of hydrocarbons

#### INDICATION

Petroleum jelly's effectiveness in accelerating wound healing stems from its sealing effect on cuts and burns, which inhibits germs from getting into the wound and keeps the injured area supple by preventing the skin's moisture from evaporating myriad ailments and cosmetic purposes, including chapped hands and lips, toenail fungus, male genital rashes (non-STD), nosebleeds, diaper rash, chest colds, and even to remove makeup

# EYE OINTMENT

#### EYE OINTMENT

#### 1.ATROPINE SULFATE OINTMENT 1% W/W

#### SALIENT ACTIONS:

It belongs to a class of drugs known as anticholinergics. Atropine works by widening (dilating) the pupil of the eye.

#### INDICATIONS AND DOSAGE REGIMENS:

Before eye examinations (e.g., refraction) treat certain eye conditions (e.g., uveitis).

#### PRECAUTIONS:

Allergic to it; or to belladonna alkaloids (e.g., scopolamine); glaucoma (narrow-angle). Before using this medication, Down's syndrome, brain damage or spastic paralysis (in children). Pregnancy, this medication should be used only when clearly needed.

#### INTERACTIONS:

Antiarrhythmic drugs (e.g., quinidine,procainamide), antihistamines (e.g., diphenhydramine, meclizine), antispasmodics (e.g., dicyclomine), certain drugs for Parkinson's disease (e.g., anticholinergics such as benztropine, trihexyphenidyl), MAO inhibitors (e.g., furazolidone, isocarboxazid, linezolid, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranylcypromine), other eye medications, tricyclic antidepressants (e.g., amitriptyline).

#### **ADVERSE EFFECTS:**

Symptoms of overdose may include: flushed/dry skin, blurred vision, fast/irregular heartbeat, fever, mental/mood changes (e.g., hallucinations), loss of coordination. Burning/stinging/redness of the eye, eye irritation, or temporary blurred vision serious side effects. dizziness, fainting,slow/shallow breathing, mental/mood changes (e.g., confusion, agitation), fast/irregular heartbeat. rash, itching/swelling (especially of the face/tongue/throat), severe dizziness,.

#### 2.CHLORAMPHENICOL Eye 1% W/W, applicaps

#### SALIENT ACTIONS:

Chloramphenicol belongs to the family of medicines called antibiotics. Chloramphenicol ophthalmic preparations are used to treat infections of the eye. chloramphenicol may be given alone or with other medicines that are taken by mouth for eye infections.

#### INDICATIONS & DOSAGE REGIMENS:

For ophthalmic ointment dosage form: Adults and children—use every three hours.

Eye drops: Adults and children—one drop every one to four hours...

#### INTERACTIONS:

Citalopram, Voriconazole, increased risk of certain side effects –Ceftazidime, Chlorpropamide Cyclosporine, Dicumarol, Fosphenytoin, Phenytoin, Rifampin, Rifapentine, Tacrolimus, Tetanus Toxoid, Tolbutamide, alcohol or tobacco.

#### 3. D-PANTHENOL OPTHALMIC GEL 5%W/W

**SALIENT ACTIONS:** Dexpanthenol ophthalmic gel has a cooling and soothing effect on the eyes. It contributes to a better wetting of the ocular surface in case of sensation of dry œoeil, burning or eye fatigue, caused for example by prolonged TV or intensive screen work use, or by the air emitted by heaters or air conditioners. Dexpanthenol ophthalmic gel contains panthenol to protect healthy eyes. Dexpanthenol belongs to the group of B vitamins

#### INDICATIONS:

Dexpenthénol is a medicament indicated for better wetting of the ocular surface in the case of: dry eye sensation, burns, eyestrain

#### DOSAGE REGIMENS:

TID FOR 5 DAYS

#### CONTRAINDICATIONS:

no information available.

#### PRECAUTIONS:

no information available.

#### INTERACTIONS:

no information available.

#### ADVERSE EFFECTS:

Panthenol is generally well tolerated. In rare cases, skin irritation and contact allergies have been reported

# EYE/EAR DROPS

#### EYE/EAR DROPS:

#### 1. ALCAFTADINE 0.25% W/V EYE DROPS

#### SALIENT ACTIONS:

Alcaftadine is a H<sub>1</sub> histamine receptor antagonist and inhibitor of the release of histamine from mast cells. Decreased chemotaxis and inhibition of eosinophil activation has also been demonstrated.

#### DOSAGE REGIMEN:

Instill one drop in each eye OD.

#### INDICATIONS:

prevention of itching associated with allergic conjunctivitis.

#### **CONTRAINDICATIONS:**

Hypersensitivity to alcaftadine.

#### PRECAUTIONS:

LASTACAFT should not be instilled while wearing contact lenses.

#### INTERACTIONS:

NA

#### ADVERSE REACTIONS:

Conjunctivitis, Eye discharge, Eye swelling, Erythema of eyelid, Eyelid edema, Lacrimation increased and Vision blurred.

#### 2. AMBROXOL HCL 7.5 MG DROP

#### SALIENT ACTIONS:

Ambroxol is the active metabolite of bromhexine. Ambroxol causes an increase in secretion in the respiratory tract. It promotes surfactant production and stimulates ciliary activity. These effects assist the flow of mucus and its removal (mucociliary clearance). An improvement in mucociliary clearance was demonstrated in clinical pharmacological studies. The increase in secretion and mucociliary clearance facilitate expectoration and reduce the cough.

#### INDICATIONS:

All forms of tracheobronchitis, emphysema with bronchitis pneumoconiosis, chronic inflammatory pulmonary conditions, bronchiectasis, bronchitis with bronchospasm asthma. During acute exacerbations of bronchitis it should be given with the appropriate antibiotic.

#### DOSAGE REGIMEN:

As a mucolytic.

Child: <2 year: 7.5 mg bid; 2-5 year: 7.5 mg bid/tid; 6-12 year: 15 mg bid/tid.

#### **CONTRAINDICATIONS:**

Hypersensitivity to ambroxol.

#### PRECAUTIONS:

Avoid use during the first trimester of pregnancy.

#### INTERACTIONS:

Antitussives: Concomitant administration of antitussives may impair the expectoration of liquefied bronchial mucus due to inhibition of cough reflex and cause congestion of secretions (see precautions).

Antibiotics: After using ambroxol, the concentrations of the antibiotics amoxicillin, cefuroxime and erythromycin in bronchial secretions and sputum are increased.

#### ADVERSE REACTION:

Mild GI effects and allergic reactions.

#### 3. BEPOTASTINE BESILATE

#### 1.5 %W/V Ophthalmic Solution

#### **SALIENT ACTIONS:**

Topical H1 receptor antagonist; inhibits histamine release from mast cells

#### INDICATIONS & DOSAGES REGIMENS:

For the treatment of itching associated with allergic conjunctivitis

1 drop into affected eye(s) BID

#### CONTRAINDICATIONS:

Hypersensitivity

#### PRECAUTIONS:

1. Remove contact lenses prior to instillation

- 2. Store at room temp; protect from light & excessive heat
- 3. To prevent contamination do not touch dropper tip to any surface
- 4. Keep bottle tightly closed when not in use

#### INTERACTIONS:

No information provided.

#### ADVERSE EFFECTS

Mild taste disturbance, Ocular irritation, Headache, Nasopharyngitis, Hypersensitivity reactions, including itching, body rash, and swelling lips, tongue and/or throat

#### 4. BRIMODINE TARTRATE 0.2%W/V EYE DROP

#### SALIENT ACTIONS:

Brimonidine is an  $\alpha$ 2-adrenoceptor agonist. As an ophthalmic agent, it works to reduce aqueous humour production and increase uveoscleral flow, thus lowering intraocular pressure (IOP). Topically, it reduces erythema through direct cutaneous vasoconstriction.

#### INDICATIONS & DOSAGE:

Ophthalmic

Ocular hypertension

Adult: As 0.1, 0.15 or 0.2% soln: Instill 1 drop into affected eye(s) bid or tid (approx 8 or 12 hrly).

Open-angle glaucoma

Adult: As 0.1, 0.15 or 0.2% soln: Instill 1 drop into affected eye(s) bid or tid (approx 8 or 12 hrly).

#### CONTRAINDICATIONS:

Childn <2 yr. Concomitant use of MAOIs

#### PRECAUTIONS:

Patient w/ severe or unstable and uncontrolled CV disease, mental depression, orthostatic hypotension, cerebral or coronary insufficiency, Raynaud's phenomenon, or thromboangiitis obliterans. Renal or hepatic impairment. Patient Counselling This drug may cause fatigue and/or drowsiness, if affected, do not drive or operate machinery. Avoid exposure to excessive sunlight and UV irradiation (topical). Remove contact lenses prior to ophth admin and reinsert after 15 min. Monitoring Parameters Monitor IOP routinely.

#### INTERACTIONS:

TCAs (e.g. imipramine) and tetracyclic antidepressants (e.g. mianserin) that affect the metabolism and uptake of circulating amines may interfere w/ IOP-lowering effect brimonidine. Additive IOP-lowering and CV effects w/  $\beta$ -blockers, antihypertensives, cardiac glycosides. Additive or potentiating effect w/ CNS depressants (e.g. barbiturates, opiates, sedatives or anaesthetics). Potentially Fatal: Interfered metabolism and increased adverse effect when used w/ MAOIs (e.g. selegiline).

#### ADVERSE REACTIONS:

Erythema, pruritus, flushing, burning sensation, paraesthesia. nasopharyngitis, increased IOP, contact dermatitis, skin irritation, dry skin, acne, papular rash, worsening of rosacea, pain of skin, warm skin, swelling face, nasal congestion, angioedema, peripheral coldness, upper resp tract infection (topical). Ocular hyperaemia, burning/stinging sensation, blurred vision, ocular allergic reaction, conjunctival follicles, corneal staining/erosion, photophobia, eyelid erythema, ocular dryness, ocular pain, conjunctival blanching, conjunctival discharge, iritis, iridocyclitis, miosis, fatigue, drowsiness, dizziness, asthenia, abnormal taste, blepharitis, depression, nasal dryness, palpitation, arrhythmias, hypotension, syncope, headache, blurred vision, dry mouth, eyelid oedema (ophth).

#### 5. BRINZOLAMIDE IP E/D

#### SALIENT ACTIONS:

Brinzolamide is a carbonic anhydrase inhibitor that decreases secretion of aqueous humour thus reducing intraocular pressure.

#### INDICATIONS & DOSAGE:

Ocular hypertension, Open-angle glaucoma

Adult: As 1% susp: Instill 1 drop 2-3 times daily, either alone or as adjunctive therapy w/ a topical β-blocker or prostaglandin analogue.

Elderly: No dosage adjustment necessary.

#### CONTRAINDICATIONS:

Hypersensitivity to brinzolamide, sulfonamides. Hyperchloraemic acidosis.

#### PRECAUTIONS:

Patient w/ low endothelial cell count. Hepatic and severe renal (CrCl <30 mL/min) impairment. Pregnancy and lactation. Patient Counselling This drug may cause temporary blurred vision or other visual disturbances, if affected do not drive or operate machinery. Monitoring Parameters Monitor intraocular pressure.

#### INTERACTIONS:

Concurrent use w/ oral carbonic anhydrase inhibitors may lead to additive systemic effects. Concurrent use w/ high-dose salicylates may lead to toxicity.

#### ADVERSE REACTIONS:

Blurred vision, taste abnormality (bitter, sour, or unusual taste), blepharitis, dermatitis, dry eye, foreign body sensation, headache, hyperaemia, ocular discharge, ocular discomfort, ocular keratitis, ocular pain, ocular pruritus, and rhinitis.

Potentially Fatal: Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anaemia, and other blood dyscrasias.

#### 6. BROMFENAC SODIUM EYE DROP

#### SALIENT ACTIONS: :

Bromfenac has anti-inflammatory activity due to its ability to block prostaglandin synthesis by inhibiting cyclooxygenase (COX) 1 and 2.

#### INDICATIONS & DOSAGE:

Adult: Ophth As 0.07% or 0.09% soln: Instill 1 drop in the affected eye(s) once daily, starting 1 day before, and continuing until 14 days after cataract surgery. Alternatively, 1 drop bid, beginning 24 hr after cataract surgery and continuing through the 1st 14 days of post-op period.

#### CONTRAINDICATIONS:

Hypersensitivity to bromfenae or other NSAIDs. Patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or by other medicinal products w/ prostaglandin synthetase inhibiting activity.

#### PRECAUTIONS:

Patient w/ complicated ocular surgeries, corneal denervation, corneal epithelial defects, DM, ocular surface diseases (e.g. dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries w/in a short period of time. Patient w/ a predisposition to bleeding (bleeding tendencies or medications which interfere w/ coagulation). Pregnancy and lactation.

#### INTERACTIONS:

Increased potential for healing problems w/ concomitant ophth corticosteroids.

#### ADVERSE REACTIONS:

Abnormal ocular sensation, conjunctival hyperaemia, ocular redness or irritation (e.g. pruritus, burning, stinging, pain), headache and iritis.

#### 7. CARBOXY METHYLCELLULOSE SODIUM EYE DROPS LP.0.5%W/V

#### SALIENT ACTIONS:

The carboxymethylcellulose sodium relieves the symptoms of dry eyes in 2 ways. Firstly, it provides lubricating and hydrating protective shield on the ocular surface of the eye. Then, it works below the tear film to provide protection to the cornea.

#### INDICATION & DOSAGE:

Temporary relief of burning, irritation and discomfort due to dryness of the eye or exposure to wind or sun. Instill 1 drop in the affected eyes

#### CONTRAINDICATIONS:

Hypersensitivity

#### PRECAUTIONS:

Use in Pregnancy & Lactation

#### INTERACTIONS:

NA

#### ADVERSE REACTIONS:

Vision may be temporarily blurred when Neotear is 1st used. Also, minor burning, stinging or irritation may temporarily occur.

# 8. CIPROFLOXACIN IP 0.3% W/V, eye / ear drops SALIENT ACTIONS:

It has rapid bactericidal activity and high potency. It spares protective intestinal streptococci and anaerobes. It is active against many Beta lactam and aminoglycoside resistant bacteria. At acidic pH it is less active. It has low frequency of mutational resistance and low propensity to select plasmid resistant mutants. It is rapidly absorbed orally, but food delays absorption and first pass metabolism occurs. It has high tissue penetrability. It is excreted primarily in urine both by glomerular filtration and tubular secretion

#### INDICATIONS & DOSAGE REGIMENS:

Bacterial conjunctivitis . Apply 0.3% solution every 15 min. till 6 hrs then every 30 min. on  $1^{st}$  day , Apply hrly on  $2^{nd}$  day & then every 4 hr on  $3^{rd}$ ,  $14^{th}$  day

#### CONTRAINDICATIONS:

Hypersensitivity, irritation

#### PRECAUTIONS:

Children, pregnancy, lactation

#### DRUG INTERACTIONS:

By Inhibiting metabolism, ciprofloxacin increases the plasma concentration of theophylline, caffein and warfarin. NSAIDs may enhance the CNS toxicity of ciprofloxacin: Seizures are reported. Antacid, sucralfate and iron salts concurrently reduce absorption of ciprofloxacin

#### ADVERSE EFFECTS:

Nausea, vomiting, bad taste.anorexia, diarrhoea, dizziness, headache, anxiety, insomnia, confusion, tremor, seizures at high dose, rash, pruritus, photosensitivity, urticaria, swelling of lips, tendinitis and tendon rupture, joint pain and joint swelling in children

#### 9. CYCLOSPORINE IP 0.5MG EYE DROP

#### SALIENT ACTION:

Ciclosporin is a strong immunosuppressant that acts mainly on the helper T-cells. It inhibits the activation of calcineurin and production of interleukin-2, thus reducing cell-mediated immune response.

#### INDICATIONS & DOSAGE:

Oral

Immunosuppression in organ transplantation

Adult: Initially, 10-15 mg/kg/day, starting 4-12 hr before procedure and continued for 1-2 wk; usual maintenance: 2-6 mg/kg/day. Lower doses may be used when combined with other immunosuppressants. Oral

Severe atopic dermatitis

Adult: Initially, 2.5 mg/kg/day, in 2 divided doses. Reduce to lowest effective dose once remission is achieved. Stop treatment if there is no sufficient improvement to max dose within 6 wk. Max: 5 mg/kg/day. Oral

**Psoriasis** 

Adult: Initially, 2.5 mg/kg/day, in 2 divided doses. Reduce to lowest effective dose once remission is achieved. Stop treatment if there is no sufficient improvement to max dose within 6 wk. Max: 5 mg/kg/day.

Rheumatoid arthritis

Adult: 2.5 mg/kg/day. in 2 divided doses. Treatment should continue for 6-8 wk. If response is insufficient, may increase dose gradually. Max: 4 mg/kg/day.

Oral

Oral

Nephrotic syndrome

Adult: 5 mg/kg daily, given in 2 divided doses.

Child: 6 mg/kg daily, given in 2 divided doses.

Intravenous

Prophylaxis of graft rejection in bone marrow transplantation

Adult: Intially, 3-5 mg/kg/day starting on the day before transplantation and continue for up to 2 wk or until oral therapy can be initiated at a maintenance of 12.5 mg/kg/day. Continue maintenance dose for at least 3-6 mth. Intravenous

Immunosuppression in organ transplantation

Adult: Initially: 5-6 mg/kg/day as a single dose, infuse dose over 2-6 hr. Switch to an oral dosage form as soon as possible.

#### CONTRAINDICATIONS:

Hypersensitivity; malignant neoplasms; uncontrolled hypertension; psoriasis; lactation.

#### PRECAUTIONS:

Renal and hepatic impairment; hyperuricaemia; anaphylaxis; history of allergic reactions; pregnancy; monitor BP, serum electrolytes, renal and hepatic function.

#### INTERACTIONS:

Increased ciclosporin level by diltiazem, doxycycline, erythromycin, ketoconazole, methylprednisolone (high doses), nicardipine, verapamil, oral contraceptives. Drugs which reduce ciclosporin level are carbamazepine, isoniazid, phenobarbitone, phenytoin and rifampicin. Increased risk of convulsion when used concurrently with high-dose methylprednisolone.

Potentially Fatal: Additive nephrotoxicity when used with aminoglycosides, amphotericin B, ciprofloxacin, colchicine, melphalan, co-trimoxazole and NSAIDs.

#### ADVERSE REACTIONS:

Hypertension; hepatoxicity; tremor; paraesthesia, hypertrichosis, facial oedema, acne; gingival hypertrophy; hyperkalaemia, fluid retention; increased susceptibility to infections; GI symptoms.

Potentially Fatal: Nephrotoxicity; convulsions.

#### 10. DIFLUPREDNATE 0.5MG EYE DROP

#### SALIENT ACTIONS:

Difluprednate is a topical corticosteroid with glucocorticoid activity. It exhibits anti-inflammatory and immunosuppressive effects by inhibiting the release of various cytokines.

#### INDICATION & DOSAGE:

Topical/Cutaneous

Corticosteroid-responsive dermatoses

Adult: Apply a thin layer of 0.02-0.05% cream, gel, oint over affected areas as directed.

#### CONTRAINDICATIONS:

Infectious dermatoses.

#### PRECAUTIONS:

Glaucoma, infection. Avoid applying to broken skin or under occlusive dressings to prevent systemic absorption effects.

#### ADVERSE REACTIONS:

Skin thinning when applied under occlusion. Folliculitis, hypertrichosis, skin atrophy, superinfection, stretch mark, loss of skin collagen and SC atrophy, local depigmentation, acne, burning sensation, pruritus, chronic glaucoma. Telangiectasia and purpura

#### 11. FLUBIPROFEN 0.03%, 5 ml eye solution

#### **SALINET ACTIONS:**

Nonsteroidal anti-inflammatory drug (NSAID) effective in treating fever, pain, and inflammation in the body. As a group, NSAIDs are non-narcotic relievers of mild to moderate pain of many causes, including injury, menstrual cramps, arthritis, and other musculoskeletal conditions. Since the response to different NSAIDs varies from patient to patient, it is not unusual for a doctor to try different NSAIDs for any given condition

#### INDICATIONS & DOSAGE REGIMENS:

Used before eye examinations (e.g., refraction), before and after certain eye surgeries, to treat certain eye conditions (e.g., uveitis). It belongs to a class of drugs known as anticholinergies. Homatropine hydrobromide works by widening (dilating) the pupil of the eye.

#### **CONTRAINDICATIONS:**

Pregnancy & Nursing Mothers

#### INTERACTIONS:

History of asthma attacks, hives, or other allergic reactions to aspirin or other NSAIDs. peptic ulcer disease or poor kidney function, since this medication can aggravate both conditions.

#### PRECAUTIONS:

Used with caution in patients taking blood thinning medications (anticoagulants), such as warfarin (Coumadin), because of increased risk of bleeding. Patients taking lithium can develop toxic blood lithium levels. Patients also taking cyclosporine (Sandimmune) can develop kidney toxicity.

#### ADVERSE EFFECTS:

Burning/stinging/redness of the eye, eye irritation, or temporary blurred vision. extreme thirst, persistentdry mouth, new or increased pressure/pain/swelling/discharge. serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severedizziness, trouble breathing.

#### 12. FLUCONAZOLE 0.35 %EYE DROPS

#### SALIENT ACTIONS:

It is an anti-fungal drug. It is used to prevent and treat infections caused by fungi and yeasts. It acts by stopping the growth and multiplication of these organisms.

#### INDICATIONS:

It is an anti-fungal drug. It is used to prevent and treat infections caused by fungi and yeasts. It acts by stopping the growth and multiplication of these organisms.

- · Oropharyngeal Candidiasis
- Esophageal Candidiasis
- Cryptococcal Meningitis
- Vaginal Candidiasis
- Urinary Tract Infection
- Peritonitis
- Candidemia

#### DOSAGE REGIMENS:

1 drop should be instilled in to the affected eye every 4 hours for 3 - 4 days followed by 1 drop every 6 hours.

#### CONTRAINDICATIONS:

- Allergy
- QT Interval prolonging drugs

#### PRECAUTIONS:

N/A

#### INTERACTIONS:

- Alprazolam
- Cisapride
- Clopidogrel
- Erythromycin
- Warfarin
- Tretinoin

#### ADVERSE EFFECTS:

- Headache
- Nausea and Vomiting
- Abdominal pain
- Diarrhea
- Skin rash
- QT Prolongation
- Alopecia
- Seizures
- · Swelling of face, lips, eyelids, tongue, hands and feet

#### 13. FLUOROMETHOLONE OPTHALMIC SUSP.(0.1%)

#### SALIENT ACTIONS:

This medication is used to treat certain eye conditions due to inflammation or injury. Fluorometholone works by relieving symptoms such as swelling, redness, and itching. It belongs to a class of drugs known as corticosteroids. It prevents the release of substances in the body that cause inflammation.

#### INDICATIONS:

Fluorometholone ophthalmic (for the eyes) is used to treat eye swelling caused by infections, injury, surgery, or other conditions.

#### DOSAGE REGIMENS:

1 drop into the conjunctival sac 2 to 4 times per day

#### CONTRAINDICATIONS:

ey e infections, recent eye surgery, cataracts, glaucoma (open-angle type), severe nearsightedness (myopia), diabetes.

#### PRECAUTIONS:

As fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid applications, fungal invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. Fungal cultures should be taken when appropriate.

#### INTERACTIONS:

NA

#### ADVERSE EFFECTS:

Adverse reactions include, in decreasing order of frequency, elevation of intraocular pressure (IOP) with possible development of glaucoma and infrequent optic nerve damage, posterior subcapsular cataract formation, and delayed wound healing.

#### 14. GATIFLOXACIN 0.3%W/V 10 ml eye drops

#### SALIENT ACTIONS:

Gatifloxacin is an 8-methoxyfluoroquinolone with a 3-methylpiperazinyl substituent at C7. The antibacterial action of gatifloxacin results from inhibition of DNA gyrase and topoisomerase IV.

#### INDICATIONS

Treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms: Aerobic Gram-Positive Bacteria: Corynebacterium propinquum, Staphylococcus aureu Staphylococcus epidermidis Streptococcus mitis, Streptococcus pneumoniae Aerobic Gram-Negative Bacteria: Haemophilus influenzae DOSAGE REGIMENS:

The recommended dosage regimen for the treatment of bacterial conjunctivitis is: Days 1 and 2: Instill one drop every two hours in the affected eye(s) while awake, up to 8 times daily. Days 3 through 7: Instill one drop up to four times daily while awake

#### CONTRAINDICATIONS:

History of hypersensitivity to gatifloxacin, to other quinolones, or to any of the components in this medication. PRECAUTIONS:

Not For Injection. should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye. patients receiving systemic quinolones, including gatifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following: cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria, and itching. If an allergic reaction to gatifloxacin occurs, discontinue the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment:Oxygen and airway management INTERACTIONS:

Quinolones has been shown to elevate plasma concentrations of theophylline, interfere with the metabolism of caffeine, and enhance the effects of the oral anticoagulant warfarin and its derivatives, and has been associated with transient elevations in serum creatinine in patients receiving systemic cyclosporine concomitantly. Pregnancy & lactation: Teratogenic Effects

#### ADVERSE EFFECTS:

Conjunctival irritation, increased lacrimation, keratitis, and papillary conjunctivitis. These events occurred in approximately 5-10% of patients. Other reported reactions occurring in 1-4% of patients were chemosis, conjunctival hemorrhage, dry eye, eye discharge, eye irritation, eye pain, eyelid edema, headache, red eye, reduced visual acuity and taste disturb

# 15. HOMATROPINE HYDROBROMIDE 5ml eye drops SALIENT ACTIONS & INDICATIONS:

Hematropine ophthalmic is used to dilate (widen) pupil in inflammatory condition or in diagnostic or postsurgery situations in which this effect may be helpful.

#### DOSAGE REGIMENS:

Instill 1 to 2 drops in the eye once. May repeat in 5 to 10 minutes if necessary. The lacrimal sacs should be compressed by digital pressure for a few minutes after instillation

#### CONTRAINDICATIONS:

Glaucoma.Do not wear soft contact lenses when the eye drops are being inserted pregnancy category c. Are breast-feeding a baby. Over 65 years of age

#### PRECAUTIONS:

Use caution when driving, operating machinery, or performing other hazardous activities, may cause blurred vision. vision, The effects of even one drop of this medication can last for up to 3 days. Be sure that your vision is clear before attempting any activity that could be dangerous. Homatropine ophthalmic may make eyes more sensitive to light.

#### ADVERSE EFFECTS:

Headache, fast heartbeat, dry mouth and skin, unusual drowsiness, and flushing. Homatropine ophthalmic eye drops contain a preservative (benzalkonium chloride), so do not wear soft contact lenses when the eye drops are being inserted. An allergic reaction (difficulty breathing; closing of your throat; swelling of your lips, tongue, or face; or hives); an irregular or fast heart rate; hallucinations or unusual behavior (especially in children); or a swollen or distended stomach (in infants).blurred vision, sensitivity to sunlight, stinging and burning, or swelling of the eyelids.

#### 16. KETOROLAC 4 mg/ml, sterile ophthalmic solution

#### SALIENT ACTIONS:

Ketorolac tromethamine is a nonsteroidal anti-inflammatory drug which, when administered systemically, has demonstrated analgesic, anti-inflammatory, and anti-pyretic activity. The mechanism of its action is thought to be due to its ability to inhibit prostaglandin biosynthesis.

#### INDICATIONS AND DOSAGE REGIMENS:

Ocular pain, burning/stinging following corneal refractive surgery. 0.4% is one drop four times a day in the operated eye as needed for pain and burning/stinging for up to 4 days following corneal refractive surgery

#### CONTRAINDICATIONS:

Hypersensitivity.

#### PRECAUTIONS:

May slow or delay healing, keratitis, epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients.

#### ADVERSE REACTIONS

conjunctival hyperemia, corneal infiltrates, headache, ocular edema and ocular pain. Transient stinging and burning on instillation. Allergic reactions, corneal edema, iritis, ocular inflammation, ocular irritation, ocular pain, superficial keratitis, and superficial ocular infections.

#### 17. LATANOPROST BENZALKONIUM 50MCG( EYE DROPS)

#### SALIENT ACTIONS:

The active substance latanoprost, a prostaglandin  $F_{2\alpha}$  analogue, is a selective prostanoid FP receptor agonist that reduces the intraocular pressure by increasing the outflow of aqueous humor, primarily through the uveoscleral route and also through the trabecular meshwork.

#### INDICATIONS:

Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma, chronic angle-closure glaucoma, and ocular hypertension.

Reduction of elevated intraocular pressure in pediatric patients with elevated intraocular pressure and pediatric glaucoma.

#### DOSAGE REGIMENS:

Adults and Elderly: I drop in the affected eye(s) once daily. Optimal effect is obtained if Xalatan is administered in the evening.

The dosage of Xalatan should not exceed once daily since it has been shown that more frequent administration decreases the intraocular pressure lowering effect.

If one (1) dose is missed, treatment should continue with the next dose as normal.

Xalatan may be used concomitantly with other classes of topical ophthalmic drug products to lower IOP. If >1 topical ophthalmic drug is being used, the drugs should be administered at least 5 min apart.

#### CONTRAINDICATIONS:

Known hypersensitivity to latanoprost or to any of the components

#### PRECAUTIONS:

LATANOPROST should be used with caution in patients with a history of herpetic keratitis, and should be

avoided in cases of active herpes simplex keratitis and in patients with a history of recurrent herpetic keratitis specifically associated with prostaglandin analogues.

LATANOPROST may gradually change eyelashes and vellus hair in the treated eye

LATANOPROST may gradually increase the brown pigment of the iris

#### INTERACTIONS:

paradoxical elevations in IOP following the concomitant ophthalmic administration of 2 prostaglandin analogs ADVERSE EFFECTS:

Nervous System Disorders: Dizziness, headache.

Eye Disorders: Corneal edema and erosions; conjunctivitis, eyelash and vellus hair changes (increased length, thickness, pigmentation and number); iritis/uveitis; keratitis; macular edema, including cystoid macular edema; misdirected eyelashes sometimes resulting in eye irritation; vision blurred, photophobia, periorbital and lid changes resulting in deepening of the eyelid sulcus

Respiratory, Thoracic and Mediastinal Disorders: Asthma, asthma aggravation, acute asthma attacks and dyspnea.

Skin and Subcutaneous Tissue Disorders: Darkening of the palpebral skin of the eyelids and localized skin reaction on the eyelids.

Musculoskeletal and Connective Tissue Disorders: Muscle/joint pain..

### 18. LOTEPREDNOL ETABONATE 5 MG EYEDROP SALIENT ACTIONS:

Topical anti-inflammatory corticosteroid for ophthalmic use. Loteprednol etabonate is a white to off-white powder.

#### INDICATIONS

Indicated for the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, comea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitides, when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation.

#### DOSAGE REGIMENS:

SHAKE VIGOROUSLY BEFORE USING.

Steroid Responsive Disease Treatment: Apply one to two drops of LOTEMAX (loteprednol etabonate ophthalmic suspension) into the conjunctival sac of the affected eye(s) four times daily. During the initial treatment within the first week, the dosing may be increased, up to 1 drop every hour, if necessary. Care should be taken not to discontinue therapy prematurely. If signs and symptoms fail to improve after two days, the patient should be re-evaluated

Post-Operative Inflammation: Apply one to two drops of LOTEMAX (loteprednol etabonate ophthalmic suspension) into the conjunctival sac of the operated eye(s) four times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the post-operative period.

#### CONTRAINDICATIONS:

contraindicated in most viral diseases of

the cornea and conjunctivaincluding epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. Also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

#### PRECAUTIONS:

The initial prescription and renewal of the medication order beyond 14 days should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

If signs and symptoms fail to improve after two days, the patient should be re-evaluated.

If this product is used for 10 days or longer, intraocular pressure should be monitored even though it may be difficult in children and uncooperative patients

Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.

#### ADVERSE DRUG REACTIONS:

Reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with optic herve damage, visual acuity and field defects, posterior subcapsular cataract formation,

secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera.

Ocular adverse reactions occurring in 5-15% of patients treated with loteprednol etabonate ophthalmic suspension (0.2%-0.5%) in clinical studies included abnormal vision/blurring, burning on instillation, chemosis, discharge, dry eyes, epiphora, foreign body sensation, itching, injection, and photophobia. Other ocular adverse reactions occurring in less than 5% of patients

include conjunctivitis, corneal abnormalities, eyeliderythema, keratoconjunctivitis, ocular irritation/pain/discomfort, papillae, and uveitis. Some of these events were similar to the underlying ocular disease being studied.

Non-ocular adverse reactions occurred in less than 15% of patients. These include headache, rhinitis and pharyngitis.

#### 19. MOXIFLOXACIN HCL 5MG EYE DROP

#### SALIENT ACTIONS:

Moxifloxacin, a fluoroquinolone anti-infective agent, acts by inhibiting DNA synthesis in susceptible organisms via inhibition of both DNA gyrase and topoisomerase IV which are essential for bacterial growth.

#### INDICATIONS & DOSAGE REGIMENS:

#### Bacterial conjunctivitis

Adult: As 0.5% soln: Instill 1 drop into the affected eye(s) tid for 7 days.

Child:  $\geq 1$  vr Same as adult dose.

#### CONTRAINDICATIONS:

Known hypersensitivity to moxifloxacin, other quinolones. Patients w/ known prolongation of QT interval, uncorrected hypokalaemia, myasthenia gravis. Concurrent use of class Ia (e.g. quinidine, procainamide, class III (e.g. amiodarone, sotalol) antiarrhythmic drugs or w/ other drugs that prolong QT interval (e.g. erythromycin, TCAs, antipsychotic agents).

#### PRECAUTIONS:

Patient w/ previous tendon disorders (e.g. rheumatoid arthritis), significant bradycardia or acute myocardial ischaemia, heart failure w/ reduced LVEF, known history of symptomatic arrhythmias, known or suspected CNS disorders (e.g. severe cerebral arteriosclerosis, epilepsy) or other risk factors that predispose to seizures; diabetes. Kidney, heart or lung transplant recipients. Hepatic impairment. Pregnancy and lactation. *Patient Counselling* This drug may cause dizziness and lightheadedness, if affected do not drive or operate machinery. Rest and refrain from doing strenuous physical activity as it may increase risk of tendon rupture. Avoid exposure to sunlight or artificial UV light (e.g. tanning beds, UVA/UVB treatment) and use protective measures (e.g. sunscreen, wear loose-fitting clothes) if staying outdoors is necessary during therapy. *Monitoring Parameters* Monitor WBC and signs of infection.

#### DRUG INTERACTIONS:

Additive effect on QT interval prolongation w/ other drugs that prolong QT interval (e.g. erythromycin, TCAs, antipsychotic agents). Decreased absorption and bioavailability w/ Al- or Mg-containing antacids, or Fe or Zn preparations. Concomitant use of corticosteroids increases the risk of severe tendon disorders esp in elderly (>60 yr). Decreased absorption w/ sucralfate or didanosine.

Potentially Fatal: Concurrent use of class Ia (e.g. quinidine, procainamide) or III (e.g. amiodarone, sotalol) antiarrhythmic drugs or w/ other drugs that prolong QT interval (e.g. erythromycin, TCAs, antipsychotic agents) may cause additive effect on QT interval prolongation.

#### ADVERSE DRUG REACTIONS:

GI disturbances (e.g. nausea, vomiting, diarrhoea), taste perversion, headache, dizziness, photosensitivity reactions. Conjunctivitis, ocular hyperemia, subconjunctival haemorrhage, tearing, ocular discomfort/dryness/pain/pruritus/irritation, reduced visual acuity, fever, increased cough, infection, otitis media, pharyngitis, rhinitis, dyspnoea, paraesthesia, rash, pruritus, palpitation, angina, vasodilatation, hyperlipidaemia, sweating, pain and phlebitis at inj site.

Potentially Fatal: Hypersensitivity reactions. Rarely, CNS effects, QT prolongation leading to ventricular arrhythmias (including torsade de pointes), *Clostridium difficile*-associated diarrhoea and colitis, damage to liver, kidneys or bone marrow, alterations in glucose homeostasis.

#### 20. NATAMYCIN OPTHALMIC SUSPENSION

#### SALIENT ACTION:

Natamycin is a polyene antifungal antibiotic which acts by increasing cell membrane permeability in susceptible

fungi. It is active against a variety of yeast and filamentous fungi.

#### INDICATIONS & DOSAGE REGIMENS:

Ophthalmic

Blepharitis, conjunctivitis and keratitis

Adult: As 5% ophth susp: Instill 1 drop in the conjunctival sac every 1-2 hr, reduce to 1 drop 6-8 times daily after 3-4 days. Duration of treatment: 2-3 wk. May reduce the dosage gradually at 4-7 day intervals to assure that the replicating organism has been eliminated.

#### CONTRAINDICATIONS:

Hypersensitivity. Concurrent application w/ a topical corticosteroid.

#### PRECAUTIONS

Epithelial ulceration. Pregnancy and lactation. *Patient Counselling* Contact lens should not be worn if signs/symptoms of fungal blepharitis, conjunctivitis, and/or keratitis are present.

#### DRUG INTERACTIONS:

Potentially Fatal: May increase spread of fungal eye infection when used w/ topical corticosteroid.

#### ADVERSE DRUG REACTIONS:

Allergic reaction, chest pain, corneal opacity, dyspnoea, eye discomfort, oedema, hyperemia, irritation and/or pain, foreign body sensation, paraesthesia, tearing, vision changes.

# 21. NEOMYCIN SULPHATE 3400 U + POLYMYXIN B SULPHATE 10000 U+ HYDROCORTISONE 10 mg 5 ml ear drops

#### SALIENT ACTIONS:

An aminoglycoside antibiotic & anti-inflammatory ear drops. Neomycin works by affecting the bacteria's production of certain proteins that are necessary for their survival. It causes the bacteria to produce abnormal and faulty proteins. This ultimately kills the bacteria and clears up the infection.

#### INDICATIONS:

Bacterial eye infections.

#### PRECAUTIONS:

Children, elderly, decreased kidney function.

#### CONTRAINDICATIONS:

Known sensitivity or allergy to any ingredient, Pregnancy and breastfeeding

#### INTERACTIONS:

Capreomycin, cisplatin, loop diuretics such as furosemide and etacrynic acid, teicoplanin, vancomycin. Increased risk of side effects:amphotericin, capreomycin, cephalosporin antibiotics, eg cephaloridine, ciclosporin, cisplatin, colistin, polymixin, tacrolimus, teicoplanin, vancomycin.

#### ADVERSE EFFECTS;

Sensitisation or allergic reactions.

#### 22. NEPAFENAC OPTHAL SUSPENTION

#### SALIENT ACTIONS:

Is a nonsteroidal anti-inflammatory drug (NSAID). It reduces pain and inflammation in the eyes, used to reduce pain and swelling after cataract surgery.

#### INDICATION&DOSAGES REGIMENS:

Before and after eve surgery, to control inflammation

#### CONTRAINDICATIONS:

contraindicated in patients with NSAID hypersensitivity.

#### PRECAUTIONS:

Use caution when administering nepafenac to **patients** who have previously exhibited sensitivities to phenylacetic acid derivatives and salicylatehypersensitivity as the potential for cross-sensitivity exists.

#### ADVERSE DRUG REACTIONS:

Eye discomfort or discharge, dry eyes, redness

Increased sensitivity to light

Blurred vision

Headache

### 23. OFLOXACIN USP0.3%W/V, 10 ml eye drops

### INDICATIONS & DOSAGE REGIMENS:

An antibiotic, used to treat bacterial infections of the eyes.

Usual Adult Dose for Bacterial Conjunctivitis: Day 1-2: Instill 1-2 drops in the affected eye(s) every 2-4 hours. Day 3-7: Instill 1-2 drops in the affected eye(s) 4 times daily.

**Usual Adult Dose for Corneal Ulcers:** Day 1-2: Instill 1-2 drops in the affected eye(s) every 30 minutes while awake, and 4 and 6 hours after retiring. Day 3 through 7 to 9: Instill 1-2 drops in the affected eye(s) every hour while awake. Day 7 to 9 through treatment completion: Instill 1-2 drops in the affected eye(s) 4 times daily.

### CONTRAINDICATIONS:

Viral or fungal infection, pregnancy, lactation

### PRECAUTIONS:

Use caution when driving, operating machinery, or performing other hazardous activities. Ofloxacin ophthalmic may cause blurred vision. If you experience blurred vision, avoid these activities. If you wear contact lenses, ask your doctor if you should wear them during treatment. Ofloxacin ophthalmic can cause the development of crystals on contact lenses. After applying this medication, wait at least 15 minutes before inserting contact lenses. Do not use other eye drops or medications during treatment with ofloxacin ophthalmic unless otherwise directed by your doctor.

### ADVERSE EFFECTS:

Burning, stinging, irritation, itching, redness, blurred vision, eyelid itching, eyelid swelling or crusting, a bad taste in mouth, tearing, or sensitivity to light may occur.

### 24. OXYMETAZOLINE 0.5 mg, 10 ml nasal solution

### INDICATIONS:

Relieving redness in the eye caused by minor irritation. Oxymetazoline Drops are a decongestant used in the eye. It works by narrowing the blood vessels in the eye, which helps you by relieving irritation.

### CONTRAINDICATIONS:

Allergic to any ingredient in Oxymetazoline Drops.furazolidone or a monoamine oxidase (MAO) inhibitor (eg, phenelzine)

### PRECAUTION:

Pregnant, breast-feeding.glaucoma, high blood pressure, diabetes, or heart or thyroid problems, or are taking medicine for high blood pressure

### INTERACTION:

Tricyclic antidepressants (eg, amitriptyline) because the effectiveness of Oxymetazoline Drops may be decreased Cocaine, furazolidone, MAO inhibitors (eg, phenelzine), or tricyclic antidepressants (eg, amitriptyline) because side effects, such as headache, fever, and high blood pressure, may be increased Bromocriptine or cocaine because the actions and side effects of these medicines may be increased

### ADVERSE EFFECTS:

Short period of stinging when the medicine is dropped into the eye. Severe allergic reactions. rash; hives difficulty breathing, tightness in the chest ,swelling of the mouth, face, lips, or tongue), changes in vision; eye pain.

### 25. PARADECHLOROBENZENE 2 %+ BENZOCAINE 2.7 %+ CHLOROBUTOL 5 %+ TURPENTINE OIL BP 15 %, 10 ml wax disolving ear drops

### INDICATIONS:

Treatment of acute otitis media, simple catarrhal otitis, furunculosis and other inflammatory conditions and infections of the ear

### DOSAGE REGIMENS:

5-10 drops, warmed to body temperature, to be instilled into the ear every two hours and the ear lightly plugged with cotton wool.

### CONTRAINDICATIONS:

Sensitivity to any of the ingredients

### PRECAUTIONS

Benzocaine may cause methaemoglobinaemia. Allergic reactions may appear. The application of local enaesthetics to the skin for prolonged periods or to extensive areas should be avoided.

### ADVERSE EFFECTS:

Acute poisoning with Chlorbutol may produce central nervous system depression with weakness, loss of

consciousness, and depressed respiration. The systemic toxicity of local anaesthetics mainly involves the central nervous system and the cardiovascular system. Excitation of the CNS may be manifested by restlessness, excitement, nervousness, dizziness, tinnitus, blurred vision, nausea and vomiting, muscle twitching and tremors, and convulsions. Numbness of the tongue and perioral region may appear as an early sign of systemic toxicity. Excitation may be transient and followed by depression with drowsiness, respiratory failure, and coma. Effects on the cardiovascular system may be myocardial depression and peripheral vasodilation resulting in hypotension and bradycardia, arrhythmias and cardiac arrest..

### 26. PILOCARPINE IP 2% W/V EYE DROP

### SALIENT ACTIONS:

Pilocarpine nitrate is clear, colorless solution for intracameral administration to induce prompt miosis, directly stimulates cholinergic receptors in the eyes causing pupillary constriction, spasm of accommodation and a transient rise in IOP followed by a fall.

### INDICATIONS:

It is used as direct acting miotic. To induce miosis during surgery for prompt miosis ( Cataract surgery with I.O.L implant ).

### DOSAGE REGIMENS:

As per opthlologists.

### CONTRAINDICATIONS:

Angle-closure glaucoma; acute iritis, anterior uveitis; hypersensitivity, pregnancy

### PRECAUTIONS:

Not to be used as injection. Lactation ,acute cardiac failure, bronchial asthma, peptic ulcer, hyperthyroidism, GIspasm, urinary tract obstruction, Parkinson's disease, recent MI, hypertension or hypotension. Retinal detachment; corneal or conjunctival damage. Patients with cognitive or psychiatric disorders, renal impairment, biliary tract disorders. Prolonged use may lead to lens opacities. May impair ability to drive or operate machines.

### INTERACTIONS:

Concomitant 2 miotics may increase risk of toxic reactions. Aminoglycosides, clindamycin, colistin, cyclopropane and halogenated inhalational anaesthetics, quinine, procainamide, lithium and  $\beta$ -blockers may reduce the efficacy of pilacarpine. Concurrent use with  $\beta$ -blockers may lead to bradycardia. May prolong the action of suxamethonium.

Potentially Fatal: Miotic and ocular hypotensive effect antagonised by anticholinergies. Conduction disturbances with  $\beta$ -blockers.

### ADVERSE EFFECTS:

Ocular: Pain and irritation, blurred vision, lachrymation, browache, conjunctival vascular congestion, superficial keratitis, vitreous haemorrhage, increased pupillary block

### 27. POLYVINYL ALCOHOL1.4%+POVIDONE 0.6% +BENZALKONIUM CHLORIDE 0.02%, 10 ml tear eye drops

### INDICATIONS:

Dry eye

### DOSAGE REGIMENS:

2 drops 2-3 times a day

### ADVERSE EFFECTS:

Irritation, blurred vision, allergic or hypersensitive reaction.

### 28. PREDNISOLONE EYE DROP

### SALIENT ACTIONS:

Solution (eye drops): 0.5% (sodium phosphate).

Prednisolone is a representative ophthalmic corticosteroid. Various drugs can serve as alternatives.

Uses: short-term local treatment of inflammation of the eye; malignant disease; suppression of inflammatory and allergic reactions.

### CONTRAINDICATIONS:

undiagnosed "red eye" caused by herpetic keratitis; glaucoma.

Precautions: cataract: corneal thinning, corneal or conjunctival infection; discontinue treatment if no

improvement within 7 days; risk of adrenal suppression after prolonged use in infants.

Administration:

NOTE. Use only under the supervision of an ophthalmologist. Inflammation of the eye, by ocular instillation, ADULT and CHILD, 1 drop every 1–2 hours, reducing frequency as inflammation is controlled.

### DRUG INTERACTIONS:

Increased requirement of insulin and oral hypoglycaemics. Actions blunted by barbiturates, phenytoin, rifampicin. Increased bioavailability with estrogens and oral contraceptives. Increases plasma salicylate levels. Increased risk of convulsions when used with ciclosporin, increased clearance by carbimazole or carbamazepine. Increased risk of GI bleeding and ulceration when used with NSAIDs. May decrease methotrexate clearance

### ADVERSE EFFECTS:

secondary ocular infection; impaired corneal healing (due to corneal thinning), optic nerve damage, cataract; glaucoma, mydriasis, ptosis, epithelial punctate keratitis, delayed hypersensitivity reactions including burning, and stinging.

### 29. PREDNISOLONE ACETATE & OFLOXACIN eye drops

### INDICATIONS:

Treating inflammation of the eyes and eyelids due to certain conditions. With antibiotic property.

### CONTRAINDICATIONS:

Allergic to any ingredient fungal, or viral infections

### PRECAUTIONS:

Prednisolone Acetate Drops may cause blurred vision. Pregnancy &lactation breast

### ADVERSE EFFECTS:

Blurred vision; temporary burning or stinging .Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); changes in vision; continued or worsening itching, swelling, or irritation; continuing blurred vision; discharge from eyes; eye pain.

### 30. SODIUM CHLORIDE SOLUTION 10 ml eye drops

### INDICATIONS:

Reduce swelling of the surface of the eye (cornea) in certain eye conditions like conjunctivitis .

### PRECAUTIONS:

Allergies, Pregnancy

### DRUG INTERACTIONS:

Not known yet

### ADVERSE EFFECTS:

Eye discomfort, burning, redness, or temporary blurred vision may occur. eye pain, vision changes. Serious allergic reaction: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

### 31. SODIUM HYALURONATE OPTHALMIC SOLUTION 1.4%

### SALIENT ACTIONS:

Sodium hyaluronate is a polysaccharide which functions as a tissue lubricant. It is widely used in ophthalmic surgery because it forms a viscoelastic solution in water which makes it a suitable substitute for aqueous and vitreous humour

### INDICATIONS & DOSAGE REGIMENS:

### Ophthalmic

Surgical aid in the anterior segment during cataract extraction and intraocular lens implantation Adult: Slowly admin a sufficient quantity into the eye.

### INTERACTIONS:

N/A

### PRECAUTIONS:

Monitor intraocular pressure. Pregnancy.

### **CONTRAINDICATIONS:**

Hypersensitivity to sodium hyaluronate or avian proteins.

### ADVERSE EFFECTS:

Ophthalmic: Transient rise in intraocular pressure:

### 32. TIMOLOL EYE DROPS

### SALIENT ACTIONS:

Timolol is a non-selective  $\beta$ -adrenergic receptor blocker. It does not have significant intrinsic sympathomimetic activity, direct myocardial depressant activity or local anaesth activity. Exact mechanism of ocular hypotensive effect is unclear, but it is thought to be related to reduction of aqueous humour formation.  $\beta$ -blockade also causes lowering of BP.

### **INDICATIONS & DOSAGE REGIMENS:**

### Ophthalmic

Open-angle glaucoma; Ocular HTN As eye drop soln: Initial: Instill 1 drop of 0.25% soln to affected eye(s) bid, increase to 1 drop of 0.5% soln bid if needed. Reduce to 1 drop once daily if controlled. As 0.25% or 0.5% gelforming eye drop: Instill 1 drop once daily.

### INTERACTIONS:

Concomitant admin w/ reserpine may increase hypotension and bradycardia. Additive effects w/ other antihypertensives (e.g. hydralazine, methyldopa). Increased  $\beta$ -adrenergic blockade (e.g. decreased heart rate) w/ quinidine. Rebound HTN due to abrupt withdrawal of clonidine. Hypotensive effect may be antagonised by NSAIDs (e.g. indomethacin, ibuprofen).

### PRECAUTIONS:

Patients w/ inadequate cardiac function, DM, myasthenia gravis, cerebrovascular insufficiency, history of atopy. Avoid abrupt withdrawal as it may exacerbate angina symptoms or precipitate MI in patients w/ coronary artery disease, or precipitate thyroid crisis in patients w/ thyrotoxicosis. Patients undergoing major surgery. May mask signs of hyperthyroidism and hypoglycaemia. Ophth soln should not be used as monotherapy for angle-closure glaucoma. Renal and hepatic impairment. Pregnancy and lactation.

### CONTRAINDICATIONS:

Present or history of bronchial asthma, severe COPD, allergic bronchospasm, sinus bradycardia, sick sinus syndrome, 2nd and 3rd degree heart block, overt heart failure, cardiogenic shock, severe peripheral vascular disease, untreated phaeochromocytoma, metabolic acidosis.

### ADVERSE EFFECTS:

Burning and stinging sensation of the eyes, bradycardia, hypotension, arrhythmia and AV or SA nodal block, CHF, pulmonary oedema, Raynaud's phenomenon, headache, dizziness, fatigue, asthenia, abdominal discomfort, nausea, constipation, hypoglycaemia.

### 33. TROPICAMIDE 1%W/V EYE DROP

### SALIENT ACTIONS:

Tropicamide is a tertiary amine antimuscarinic which causes relaxation of the sphincter muscle of the iris resulting in pupillary dilatation. It also causes paralysis of the ciliary muscle leading to loss of accommodation. Onset: Mydriasis: 20-40 min; cycloplegia: 30 min.

Duration: Mydriasis: 6 hrs; cycloplegia: 6 hrs.

### INDICATIONS & DOSAGE REGIMENS:

Ophthalmic

Production of cycloplegia

Adult: Instill 1-2 drops of a 1% solution repeated after 5 minutes. An additional drop may be admin after 20-30 minutes for prolonged effect.

Ophthalmic

Production of mydriasis

Adult: Instill 1-2 drops of a 0.5% solution 15-20 minutes before examination.

### INTERACTIONS:

May antagonise effects of ophthalmic carbachol, pilocarpine, or cholinesterase inhibitors.

### PRECAUTIONS:

Elderly, children, pregnancy. Hypertension, hyperthyroidism, DM, cardiac disorders. To reduce systemic absorption, press on the lacrimal sac for 1-2 minutes following instillation. Do not drive or engage in hazardous activities and protect eyes from bright illumination when pupils are dilated. May fail to produce adequate eveloplegia in children.

### CONTRAINDICATIONS:

Hypersensitivity. Narrow-angle glaucoma or shallow anterior chamber.

### ADVERSE EFFECTS:

Increased intraocular pressure, transient stinging, dry mouth, blurred vision, photophobia, tachycardia,

headache, superficial punctate keratitis, systemic anticholinergic effects, severe CNS disturbances in children (rare).

### 34. TROPICAMIDE 0.8% W/W + PHENYLEPHRINE HYDROCHLORIDE 5% ,5 ml eye drops SALIENT ACTIONS:

Phenylephrine/tropicamide is a combination of a mydriatic/cycloplegic drug. Phenylephrine is a synthetic sympathomimetic (adrenergic mydriatic following topical application, phenylephrine brings about contraction of the radial muscle thereby bringing about dilatation of the pupil. Tropicamide is a parasympatholytic drug which inhibits the contraction of the circular muscle and also paralyses the ciliary muscle. Tropicamide functions as a cycloplegic/mydriatic drug.

### INDICATIONS:

Inflammatory conditions of the uveal tract ,Retinal photography ,Refractive errors ,Fundus examination /photography ,Slit lamp examination Pre-operative use , In order to undergo surgical procedure that requires the visualization of structures behind the iris, such as cataract extraction, vitrectomy and retinal detachment surgery, the pupil must be adequately dilated before surgery.

### DOSAGE REGIMENS:

Uveitis: 1-2 drops bid-qid or as required.

Diagnostic purpose/Pre-operative purpose: 1-2 drops in the eye(s) 15-30 minutes prior to the procedure.

### CONTRAINDICATIONS:

Hypersensitivity to any of the components ,Narrow angles or narrow angle glaucoma 

Low birth weight infants and some elderly adults with severe arteriosclerotic cardiovascular or cerebrovascular disease During intraocular operative procedures when the corneal epithelial barrier has been disturbed.

### PRECAUTIONS:

Use with caution when administered with, or up to 21 days after administration of MAO inhibitors as exaggerated adrenergic effects may result. The pressor response of adrenergic agents may also be potentiated by tricyclic antidepressants. Rebound miosis has been reported in older persons one day after receiving phenylephrine solutions, and reinstillation of the drug produced a reduction in mydriasis. Development of psychotic reactions and behavioral disturbances should be considered in patients hypersensitive to anticholinergic drugs. Pregnancy Category C Safety for use during pregnancy has not been established.

### ADVERSE EFFECTS:

Elevated IOP, stinging on application, dryness of the mouth, blurred vision, tachycardia, photophobia with or without corneal staining, headache, parasympathetic stimulation and allergic reactions.

## LOTION

### LOTION

### 1. ANTISEPTIC LIQUID

It contains cetrimide+ chlorhexidine

### SALIENT ACTIONS:

Cetrimide is a quaternary ammonium antiseptic; it has bactericidal activity against both gram-positive and gram-negative organisms. Chlorhexidine is an antimicrobial agent; it is active against a wide range of gram-negative and gram-positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses.

### INDICATIONS:

As an antiseptic agent.

### DOSAGE REGIMEN:

For First Aid treatment – Apply the diluted liquid carefully to the affected area. Add 2 capfuls (30ml) of the liquid to ½ litre of warm water.

For personal hygiene and midwifery – Add 2 capfuls (30ml) of the liquid to ½ litre of warm water.

### CONTRAINDICATIONS:

Not to be used in the eye, ear, mucous membrane or body cavities.

### PRECAUTION:

Prolonged and repeated use may increase risk of hypersensitivity reactions. Blood, soap, cotton or other organic matter may decrease antibacterial efficacy.

### ADVERSE REACTIONS:

Repeated application may lead to skin irritation.

### 2. CALAMINE 8%W/V WITH GLYCERINE aqu.base, liquid 100 gm

### **SALIENT ACTIONS & INDICATIONS:**

This medication is used to relieve pain, itching, and discomfort from minor skin irritations such as poison ivy, poison oak, and poison sumac. It also helps to dry the oozing and weeping caused by irritation due to these plants. Act as protective layer on skin. Calamine have some sun screening property

### ADVERSE EFFECTS:.

skin irritation. A very serious allergic reaction to this drug is rare. allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

### 3. CLOTRIMAZOLE LOTION

### SALIENT ACTIONS:

Clotrimazole is a broad-spectrum antifungal which binds to phospholipids in the cell membrane altering cell wall permeability causing a loss in essential intracellular elements.

### INDICATION & DOSAGE:

Otic/Aural

Fungal otitis externa

Adult: Apply 1% solution to affected area.

Topical/Cutaneous

Skin fungal infections

Adult: Apply a 1% cream/lotion/solution bid-tid for 2-4 wk, may be used with a 1% powder to prevent reinfection.

### CONTRAINDICATIONS:

Hypersensitivity.

### PRECAUTIONS:

Avoid contact with eyes upon topical application. Childn <3 yrs. Pregnancy. lactation.

### INTERACTIONS:

Antagonism with polyene antibiotics.

### ADVERSE REACTIONS:

Topical: Erythema, stinging, irritation; hypersensitivity reactions; contact dermatitis. Oral: GI disturbances, dysuria, mental depression, elevated liver enzymes.

### 4. HALOBETASOL PROPIONATE LOTION 36ML

### SALIENT ACTIONS:

This medication is used to treat a variety of skin conditions (e.g., eczema, dermatitis, allergies, rash). Halobetasol reduces the swelling, itching, and redness that can occur in these types of conditions. This

medication is a very strong (super-high potency) corticosteroid.

### INDICATIONS:

This medication is used to treat a variety of skin conditions (e.g., eczema, dermatitis, allergies, rash).

### DOSAGE REGIMENS:

Apply a thin layer of the ointment, cream, or lotion to your affected skin once or twice per day

### CONTRAINDICATIONS:

Halobetasol propionate cream is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

### PRECAUTIONS:

Halobetasol propionate cream should not be used in the treatment of rosacea or perioral dermatitis, and it should not be used on the face, groin, or in the axillae.

### INTERACTIONS:

N/A

### ADVERSE EFFECTS:

dry skin, erythema, skin atrophy, leukoderma, vesicles and rash folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, striae and miliaria

### 5. KETOCONAZOLE LOTION

### SALIENT ACTIONS: Antifungal

### INDICATIONS:

Indicated for the treatment of DANDRUFF AND systemic fungal infections blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis

### DOSAGE REGIMENS:

Apply to the affected and immediate surrounding area once a day for 2 weeks.

### CONTRAINDICATIONS:

Hypersensitivity; preexisting liver disease. Concurrent use w/ CYP3A4 substrates e.g. HMG-CoA reductase inhibitors (e.g. lovastatin, simvastatin), midazolam, triazolam, cisapride, dofetilide, eplerenone, nisoldipine, pimozide, quinidine, terrenadine, astemizole, ergot alkaloids (e.g. ergotamine, dihydriergotamine).

### QT Interval prolonging drugs

### PRECAUTIONS:

Predisposition to adrenocortical insufficiency. Admin w/ acidic drink in patients w/ achlorhydria. Pregnancy, lactation. Monitoring Parameters Assess liver status prior to therapy and monitor serum ALT during treatment. Discontinue if there is persistent or worsening of liver enzyme elevation. Monitor adrenal function in patients w/ adrenal insufficiency or w/ borderline adrenal function and in patients under prolonged periods of stress (e.g. major surgery, intensive care).

### INTERACTIONS:

Reduced absorption w/ antimuscarinics, antacids, H<sub>2</sub>-blockers, PPIs, sucralfate. Reduced plasma concentrations w/ rifampicin, isoniazid, efavirenz, nevirapine, phenytoin. May also reduce concentrations of isoniazid and rifampicin. May reduce efficacy of oral contraceptives. May increase serum levels of CYP3A4 substrates e.g. digoxin, oral anticoagulants, sildenafil, tacrolimus.

Potentially Fatal: May potentiate and prolong sedative and hypnotic effects of midazolam and triazolam. Increased plasma levels and prolonged QT intervals of astemizole, cisapride, dofetilide, pimozide, quinidine and terfenadine which may lead to torsade de pointes. Increased risk of myopathy w/ HMG-CoA reductase inhibitors (e.g. lovastatin, simvastatin). Markedly increased plasma levels of nisoldipine. Increased risk of hyperkalaemia and hypotension w/ eplerenone. Increased risk of vasospasm potentially leading to cerebral ischaemia w/ ergot alkaloids (e.g. ergotamine, dihydroergotamine).

### ADVERSE EFFECTS:

Adrenal insufficiency; GI disturbances (e.g. abdominal pain, nausea, vomiting); rash, irritation, dermatitis, burning sensation, pruritus, urticaria, angioedema, anaphylaxis; alopecia, headache, dizziness, somnolence, fever and chills; thrombocytopenia, paraesthesia; menstrual irregularities, oligospermia, adrenal cortex supression, gynaecomastia, impotence; raised intracranial pressure; photophobia, photosensitivity; asymptomatic, transient elevations in LFTs.

Potentially Fatal: Hepatotoxicity.

### MOUTHWASH

### 6. LINDANE LOTION USP 1%W/V

### SALIENTACTIONS:

Lindane Lotion USP, 1% is an ectoparasiticide and ovicide effective against Sarcoptes scabiei (scabies). In addition to the active ingredient, lindane, it contains glycerol monostearate, cetyl alcohol, stearic acid, trolamine, carrageenan, 2-amino-2-methyl-1-propanol, methylparaben, butylparaben, perfume and water to form a nongreasy lotion.Lindane which is the highly purified gamma isomer of 1, 2, 3, 4, 5, 6, hexachlorocyclohexane.

### INDICATIONS

Scabies

Pediculosis

### DOSAGE REGIMENS:

Adult: Topical Scabies As 1% preparation: Apply on all skin areas from the neck to toes. Wash off after 8-12

Pediculosis As 1% shampoo: Apply 30-60 mL to dry hair. Max: 60 mL. Massage into hair for 4 mins, then rinse thoroughly.

### **CONTRAINDICATIONS:**

Hypersensitivity. Uncontrolledseizures; brokenskin; prematureinfant. Lactation.

### PRECAUTIONS:

Infants, small children, patients <50 kg, history of seizures or conditions which may increase risk of seizures. Hepatic impairment. Avoid contact with face, eyes, mucous membranes and urethral meatus. Pregnancy.

### ADVERSE DRUG REACTIONS:

Cardiac arrhythmia, ataxia, dizziness, headache, restlessness, seizure, pain, alopecia, contact dermatitis, eczematous eruptions, pruritus, urticaria, nausea, vomiting, aplastic anaemia, hepatitis, burning and stinging, paraesthesia, haematuria, pulmonary oedema.

Potentially Fatal: Severe neurologic toxicities.

### INTERACTIONS:

Enhanced absorption and increased risk of toxicity with oils and oil-based preparations.

Potentially Fatal: Increased toxicity with drugs that lower seizure threshold e.g. antidepressants, antipsychotics, ciclosporin, isoniazid.

### 7. MINOXIDIL SOLUTION

### SALINET ACTIONS:

Minoxidil reduces elevated systolic and diastolic BP by decreasing peripheral vascular resistance via vasodilation. Applied topically, it stimulates hair growth secondary to vasodilation, increases cutaneous blood flow and stimulates resting hair follicles.

### INDICATION & DOSAGE REGIMENS:

Topical/Cutaneous

### Male pattern baldness

Adult: Male: As 2% or 5% soln: Apply 1 mL to the scalp bid. As 5% foam or aerosol: Apply ½ capful to the scalp bid. Female: As 2% soln: Apply 1 mL to the scalp bid. As 5% foam or aerosol: Apply 1/2 capful to the scalp once daily.

### INTERACTION:

Additive effect w/ other hypotensive drugs. Risk of orthostatic hypotension w/ sympathetic blocking drugs (e.g. guanethidine). Topical: Enhanced absorption w/ other topical medical preparations (e.g. corticosteroids, retinoids or occlusive ointment bases).

### CONTRAINDICATION:

Phaeochromocytoma. Topical: Patient w/ treated or untreated HTN, scalp abnormality (e.g. psoriasis, sunburn), shaved scalp.

### PRECAUTION:

Patient w/ pulmonary HTN, angina pectoris, chronic heart failure, recent MI. Renal impairment. Elderly, childn. Pregnancy and lactation.

### ADVERS EFFECT

Reflex tachycardia, fluid retention, changes in ECG, hypertrichosis, pericardial effusion and tamponade, pericarditis, exacerbation of angina pectoris, headache, nausea, gynaecomastia, breast tenderness, polymenorrhoea, allergic rashes, Stevens-Johnson syndrome. Rarely, thrombocytopenia and leucopenia. Topical: Contact dermatitis, pruritus, local burning, flushing, changes in hair colour or texture.

### **MOUTHWASH**

### 1.CHLORHEXIDINE GLUCONATE

### SALIENT ACTIONS:

Germicidal mouthwash that reduces bacteria in the mouth

### INDICATIONS:

Treat gingivitis (swelling, redness, bleeding gums)

### DOSAGE REGIMENS:

Rinse:15 mL twice daily after brushing. Oral rinse should be retained for 30 seconds then expectorated after rinsing. Rinse your mouth with chlorhexidine gluconate twice daily after brushing your teeth.

### CONTRAINDICATIONS:

Allergic to chlorhexidine gluconate

### PRECAUTIONS:

Do not add water to chlorhexidine gluconate oral rinse. Do not rinse your mouth with water or other mouthwashes right after using chlorhexidine gluconate. Avoid eating, drinking, or brushing your teeth just after using this medication.

### ADVERSE EFFECTS:

Stain teeth, dentures, tooth restoration, If over dose /ingestion: nausea, stomach pain, or the appearance of being drunk. ,white patches or sores inside mouth or on lips;mouth ulcers; orswelling salivary glands, Less serious side effects may include:mouth irritation;dry mouth;unusual or unpleasant taste; ordecreased taste sensation

## PATCH

### PATCH

### 1. BUPRENORPHINE TRANSDERMAL PATCH

### SALIENT ACTIONS:

Buprenorphine exerts its analgesic effect via high affinity binding to the mu-opioid receptors in the CNS. It displays partial mu agonist activity and weak kappa antagonist activity.

### INDICATION & DOSAGE:

Moderate to severe pain

Adult: Non-malignant pain: Initial: 5 mcg/hr. Replace patch every 7 days and apply new patch to a different site. Avoid using the same area of the skin for the next 3-4 wk.

Cancer pain: Initial: Opioid-naive patient: 35 mcg/hr; patient receiving a strong opioid analgesic: Base dose on previous 24-hr opioid requirement. Replace patch every 96 hr at the latest and apply new patch to a different site. Avoid using the same area of the skin for at least the next 2 applications.

### CONTRAINDICATIONS:

Transdermal: Patient w/ known or suspected paralytic ileus, substantial resp depression or severe bronchial asthma. Management of acute, intermittent, mild, or short-term (including post-op) pain. Concomitant admin of IV buprenorphine and oral diazepam. Concurrent use or w/in 14 days of discontinuation of MAOIs.

### PRECAUTIONS:

Patient w/ pulmonary impairment or compromised resp function (e.g. COPD, cor pulmonale, decreased resp reserve [e.g. asthma, severe obesity, sleep apnoea], hypoxia, hypercapnia, pre-existing resp depression). Patient w/ hypothyroidism, myxedema, adrenocortical insufficiency (e.g. Addison's disease), dysfunction of biliary tract including acute pancreatitis, acute alcoholism, delirium tremens, toxic psychoses, kyphoscoliosis, prostatic hypertrophy or urethral stricture; comatose patients. Patient w/ CNS depression, history of seizure disorders, head injury, intracranial lesions or conditions in which intracranial pressure may be increased. Patient w/ personal or family history of QT interval prolongation, hypokalaemia or unstable cardiac disease (e.g. AF, CHF, myocardial ischaemia), particularly in transdermal admin. Hepatic or renal impairment. Pregnancy and lactation. Patient Counselling May impair ability to drive or operate machinery. Avoid exposing the patch to external heat.

Monitoring Parameters Establish baseline liver function levels prior to therapy and periodically monitor liver function throughout therapy in patients treated for opioid dependence.

### INTERACTIONS:

Plasma-buprenorphine concentrations may be affected when co-administered w/ drugs that induce or inhibit CYP3A4 isoenzyme. Enhanced depressant effects of other CNS depressants, other opiate agonists, anaesth, antihistamines, muscle relaxants, tranquilisers (e.g. phenothiazines), sedatives and hypnotics (e.g. benzodiazepines). Increased and/or prolonged activity w/ drugs that may reduce hepatic blood flow (e.g. halothane). Receiving class IA (e.g. quinidine, procainamide) or class III (e.g. sotalol, amiodarone) antiarrhythmic agents w/ transdermal buprenorphine may increase the risk of QT interval prolongation. Potentially Fatal: Concomitant admin of IV buprenorphine and oral diazepam may produce resp and CV collapse. MAOIs may be additive w/ or may potentiate action of CNS depressants.

### ADVERSE REACTIONS:

CNS depression, including somnolence, dizziness, alterations in judgment and levels of consciousness, including coma; sedation, dizziness, sweating, vertigo, headache; nausea, vomiting, dry mouth, constipation, dyspepsia, abdominal cramps, flatulence, diaphoresis; rash, urticaria, pruritus; miosis, blurred vision, hallucinations and other psychotomimetic effects; hypotension leading to syncope, HTN, tachycardia, bradycardia, ECG abnormalities.

Potentially Fatal: Resp depression (transderma!).

### 2. NITROGLYCERINE 25MG (PATCHES)

### SALIENT ACTIONS:

Glyceryl trinitrate forms free radical nitric oxide (NO), which stimulates guanylate cyclase in the vascular smooth muscle cells resulting in relaxation of smooth muscles. It reduces cardiac oxygen demand by decreasing preload and may modestly reduce afterload, dilates coronary arteries and improves collateral flow to ischaemic regions. It also decreases sphincter tone and intra-anal pressure when administered rectally.

### INDICATION&DOSAGES REGIMENS:

Transdermal

Stable angina

Adult: As patch releasing 2.5-20 mg/24 hr: Apply 1 patch onto a fresh area of skin (chest, upper arms, thigh or

shoulder). Max: 20 mg daily.

Transdermal

Prophylaxis of phlebitis and extravasation secondary to venous cannulation

*Adult:* As patch releasing 2.5-20 mg/24 hr: Apply 5 mg patch distal to the IV site, replace patch at a different skin site either daily or after 3-4 days depending on the patch; continue for as long as the IV infusion is maintained.

### CONTRAINDICATIONS:

Uncorrected hypovolaemia, postural hypotension, hypotension, marked anaemia, hypertrophic obstructive cardiomyopathy, constrictive pericarditis or pericardial tamponade, aortic or mitral stenosis, raised intracranial pressure (e.g. cerebral haemorrhage, head trauma), migraine or recurrent headache, closed-angle glaucoma. Concomitant use w/ phosphodiesterase type 5 (PDE5) inhibitors, riociguat, other organic nitrates w/ nitric oxide (NO) donors, heparin.

### PRECAUTIONS:

Patient w/ hypothyroidism, hypothermia, malnutrition, recent MI, arterial hypoxaemia due to severe anaemia, hypoxaemia or ventilation/perfusion imbalance due to lung disease or ischaemic heart failure. Severe renal or hepatic impairment. Pregnancy and lactation. *Patient Counselling* This drug may cause postural hypotension, dizziness. light-headedness, blurred vision, headache or tiredness, if affected, do not drive or operate machinery. *Monitoring Parameters* Monitor heart rate and BP.

### INTERACTIONS:

Enhanced hypotensive effect w/ vasodilators and other hypotensive drugs. Reduced efficacy (oral/buccal preparations) w/ drugs that cause dry mouth (e.g. TCAs, other antimuscarinics). Increased vasodilatory effect w/ acetyleysteine. May reduce the thrombolytic activity of alteplase. May increase the bioavailability of dihydroergotamine which may lead to coronary vasoconstriction.

Potentially Fatal: Potentiation of hypotensive effect w/ PDE5 inhibitors (e.g. sildenafil, tadalafil, vardenafil), riociguat and other organic nitrates w/ nitric oxide (NO) donors. May reduce the anticoagulant effect of heparin.

### ADVERSE DRUG REACTIONS:

Orthostatic hypotension, peripheral oedema, bradycardia, tachycardia flushing, hypotension, syncope, dizziness, headache, light-headedness, nausea, vomiting, xerostomia, weakness, paraesthesia, diaphoresis, dyspnoea, rhinitis, pharyngitis.

## SUPPOSITORIES

### SUPPOSITORIS

### 1. BISACODYL SUPPOSITORIES 10 MG(ADULT)

### SALIENT ACTIONS:

Bisacodyl stimulates peristalsis by directly irritating the smooth muscle of the large intestine. It alters water and electrolyte secretion, producing net interstitial fluid accumulation and laxation.

### INDICATIONS & DOSAGE:

Constipation

Adult: As supp or enema: 10 mg in the morning.

Child:  $\leq 10$  yr 5 mg in the morning;  $\geq 10$  yr Same as adult dose.

### CONTRAINDICATIONS:

Acute abdominal conditions (e.g. appendicitis, intestinal inflammatory bowel disease), intestinal obstruction, ileus, severe dehydration, severe abdominal pain associated w/ nausea and vomiting. Presence of anal fissures or ulcerative colitis w/ mucosal damage (rectal).

### PRECAUTIONS:

Childn. Pregnancy and lactation. Patient Counselling This drug may cause dizziness and/or syncope due to vasovagal response (e.g. abdominal spasm), if affected, do not drive or operate machinery.

### INTERACTIONS:

Risk of dyspepsia and gastric irritation w/ antacids. Increased risk of electrolyte imbalance w/ diuretics or adreno-corticosteroids.

### ADVERSE REACTIONS:

Abdominal discomfort (e.g. colic, cramps), diarrhoea, electrolyte disturbance, nausea, vertigo, vomiting, haematochezia; irritation and proctitis (rectal). Rarely, hypersensitivity reactions (e.g. angioedema, anaphylactoid reactions).

### 2. GLYCERIN SUPPOSITORY

### SALIENT ACTIONS:

Glycerin belongs to a class of drugs known as hyperosmotic laxatives. It works by drawing water into the intestines. This effect usually results in a bowel movement within 15 to 60 minutes.

### INDICATIONS:

It is used to treat hard stools (constipation).

### DOSAGE REGIMENS:

2-2.8 g suppository, retain 15 min

### CONTRAINDICATIONS:

rectal bleeding, intestinal blockage (obstruction).

### PRECAUTIONS:

other bowel problems (e.g., ulcerative colitis, hemorrhoids), current stomach/abdominal symptoms (e.g., pain, cramping, persistent nausea/vomiting).

### INTERACTIONS:

N/A

### ADVERSE EFFECTS:

severe/persistent stomach/abdominal pain, bloody stools, rectal bleeding, persistent urge to have a bowel movement, persistent diarrhea

### 3. PARACETAMOL SUPPOSITORY

### SALIENT ACTIONS:

Belong to the class of NSAIDs and act by non selectively inhibiting the COX-1 and COX-2 Ezymes. It has analgesic and antipyretic action and no anti-inflammatory action.

### INDICATIONS & DOSAGE REGIMENS:

Rectal

### Mild to moderate pain and fever

∠Adult: As supp: 0.5-1 g 4-6 hrly, Max: 4 g daily.

Child: 3 mth to <1 yr 60-125 mg; 1 to <5 yr 125-250 mg; 5-<12 yr 250-500 mg. Given 4-6 hrly if necessary, up to 4 times daily.

Rectal

### Post-immunisation pyrexia

Child: 2-3 mth 60 mg. If necessary, a 2nd dose may be given after 4-6 hr.

### CONTRAINDICATIONS:

Gastro-duodenal ulcer, chronic alcoholic.

### PRECAUTIONS:

Pregnancy Category (US FDA) – B. Renal or hepatic impairment; alcohol-dependent patients; G6PD deficiency INTERACTIONS:

Reduced absorption of cholestyramine within 1 hr of admin. Accelerated absorption with metoclopramide. Decreased effect with barbiturates, carbamazepine, hydantoins, rifampicin and sulfinpyrazone. Paracetamol may increase effect of warfarin.

Potentially Fatal: Paracetamol increases the risk of liver damage in chronic alcoholics. Increased risk of toxicity with other hepatotoxic drugs or drugs which induce microsomal enzymes e.g. barbiturates, carbamazepine, hydantoins, rifampicin and sulfinpyrazone.

### ADVERSE EFFECTS:

Nausea, allergic reactions, skin rashes, acute renal tubular necrosis.

Potentially Fatal: Very rare, blood dyscrasias (e.g. thrombocytopenia, leucopenia, neutropenia, agranulocytosis); liver damage.

## INHALATIONS

## RESPULES & INHALERS

### RESPULES & INHALERS

### 1. BUDESONIDES 0.5 mg, respules

### SALIENT ACTIONS:

Corticosteroid drug

### **INDICATIONS:**

Bronchial asthma, Treatment & prophylaxis of rhinitis

### DOSAGE REGIMENS:

Adults 100-200mcg bid, Max. 1600mcg/day. children; 50-IOOmcg two times a day, Max.

### 800mcg/day.CONTRAINDICATIONS:

Hypersensitivity. Acute infection uncontrolled by antibiotics

### PRECAUTIONS:

Carefully treat the patients of pulmonary TB, Paradoxical bronchospasm, Children, elderly;pregnancy, lactation ADVERSE EFFECTS:

Mild irritation, dryness, loss of skin collagen & Sc atrophy ,local hypo pigmentation of deeply pigmented skin, epistaxisis , rarely ulceration, candidiasis

### 2. FLUTICASONE PROPIONATE IP 0.5MG REPSULES

### SALIENT ACTIONS:

Fluticasone propionate given by inhalation at recommended doses has potent glucocorticoid activity in the airway, which results in reduced symptoms and exacerbations of asthma. The potent anti-inflammatory action improves the symptomatic control of asthma.

### INDICATIONS:

- Treatment of asthma (oral inhalation)
- Management of the nasal symptoms of perennial nonallergic rhinitis (nasal)
- Relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatose (topical)

### DOSAGE REGIMENS:

1 mg twice daily.

### CONTRAINDICATIONS:

- Acute episodes of asthma (Oral inhalation)
- Hypersensitivity to formaldehyde (Topical)
- Hypersensitivity to this drug (Nasal)
- Hypersensitivity to this drug (Topical)
- Primary treatment of status asthmaticus (Oral inhalation)
- Severe hypersensitivity to milk proteins (Oral inhalation)

### PRECAUTIONS:

N/A

### INTERACTIONS:

N/A

### ADVERSE EFFECTS:

- Headache (nasal)
- Pharyngitis (nasal)
- Epistaxis (nasal)
- Nasal burning (nasal)
- Nasal irritation (nasal)

### 3. IPRATROPIUM BROMIDE 250 mcg/ ml , 15 ml solution

### INDICATIONS:

Chronic obstructive pulmonary disease

### DOSAGE REGIMENS:

As nebulised solution: 500mcg 3-4 times /day

### CONTRAINDICATIONS:

Hypersensitivity to atropine./increases sensitivity to other anticholinergies

### PRECAUTIONS:

Narrow angle glaucoma, prostatic hypertrophy, pregnancy and factation renal &hepatic impairment

### INTERACTIONS:

Increased toxicity with other anticholinergic drugs

### ADVERSE EFFECTS:

Nausea, headache, dry mouth, dizziness. Gl uspests. additive effect with adrenergic. Urinary retention. Paradoxical bronchospasm. Anaphylactis reaction . Atrial fibrillation , supraventricular tachycardia

### 4. LEVOSALBUTAMOL 1.25 mg respules / SALBUTAMOL SUPLHATE 5 mg, 15 ml solution INDICATIONS :

Bronchospasm in adults and adolescents

### CONTRAINDICATIONS:

Hypersensitivity, Eclampsia & pre eclampsia, Intrauterine infection ,intrauterine foetal death , antepartum haemmorhage, Placenta praevia ,cord compression ,threatened miscarriage, Cardiac disease

### DOSAGE REGIMENS:

Adults and children above 12 years of age 0.63 mg (2.5ml) three times a day, every 6-8 hours by nebulization. In severe asthma 1.25mg (2.5ml) three times a day

### PRECAUTIONS:

Pregnancy, Cardiac disease, DM

### INTERACTIONS:

Diuretics, steroids ,xanthenes augment hypokalemia, Increased absorption of sulphamethoxazole if used together.Reduces serum level of digoxin, Digitalis toxicity

### ADVERSE EFFECT:

Fine skeletal musle tremor, Tachycardia ,palpitation ,headache, Muscle cramp ,paradoxical bronchospasm, Angioedema ,urticaria , Hypotension ,hypokalaemeia

### 5. MESNA RESPIRATOR SOLUTION

### SALIENT ACTIONS:

Mesna reduces the toxicity of urotoxic compounds that may form after chemotherapy administration. Mesna is a water-soluble compound with antioxidant properties, and is given concomitantly with the chemotherapeutic agents cyclophosphamide and ifosfamide. Mesna concentrates in the bladder where acrolein accumulates after administration of chemotherapy and through a Michael addition, forms a conjugate with acrolein and other urotoxic metabolites. This conjugation reaction inactivates the urotoxic compounds to harmless metabolites. The metabolites are then excreted in the urine.

### INDICATIONS& DOSAGE REGIMENS:

Adult: PO/IV Prophylaxis against urothelial toxicity Refer to individual and local protocol. Dose calculated based on cytotoxic dose. Usually given at a dose ≥cytotoxic dose. Treatment duration should be as long as cytotoxic treatment; plus the time it takes for concentration of antineoplastic metabolites in urine to fall. Inhalation Mucolytic in cystic fibrosis As 20% soln: Nebulise 3-6 mL twice daily.

### CONTRAINDICATIONS:

Hypersensitivity to thiol-containing compounds.

### PRECAUTIONS:

Protective effect applies only to the urinary tract; pregnancy, lactation. Patients with auto-immune disorders. IV formulation may contain benzyl alcohol as a preservative; avoid in neonates or infants. Instruct patients to seek medical attention if discolouration of urine occurs. During treatment, monitor urine for erythrocytes and haematuria. Maintain adequate hydration in all patients. Patients who vomit within 2 hr of oral dose should repeat dose or receive IV dose.

### ADVERSE EFFECTS:

Nausea, vomiting, colic, diarrhoea, anorexia, dyspepsia, unpleasant taste, constipation; headache, malaise, fatigue, depression, irritability, somnolence, hyperaesthesia, dizziness, confusion; rash, pruritus, generalised urticaria, alopecia, inj site reactions, flushing; leucopenia, thrombocytopenia, anaemia, granulocytopenia, chest pain, oedema (peripheral, facial and periorbital), hypotension, tachycardia, hypertension, increased heart rate, ST-segment elevation; dyspnoea, coughing, pneumonia, tachypnea; fever; hypocalcaemia; increased sweating; back pain, limb pain, myalgia; increased hepatic enzyme concentrations; pharyngitis; ulceration of mucous membranes. In patients receiving oral and/or IV mesna and were specifically not treated with concurrent cytotoxic therapy; flatulence; rhinitis; rigors; back pain; rash; conjunctivitis; arthralgia, Inhalation; bronchospasm.

Potentially Fatal: May cause haemorrhagic cystitis, systemic anaphylactic reactions.

### 6. MIDAZOLAM 0.5MG NASAL SPRAY

### SALIENT ACTIONS:

Midazolam is a short-acting benzodiazepine. It exerts sedative and hypnotic, muscle relaxant, anxiolytic and anticonvulsant actions. While the probable anxiolytic action might be as a result of the drug's ability to increase glycine inhibitory neurotransmitter level, the hypnotic/anaesthetic action may be due to the occupation of the benzodiazepine and GABA receptors leading to membrane hyperpolarisation and neuronal inhibition, and further interfering with the re-uptake of GABA at the synapses.

### INDICATIONS

Premedication before induction of anaesthesia

Conscious sedation before diagnostic or surgical interventions carried out under local anaesthesia For the emergency treatment of seizures, both in and out of hospital (for patients who often have seizures lasting longer than 5 minutes, and/or have a pattern of seizures that recur close together)

### DOSAGE REGIMENS:

### Adults

The recommended dose of MIDACIP Nasal Spray is as below:

Weight <50 kg: 5 mg Weight >50 kg: 10 mg

The dose should be equally divided and administered into each nostril.

### Children

The recommended dose of MIDACIP Nasal Spray is 0.2 mg/kg body weight. The dose should be equally divided and administered into each nostril.

Placing half the medication in each nostril will reduce the volume while doubling the available surface area for absorption.

Dosing Guidelines of MIDACIP Nasal Spray

Age (years)	Weight (kg)	Dose (mg)	Metered Doses in Each Nostril
1/2 - 1	<10	1.25 - 2	1 - 2
1 – 4	10 - 16	2.5	2 - 3
4 – 10	16 - 32	5	4 - 6
>10	> 32	10	10

### CONTRAINDICATIONS:

contraindicated in patients with Myasthenia gravis, or those with hypersensitivity to the active substance, benzodiazepines or to any of the excipients. It should also not be used in patients with existing CNS depression, shock, acute alcohol intoxication, coma, and uncontrolled pain. Benzodiazepines are contraindicated in patients with acute narrow-angle glaucoma. Benzodiazepines may be used in patients with open-angle glaucoma only if they are receiving appropriate therapy.

### PRECAUTIONS:

Paediatric patients with cardiovascular instability; chronic renal failure; open-angle glaucoma; cardiac disease; respiratory disease; myasthenia gravis; neonates; history of drug or alcohol abuse; elderly and debilitated (reduce dose); avoid prolonged use or abrupt withdrawal; hepatic impairment; severe fluid or electrolyte disturbances. May impair ability to drive or operate machinery; titrate dose carefully; monitor for early signs of hypoventilation, alrway obstruction, or apnea. Pregnancy, lactation

### INTERACTIONS:

Increased CNS depression with alcohol, opioids, barbiturates, other sedatives and anaesthetics. Increased respiratory depression with opiates phenobarbital, other benzodiazepines. Plasma concentrations increased by CYP3A4 inhibitors such

as cimetidine, erythromycin, clarithromycin, diltiazem, verapamil, ketoconazole and itraconazole, antiretroviral agents, quinupristin with dalfopristin. Midazolam concentration decreased byphenytoin, carbamazepine, phenobarbital, rifampicin. Halothane, thiopental requirements may be reduced during concurrent use

### ADVERSE DRUG REACTIONS:

Physical and psychological dependence with withdrawal symptoms; decreased tidal volume and respiration rate; apnoea; headache; hiccup; nausea, increased appetite, vomiting; cough; oversedation; seizure-like activity (paediatrics); paradoxical reactions; kernicterus; nystagmus; skin rash, pruritus; reduced alertness, confusion. euphoria, hallucinations, fatigue, dizziness, ataxia, post-operative sedation, anterograde amnesia; jaundice; cardiac arrest, heart rate changes, thrombosis; anaphylaxis; laryngospasm, bronchospasm, Potentially Fatal: Respiratory depression, respiratory arrest; hypotension.

### 7. SALINE NASAL SPRAY

### SALIENT ACTIONS:

Sodium chloride is the major extracellular cation. It is important in electrolyte and fluid balance, osmotic pressure control and water distribution as it restores sodium ions. It is used as a source of electrolytes and water for hydration, treatment of metabolic acidosis, priming solution in haemodialysis and treatment of hyperosmolar diabetes. It is also used as diluents for infusion of compatible drug additives.

### INDICATION & DOSAGE:

Oral

Chronic salt-losing conditions

Adult: As modified-release preparation: 2.4-4.8 g (40-80 mmol sodium) daily accompanied by suitable fluid intake. Up to 12 g daily may be necessary in severe cases.

Renal impairment: Dosage adjustment may be necessary.

Prophylaxis of muscle cramps during routine haemodialysis

Adult: As modified-release preparation: 6-10 g every dialysis session.

Oral hygiene

Adult: Used as mouthwash.

Nasal

Nasal congestion

Adult: 0.9% used as nasal drops or spray.

Child: 0.9% used as nasal drops.

Intravenous

Replacement of fluid and electrolytes

Adult: As 0.9%, 3% or 5% solution: Dosage depends on age, wt, clinical condition and laboratory determinations of the patient. Dose to be administered via a large vein, with care taken to prevent infiltration. Intravenous

Hypernatraemia

Adult: As 0.9% solution: Dosage depends on age, wt, clinical condition and laboratory determinations of the patient. Dose to be administered via a large vein, with care taken to prevent infiltration.

Irrigation

Irrigation of the bladder, eye, general skin and wound cleansing

Adult: 0.9% solution is used.

### CONTRAINDICATION:

Conditions whereby admin of sodium chloride would be detrimental. Not to be used to induce emesis. Sustained release tablets: GI disorders associated with strictures or diverticula.

### PRECAUTION:

Hypertension, heart failure, peripheral or pulmonary oedema, impaired renal function, liver cirrhosis, preeclampsia. Maintain adequate water intake. Pregnancy, Inj of 3 or 5% sodium chloride solution should be given via a large vein at a rate not exceeding 100 ml/hr. Monitor fluid balance, serum electrolytes and acid base balance espeially during prolonged treatment. Caution when used in patients who are receiving corticosteroids or corticotropin.

### INTERACTION:

May affect serum concentrations of lithium.

### ADVERSE REACTION:

Hypernatremia; thirst, reduced salivation and lachrymation, fever, tachycardia, hypertension, headache, dizziness, restlessness, irritability and weakness.

Potentially Fatal: Intra-amniotic Inj of hypertonic solutions: Disseminated intravascular coagulation, renal necrosis, cervical and uterine lesions, pulmonary embolism, pneumonia and death.

### 8. SODIUM CHLORIDE NASOMIST SALINE NASAL SPRAY 20ML INDICATION & DOSAGE:

His product is used to treat dryness inside the nose (nasal passages). It helps add moisture inside the nose to dissolve and soften thick or crusty mucus. In babies and young children with stuffy noses who cannot blow their noses, using this product helps to make the mucus easier to remove with a nasal bulb syringe. This helps relieve stuffiness and makes breathing easier.

**PRECAUTION:** Before using this product, tell your doctor if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems.

### ADVERSE REACTION:

Dryness, Itching Stinging, Local irritation, Soreness

### 9. XYLOMETAZOLINE HCL IP 0.05% NASAL SPRAY

### SALIENT ACTIONS:

Xylometazoline is a direct-acting sympathomimetic which has a vasoconstrictor effect by reducing swelling and congestion when applied to mucous membranes.

### INDICATIONS & DOSAGE REGIMENS:

Nasal

Nasal congestion

Adult: As 0.1% solution: Instill into each nostril bid-tid. Max duration: 7 days.

Child: As 0.05% solution: 3 mth-12 yr: 1-2 drops into each nostril once or bid. Max duration: 7 days.

### INTERACTIONS:

ncreased heart rate or BP with sibutramine.

Potentially Fatal: Hypertensive crisis with MAOIs.

### PRECAUTIONS:

Young children, pregnancy and lactation. Hypertension, CV abnormalities, DM, hyperthyroidism, history of excessive reaction to sympathomimetics, difficulty in urination secondary to prostate enlargement. Rebound congestion may occur after prolonged regular use.

### CONTRAINDICATIONS:

Angle closure glaucoma; dry rhinitis; post trans-sphenoidal hypophysectomy, trans-nasal, trans-oral surgery where dura mater is exposed.

### ADVERSE EFFECTS:

Nasal drops: Local stinging or burning, sneezing, dryness of mouth and throat, nausea.

## ANAESTHETICS

### ANAESTHETICS

### 1. DESFLURANE USP ANAESTHETICS

### SALIENT ACTIONS:

Desflurane is a volatile halogenated methylethylether anaesthetic. It enhances inhibitory postsynaptic activity and inhibits excitatory synaptic activity, resulting in reversible loss of consciousness and of pain sensations, suppression of voluntary motor activity, reduction of autonomic reflexes, and sedation of respiratory and the cardiovascular system.

### INDICATION & DOSAGE:

Inhalation

Induction and maintenance of general anaesthesia

Adult: Induction: Initially, 3% v/v inhaled via calibrated vaporiser, increased in 0.5-1% increments every 2-3 breaths (end-tidal concentrations of 4-11% v/v). Maintenance: 2-6% v/v w/ nitrous oxide or 2.5-8.5% v/v in oxygen or oxygen-enriched air.

Child: Maintenance (after induction w/ agents other than desflurane): 5.2-10% v/v w/ or w/o nitrous oxide. Renal impairment: Chronic impairment and during renal transplantation surgery: 1-4% v/v in oxygen and nitrous oxide.

Hepatic impairment: Chronic impairment: 1-4% v/v in oxygen and nitrous oxide.

### CONTRAINDICATIONS:

Known or genetic susceptibility to malignant hyperthermia, coronary artery disease. History of moderate to severe hepatic impairment associated w/ halogenated anaesthetics.

### PRECAUTIONS:

Patient w/ or at risk of raised intracranial pressure, neuromuscular disease (particularly Duchenne muscular dystrophy), and those at risk of QT prolongation. Not indicated as induction agent in paediatric patients or for maintenance of anaesth in non-intubated childn <6 yr. Chronic renal or hepatic impairment. Childn. Pregnancy and lactation. Patient Counselling May impair ability to drive or operate machinery, if affected, avoid such task for a period of 24 hours. Monitoring Parameters: Monitor BP, heart rate and rhythm, temp, oxygen saturation, end-tidal CO<sub>2</sub> and end-tidal desflurane concentration prior to and throughout procedure. Monitor signs and symptoms of airway narrowing for paediatric patients. Assess for malignant hyperthermia, hypercapnia, muscle rigidity, tachycardia, cyanosis, arrhythmias, hypotension or HTN.

### INTERACTIONS:

Enhanced effects of neuromuscular blockers (e.g. atracurium) and muscle relaxants. Reduced minimum alveolar concentration (MAC) w/ opioids and benzodiazepines.

### ADVERSE REACTIONS:

Cough, apnoea, laryngospasm, increased secretions, nausea, vomiting, breath-holding, resp depression, hypotension, arrhythmia, coagulopathy, metabolic acidosis, convulsion, dizziness, migraine, ocular icterus, malignant HTN, haemorrhage, shock, abdominal pain, pancreatitis, urticaria, erythema, jaundice, decreased blood flow, increased intracranial pressure.

Potentially Fatal: Rarely, malignant hyperthermia, hyperkalaemia resulting in cardiac arrhythmias (particularly in childn).

### 2. ISOFLURANE 250 ml bottle

### SALIENT ACTIONS:

A nonflammable liquid administered by vaporizing, is a general inhalation anesthetic drug. It is 1-chloro-2,2,2-trifluoroethyl difluoromethyl ether. CIsoflurane is a clear, colorless, stable liquid containing no additives or chemical stabilizers. Isoflurane has a mildly pungent, musty, ethereal odor. Induction of and recovery from Isoflurane anesthesia are rapid. Isoflurane has a mild pungency, which limits the rate of Induction, although excessive salivation or tracheobronchial secretions do not appear to be stimulated. Pharyngeal and laryngeal reflexes are readily obtunded. The level of anesthesia may be changed rapidly with Isoflurane. Isoflurane is a profound respiratory depressant.

### INDICATIONS & DOSAGE REGIMENS:

Isoflurane, USP may be used for induction and maintenance of general anesthesia. Adequate data have not been developed to establish its application in obstetrical anesthesia Inspired concentrations of 1,5 to 3.0% Isoflurane usually produce surgical anesthesia in 7 to 10 minutes. Maintenance Surgical levels of anesthesia may be sustained with a 1.0 to 2.5% concentration when nitrous oxide is used concomitantly. An additional 0.5 to 1.0% may be required when Isoflurane is given using oxygen alone.

### CONTRAINDICATIONS:

Known sensitivity to Isoflurane, USP or to other halogenated agents. Known or suspected genetic susceptibility to malignant hyperthermia

### PRECAUTIONS:

As with any potent general anesthetic. Isoflurane, USP should only be administered in an adequately equipped anesthetizing environment by those who are familiar with the pharmacology of the drug and qualified by training and experience to manage the anesthetized patient. Regardless of the anesthetics employed, maintenance of normal hemodynamics is important to the avoidance of myocardial ischemia in patients with coronary artery disease 4.5.6,7. Isoflurane, USP, like some other inhalational anesthetics, can react with desiccated carbon dioxide (CO 2) absorbents to produce carbon monoxide, which may result in elevated levels of carboxyhemoglobin in some patients. Case reports suggest that barium hydroxide lime and soda lime become desiccated when fresh gases are passed through the CO2 absorber canister at high flow rates over many hours or days. When a clinician suspects that CO2 absorbent may be desiccated, it should be replaced before the administration of Isoflurane, USP. As with other halogenated anesthetic agents, Isoflurane, USP may cause sensitivity hepatitis in patients who have been sensitized by previous exposure to halogenated anesthetics

### INTERACTIONS:

Isoflurane potentiates the muscle relaxant effect of all muscle relaxants, most notably nondepolarizing muscle relaxants, and MAC (minimum alveolar concentration) is reduced by concomitant administration of N2O.

### ADVERSE DRUG REACTIONS:

Adverse reactions encountered in the administration of Isoflurane, USP are in general dose dependent extensions of pharmacophysiologic effects and include respiratory depression, hypotension and arrhythmias. Shivering, nausea, vomiting and ileus have been observed in the postoperative period. As with all other general anesthetics, transient elevations in white blood count have been observed even in the absence of surgical stress, postoperative hepatic dysfunction and hepatitis. Isoflurane USP has also been associated with perioperative hyperkalemia. There have been rare post-marketing reports of hepatic failure and hepatic necrosis associated with the use of potent volatile anesthetic agents, including Isoflurane USP

### 3. SEVOFLURANE 250 ml bottle

### SALIENT ACTIONS:

Sevoflurane, USP, volatile liquid for inhalation, a nonflammable and nonexplosive liquid administered by vaporization, is a halogenated general inhalation anesthetic drug. Sevoflurane, USP is fluoromethyl 2,2,2,-trifluoro-1-(trifluoromethyl) ethyl ether

### INDICATIONS & DOSAGE REGIMENS:

Sevoflurane, USP is indicated for induction and maintenance of general anesthesia in adult and pediatric patients for inpatient and outpatient surgery. Sevoflurane, USP should be administered only by persons trained in the administration of general anesthesia. Facilities for maintenance of a patent airway, artificial ventilation, oxygen enrichment, and circulatory resuscitation must be immediately available. Since level of anesthesia may be altered rapidly, only vaporizers producing predictable concentrations of Sevoflurane, USP should be used.

### CONTRAINDICATIONS:

Sevoflurane, USP can cause matignant hyperthermia. It should not be used in patients with known sensitivity to Sevoflurane, USP or to other halogenated agents nor in patients with known or suspected susceptibility to malignant hyperthermia

### INTERACTIONS:

In clinical trials, no significant adverse reactions occurred with other drugs commonly used in the perioperative period, including: central nervous system depressants, autonomic drugs, skeletal muscle relaxants, anti-infective agents, hormones and synthetic substitutes, blood derivatives, and cardiovascular drugs

# MEDICAL DEVICE AND IMPLANTS

### MEDICAL DEVICE AND IMPLANTS

SR. NO.	ITEM NAME	
1	ADLER CEMENT RESTRICTOR	
2	ADLER ENDOFIT STEM SIZE O,36MM OFFSET	
3	ADLER MODULAR BIPOLAR CUP 49/28	
4	ADLER MODULAR HEAD HI-N STEEL 28MM-3.5MM	
5	ALTRX NEUTRAL 32 X 50	
6	ARTICUL/EZE BALL 32+	
7	BIPOLAR HEAD SS- 47 LONG	
8	6.5 MM C C FULLY THRD	
9	6.5 MM C C SCREW	
10	6.5 MM C C SCREW 16TH 45MM	
11	6.5 MM C C SCREW 16TH 65MM	
12	6.5 MM C C SCREW 16TH 70MM	
13	6.5 MM C C SCREW 32TH 70MM	
14	6.5MM C C SCREW F/T 85MM	
15	6.5 MM C C SCREW F/T 65MM	
16	C SCREW 4.5 MM	
17	6.5 C.C .SCREW 75 MM	
18	6.5 MM CAN LOC SCREW F T	
19	CANC SCREW 30MM	
20	CANC SCREW 32MM	
21	CANC SCREW 5 MM LOC	
22	6.5 MM CANCELLOUS SCREW F T	
23	4MM CANCELLOUS SCREW TIT	
24	4MM CANNECTING ROD 250M	
25	CANNULA 7.0 *72 (72200905)	
26	CANNULA 8.5*72 (72200903)	
27	CEMENT	
28	CEMENT PRESSURISER( INSTRUMENT)	
29	CEMENT SYRINGE KIT	
30	CONNECTING ROD 8MM*150MM	
31	CONNECTING ROD TIT 5.5*150	
32	CONNECTION BOLT 10MM	
33	CONNECTION BOLT 16MM	
34	CONNECTION BOLT 20MM	
3.5	CORAILZ STD SIZE 11	
36	2.4 MM CORTEX SCREW	
37	2.7 MM CORTEX SCREW	
38	3.5 MM CORTEX SCREW	
39	4.5 MM CORTEX SCREW	
40	3.5 MM CORTEX SCREW 20TPI 20MM	

	41	3.5 MM CORTEX SCREW 20TPI 24MM
	42	3.5 MM CORTEX SCREW 20TPI 26MM
1	43	4.5 MM CORTEX SCREW 24MM
ľ	44	4.5 MM CORTEX SCREW 34MM
ŀ	45	4.5 MM CORTEX SCREW 36MM
-	46	4.5 MM CORTEX SCREW 38MM
1	47	4.5 MM CORTEX SCREW 42MM
	48	2.4 MM CORTEX SCREW.
	49	3.5 CORTICAL SCREW 14MM
Ţ	50	3.5 CORTICAL SCREW 16MM
Ī	51	3.5 CORTICAL SCREW 18 MM
	52	3.5 CORTICAL SCREW 18MM
	53	3.5 CORTICAL SCREW 22 MM
Ī	54	4.5 CORTICAL SCREW 26MM
	55	3.5 CORTICAL SCREW 42MM
	56	4.5 CORTICAL SCREW 42MM
	57	D C ROD MEDIUM
	58	95D. DCS PLATE DCP HOLE 10HOLE
	59	DENHEMS PIN 4.5MM
	60	DHENMAN PIN 4.5MM* 9
	61 .	DHS NAIL 85 MM
	62	DHS PLATE 130X4H
	63	DHS SCREW HEXAGOANAL 75MM
	6.4	DISTAL FEMURAL LOCKING PLATE 5H(L)
	65	DISTAL RADIUS VOLAR PLATE L 5H
	66	DISTRACTOR
	67	DLX STEM SS TMOD MEDIUM 140
	68	DRILL BIT 1.5 MM
	69	DRILL BIT 2MM
	70	EXTRA ARTICULAR DIST HUM LCP PLATE L 8H
	71	FLAT SIDED WASHER 2MM
	72	FLAT SIDED WASHER 4MM
	73	GLUCAGON HCL 1MG HYPOKIT
	74	GUIDE WIRE 1.8MM X9"
	75	4 MM HERBUT SCREW (TIT)
	76	HINGES FEMALE STANDARD
	77	2 X 4 HOLE L PLATE L+R
	78	2 X4 HOLE L -SHAPE PLATE
	79	2 X 2 HOLE WITH GAP
	80	2 X 4 HOLE WITH GAP
3	81	2.5 X 4HOLE WITH GAP
	82	2 X4 HOLE WITH GAP ORIBITAL PLATE
	83	1 L BOLT 4.9 MM 38
	84	I L BOLT 4.9 MM 50

85	I L BOLT 4.9 MM 52	
86	I L BOLT 4.9 MM 32	
87		
88	I L BROKEN NAIL EXTRACTOR SET(TIBIA, FEMUR, HAMMER)  I.L BOLT 4.9 34MM	
89 IMPLANT NAIL REMOVAL SET		
90 INSULIN PEN		
91	K WIRE	
92	K WIRE 1.5 MM 06	
93	K WIRE IMM X 6"	
94	K WIRE 2MM X 6"	
95	K.WIRE	
96	K.WIRE 6"	
97	L WIRE	
98	LATERAL TIBIA LOCKING PLATE L 9H	
99	LATERAL TIBIA LOCKING PLATE R 11H	
100	3.5 MM LOC SCREW 14MM	
101	3.5 MM LOC SCREW 18MM	
102	3.5 MM LOC SCREW 20MM	
102	3.5 MM LOC SCREW 20MM	
104	6.5 LOCKING CANCELLOUS 32 TH -50MM	
105	6.5 LOCKING CANCELLOUS F. TH -50MM	
105	2.7 MM LOCKING SCREW	
107	3.5MM LOCKING SCREW	
107	4.8 MM LOCKING SCREW	
109	- H	
110	4.9 MM LOCKING SCREW 5MM LOCKING SCREW	
111	201000000 a.c. He support to the support of the sup	
112	3.5 LOCKING SCREW 14MM 2.7 LOCKING SCREW 16MM	
113	2.7 LOCKING SCREW 16MM  2.7 MM LOCKING SCREW 16MM	
114	2.7 LOCKING SCREW 22MM	
115	3.5 LOCKING SCREW 22MM	
116	2.7 LOCKING SCREW 26MM	
117	4.9 LOCKING SCREW 26MM	
118	3.5 LOCKING SCREW 26MM	
119	3.5 LOCKING SCREW 36MM	
120	4.9 LOCKING SCREW 44MM	
121	5MM LOCKING SCREW 5MM X 30MM	
122	LONG P F N L 130 10*38	
123	MEDTRONIC NETTERVILLE PHONOFORM, SILICON, LEFT (SI BLOCK).	
124 ·		
125	MONOLOCK MONOLP 6.5*35	
126	MONOLOCK MONOLP 6.5*40 NOZZEL	
127		
127	ONBUTTON CL LOOP SIZE- 20MM	
120	P BOLT 6.4 X 65	

129	P.F.N BOLT 6.4-60MM
130	P.F.N BOLT 8MM- 80MM
131	P.F.N BOLT 8MM-85MM
132	PIN FIXATION BOLT FOR PIN
133	PINNACLE SECTOR II C
134	PISTON TEFLON ROUND SHAPE 0.5 X 5.0 MM
135	PISTON TEFLON ROUND SHAPE 0.6 X 5.0 MM
136	PLANE DRIVER 2 MM
137	PLANE DRIVER 2.5 MM
138	PORP TEFLON
139	PROXIMAL FEMORAL LOCKING COMPRESSION PLATE 7H + 7H
140	PREGNANCY TEST DEVICE
141	3.5 MM RECON LOCKING PLATE 6H
142	RESTRICTOR
143	3.5 MM ROUND CLAMP
144	ROUND CLAMP 8*5
145	SCHANZ PIN
146	2.5MM SCHANZ SCREW
147	3.5MM SCHANZ SCREW
148	SCHANZ SCREW 2.5 MM
149	SCHANZ SCREW 3.5 MM
150	SCHANZ SCREW 4.5MM
151	5MM SCHANZ SCREW 5MM*32 TH *9
152	2 X 10 MM SCREW
153	2 X 8MM SCREW
154	2.5 X 12 MM SCREW
155	SHEPARD GROMMET TEFLON TYPE(MEDIUM)
156	SINGLE LOCK MONO SCREW (TIT)5.5*30MM
157	SINGLE LOCK MONO SCREW (TIT)6.5MM*40MM
158	SMALL DCP 6H
159	3.5 MM SMALL DCP 8 HOLE
160	3.5 MM SMALL LC DCP 7 HOLE
161	SMALL T LOCKING PLATE 7H
162	SOFTFIX INTERFERENCE SCREW ,CANNULATED ROUNDHEAD DIA.10.0* LEN.25MM TITANIUM STERILE
163	SPACER
164	STEM CENTRALISER DIA 10 ENDOFIT
165	STIMULAN KIT RAPID CURE 10CC
166	STIMULAN RAPID CURE 5CC
167	STOKINET
168	SUPERIOR ANTERIOR CLAVICAL LCP (L) 3H
169	SURGICAL SIMPLEX BONE CEMENT 40G .
170	SUTURE FIX ULTRA ANCHOR1.7 (72203853)

171	SUTUREFIX TIBIAL BASE PLATE ROUND HOLE TITANIUM STERILE
172	T BUTTRESS LOCKING PLATE 5MM X 4HOLE
173	T. B. W.
174	T.F.N NAIL 135.12
175	THR K WIRE
176	THREADED ROADS 120 MM
177	THREADED ROADS 200 MM
178	THREADED RODS 100MM
179	THREADED SOCKET
180	TIT MINI PLATE 2 MM (WITHOUT GAP)
181	TIT MINI SCREW 2 MM SLOT (32TPI)
182	TOP LOADING CROSS LINK SM
183	TORP TEFLON
184	3.5 MM 1/3 TUBULAR PLATE 9 HOLE
185	1/3 TUBULAR PLATE LOCKING 4H
186	ULNA SQUARE NAIL
187	VOLAR DORSAL LOC PLATE R 3H
188	VOLAR DORSAL LOCKING PLATE RIGHT SIDE 4 HOLE
189	6.5 MM WASHER **
190	WASHER 6.5
191	4MM WASHER TIT
192	WASHER TIT
193	WIRE FIXATION BOLT CANNULATED
194	WIRE FIXATION BOLT SLOTTED
195	WIRE TROCHAR POINT 1.8 MM
196	WIRE WITH STOPPER BAYONET POINT

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