

Ethiopian Rural Drug Vender Formulary

First Edition



Ethiopian Food, Medicine and Health Care
Administration and Control Authority

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FOREWORD

As per the National Drug Policy, Ensuring Availability and proper use of medicines of proven safety, efficacy and quality at an affordable price is a critical issue. Availability of medicines formulary is one of the corner stone for good pharmaceutical management and rational medicine use. Moreover, Standards of medication and proper medicines use is very essential in order to practice quality health service and to utilize the available medicines.

As a result, it gives me a great pleasure to introduce this edition of the Rural Drug Vender Formulary (RDVF) to all beneficiaries, which is the fruit of the joint effort of the staff of the Authority, development partners as well as the participants of the review workshops

The RDVF aims to provide prescribers, dispensers and other healthcare professionals with sound up-to-date information about the use of medicines. This formulary includes medicines which are available in the rural drug vender medicine list and has key information on the selection, prescribing, dispensing and administration of medicines.

I hope that this formulary will serve as useful guides for the good pharmaceutical management and rational medicine use as well as patient safety.

Finally, I would like to express my gratitude to all those who have directly or indirectly extended their helping hands in the development and printing of the formulary. I also call upon all users and interested parties to continue their usual support in updating the formulary by forwarding comments and suggestions to the Food, Medicines and Healthcare Administration and Control Authority of Ethiopia.

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Introduction

Proper medicines use including rational prescribing, rational dispensing and proper administration of medicines by the patient's is important in the health of the public. Defining the patient's problems, setting therapeutic objectives and proper communication with patients promotes rational use of medicines which eventually help to reduce harm to the health of each individual and the effects on the overall health-care delivery service. Surely, medicines should be prescribed and dispensed only when the benefits outweigh the risks to the individual patient.

In Ethiopia, as the health service expands quite rapidly, medicines information resources need to be made available and accessible at equal pace. In relation to this the government recognizes the unmet need on medicines information and has been striving to develop and make accessible information using different mechanisms. As a result, it is our pleasure to introduce and provide all beneficiaries this comprehensive Rural Drug Vendor Formulary (RDVF)

The Formulary aims to provide standard information on medicines and to help health professionals base their practice on solid information and knowledge to promote rational use of medicines.

The formulary contains detailed information on each pharmacotherapeutic class of drugs and specific information for each drug including indication, caution, drug interaction, contraindication, side effect, dose and administration and information on storage condition. The formulary also contains general notes on good prescribing and dispensing practices, and other necessary information.

While developing the formulary the "British National Formulary, Drug Information Handbook, Ethiopian National Drug Formulary,

Martindale Complete Drug Reference, AHFS Drug Information, South Africa Medicines Formulary (SAMF), World Health Organization (WHO) Model Drug Formulary and standard text books of pharmacy, pharmacology and therapeutics have been used as a reference. The pharmaco-therapeutic classification is based on the rural drug venders medicines list for Ethiopia 4th edition , 2011.

We hope, that this formulary will be of assistance in providing useful information to the health workers and in promoting the rational use of drugs and as result provision of quality health services. It is also hoped that the formulary will be of particular use to those health professionals working at the periphery who have no access to adequate and up to date information. It is designed as a digest for rapid reference and it may not always include all the information necessary for prescribing and dispensing. And by no means it does not substitute standard treatment guidelines.

Subsequently, the authority will continuously update the formulary and all readers and users are strongly invited to share their expertise in the field and provide comments and suggestions to the following address.

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General

Medicines or drugs are chemical or biological substances that are used in the treatment, cure, prevention, or diagnosis of diseases or used to otherwise enhance physical or mental well being.

In order to achieve the maximum benefit from medicines; they need to be properly stored, properly handled, properly dispensed and used rationally. On the other hand if drugs are not handled properly they could contribute to the extent of a life threatening situation to the user. The irrational use of medicines is a critical problem in the Ethiopian health care system that it is every professional responsibility including professional working at rural drug vendor level to change the situation.

The Third Edition of the List of Drugs for Rural Drug Vendors was published on September, 2002. The Fourth and Current Edition of this list developed as a formulary for the first time.

The main purpose of this formulary is to provide first hand information and quick reference to owners and professionals working in the rural drug vendors about all the list of medicines included and allowed to be dispensed and in effect improve the access and quality of services rendered to the rural population.

The Formulary include both over the counter drugs/ OTC/ and prescription only medicines /POM/ with their pharmacological group and provides standard information about indications, cautions, drug interactions, contra-indications, warnings, side effects, dose, frequency and route of administration about the specific drug.

Dispensing and Counseling Practices

Rational use of drugs is a tool through which safe, effective and affordable essential medicines are provided to the needy people. The promotion of rational use of drugs is a collaborative effort by prescribers, dispensers and end drug users. The rational dispensing of drugs at any level of dispensing practices plays an important role in the health care system.

Especially professionals at the RDV level should take their time to explain and advise the patients and or relatives about the proper administration, use of drugs, warnings and potential side effects to improve the compliance of medicines.

Considering the level of literacy and knowledge about drug; dispensers should advise their clients slowly and repeatedly until they are clear about when and how to take the drugs and the required precautions.

Dispensers should listen attentively and with full concern by creating the appropriate environment during dispensing and counseling; so that the patient can openly and freely forward and clear all his doubts about the dispensed drugs.

Additional written communication using the local language should be practiced during dispensing and counseling to make the information disseminated more reliable to clients.

In general the dispenser at rural drug vendor level should look carefully for the following basic information, when receiving a prescription.

- Check the legality of the prescription;
- Check completeness and accuracies of the prescription;
- Check for whom the medicine is being dispensed: actual client or care taker;
- If in doubt about the contents of the prescription; call and verify with the prescriber;
- Medicinal envelops/containers for packaging dispensed drugs must be appropriate for the product;
- Keep filled prescriptions at least for 2 years;
- Sample of a Standard Prescription Form is annexed for your reference.

Once sure about the prescription; the dispenser should clearly explain verbally and possibly in written form the following basic information during dispensing.

- Name of medicine(trade name, generic, or other descriptive name(s));
- Route of administration;

- Frequency of administration;
- Special direction for administration;
- How long the drug should be taken;
- Outcome of the therapy;
- Common side effects;
- Any restriction when taking the drug (diet, alcohol, etc.);
- Action to be taken in the events of missed dose;
- Proper storage of dispensed drugs;
- Other non-drug therapy;
- Stickers/labels should be clearly legible and indelible and should be written in pen not ink.

Adverse Drug Reaction

Adverse drug reaction (ADRs) is noxious unwanted effects of drugs that occur at therapeutic doses. Rapid detection and recording of adverse reaction is of vital importance so that unrecognized and hazardous reactions are identified promptly and appropriate regulatory action is taken to ensure that medicines are used safely.

Adverse drug reaction can be:-

- Mild – Where no intervention is required;
- Moderate – Where switch is necessary to another drug;
- Severe – Where antidotes should be employed to alleviate the situation.

ADRs are different from toxic reactions which occur at higher doses due to accidental or intentional reactions.

Suspected adverse drug reactions to any medicines should be immediately reported, including blood products, vaccines, radiographic contrast media, herbal products, etc. Particular vigilance is required in following the cases of elderly ages and children.

A Free Postage – Yellow Form is available to report to FMHACA. Sample of the Yellow Reporting Form is annexed for your reference.

Antimicrobial Resistance (AMR)

According to WHO definition, Antimicrobial Resistance (AMR) is resistance of microorganisms to an antimicrobial medicine to which it was previously sensitive. Resistance organisms include bacteria, viruses and some parasites and are able to withstand attack by antimicrobial medicines, such as antibiotics, antivirals, antimalarials, become ineffective and infectious persist and may spread to others.

Antimicrobial resistance has become a global concern and it is the responsibility of all policy makers, health institutions, professionals (prescribers, dispensers, etc.) and patients to alleviate the emerging critical problem. The followings are some of the sever problems that may happen because of AMR.

- Because of antimicrobial resistance treatment can become impossible and patients may die;
- Antimicrobial resistance hampers the control of infectious diseases and resistant microorganisms are spread easily to others;
- Antimicrobial resistance increases the cost of treatment and becomes financial burden to families and societies;

The followings are some of the reasons for the cause of antimicrobial resistances to emerge and spread.

- Inappropriate and irrational use of antimicrobials;
- When patients fail to take the full course of a prescribed antimicrobial;
- When poor quality antimicrobials are used.

To combat the emergence of antimicrobial resistance a lot is expected from policy-makers, prescribers, dispensers and patients and professionals working at RDV level are expected to strictly follow and adhere to the following practices.

- Check and give special consideration to prescriptions holding antibacterials;
- Never dispense under dose of antimicrobial preparations;

- Strongly advise patients to take the full course of antimicrobials as prescribed;

Always dispense antimicrobials on submission of prescription papers.

1. DRUGS ACTING ON THE GASTROINTESTINAL SYSTEM

1.1. Antacids

Antacids are inorganic salts that dissolve in gastric acid secretions releasing anions that partially neutralized gastric hydrochloric acid.

Antacids (usually containing aluminium or magnesium compounds) can often relieve symptoms in ulcer dyspepsia and in non-erosive gastro-oesophageal reflux; they are also sometimes used in non-ulcer dyspepsia but the evidence of benefit is uncertain. Antacids are also used for the relief of acid indigestion, heart burn and sour stomach; prevention of stress ulceration and gastrointestinal bleeding; and to reduce the risk associated with gastric aspiration and for the management of hyperphosphatemia. Antacids are best given when symptoms occur or are expected, usually between meals and at bedtime, 4 or more times daily; additional doses may be required up to once an hour.

Aluminium and/or Magnesium containing antacids (for example **aluminium hydroxide, magnesium hydroxide, (trisilicate)**) are the most commonly used and are often administered concurrently or in commercially available combination as to control the frequency and consistency of bowel movements. Magnesium-containing antacids have a laxative effect whereas aluminium-containing antacids may be constipating.

Aluminium salts tend to produce constipation and to delay gastric emptying because of its astringent property, while magnesium salts have the reverse effect; antacids containing both magnesium and aluminium may reduce adverse gastro-intestinal effects. Another advantage of combined antacid formulations is that a slow-acting antacid such as aluminium hydroxide may be combined with a more rapidly acting agent such as magnesium hydroxide to improve the onset and duration of effect.

Some of the antacid combinations contain other ingredients that have no antacid properties. Simethicone (i.e. antiflatulent) has been added as an aid in those conditions in which the retention of gas may be a problem.

Antacids should not be given to young children (up to 6 years of age) unless prescribed by a physician. Use of magnesium-containing antacids is contraindicated in very young children because there is a risk of hypermagnesemia, especially in dehydrated children or children with renal failure. Use of aluminum-containing antacids is contraindicated in very young children because there is a risk of aluminum toxicity, especially in dehydrated infants and children or infants and children with renal failure.

Antacids interfere with the gastro-intestinal absorption of a number of drugs taken orally by forming insoluble complexes, altering the gastric pH, or by effects on gastric emptying rates (fluoroquinolones, isoniazid, ketoconazole, tetracyclines, oral phosphates); changes in the urinary pH also affect tubular reabsorption (mecamylamine, methenamine; concurrent use is not recommended). Antacids may also damage enteric coatings designed to prevent dissolution in the stomach. The interaction between an antacid and another orally administered drug may be minimized by giving the drug 2 to 3 hours before or after antacid administration.

Osteomalacia, encephalopathy, dementia, and microcytic anaemia have been associated with aluminium accumulation in patients with chronic renal failure. Patients with renal failure taking aluminium compounds should avoid citrate - containing preparations. Use of magnesium-containing antacids is contraindicated in patients with renal failure because of increased risk of hypermagnesemia. Chronic administration of Magnesium Trisilicate infrequently produces silica renal stones.

Aluminium Hydroxide

Gel, 320 mg/5ml

Suspension, 360mg/5ml

Chewable tablet, 500mg

Indications: ulcer and non ulcer dyspepsia; gastro-oesophageal reflux, hyperphosphatemia.

Cautions: See notes above, uremia, congestive heart failure, renal failure, edema, cirrhosis, low sodium diets, gastrointestinal hemorrhage, and elderly.

Drug interactions: allopurinol, antibiotics (tetracycline, quinolones, some cephalosporins), biphosphonate derivatives, corticosteroids, cyclosporine, iron salts, imidazole antifungals, isoniazide, phenytoin, phenothiazines- absorption will be decreased; citric acid derivatives may decrease absorption of aluminum hydroxide. See also notes above

Contraindications: see notes above, hypophosphatemia, undiagnosed gastro intestinal or rectal bleeding; appendicitis; porphyria.

Side effects: see notes above, constipation, stomach cramps, fecal impaction, nausea, vomiting, and discoloration of feces, hypophosphatemia, and hypomagnesemia.

Dose and Administration: *Dyspepsia, gastro-oesophageal reflux:*
Oral:

Adult: 5–10 ml suspension 4 times daily between meals and at bedtime

Child: 6–12 years 5 ml up to three times daily

Hyperphosphatemia: Oral: Adult: 2–10 g daily in divided doses with meals

Patient Advice: Do not take other medicines with 2–4 hours after taking aluminium hydroxide preparations.

Storage: at room temperature

Aluminium Hydroxide and Magnesium Hydroxide*

Tablet (chewable), 400mg + 400mg

Suspension, 220mg+195mg/ 5 ml

* Any combination ratio proven to be therapeutically effective can be used.

Indications, Cautions, Drug interactions, Contraindications, Side effects and Storage: see under individual preparations and notes above.

Dose and Administrations: *Oral:* shake the bottle well before use. 5-10 ml (2 teaspoonfuls) or 1-2 tablets every 6 hours between meals and at bedtime, or as required.

Aluminium Hydroxide and Magnesium Trisilicate*

Tablet (chewable), 120 mg+250 mg, 250mg + 500mg

Suspension, 310mg+ 620 mg in 5 ml

Indications, Cautions, Drug interactions, Contraindications, Side effects and Storage; see under individual preparations and notes above.

Note: Magnesium Trisilicate is often given in conjunction with other antacids in order to reduce adverse gastro-intestinal effects

Dose and Administrations: *Oral: Adult:* shake the bottle well before use. 5-10 ml (2 teaspoonfuls) every 6 hours between meals and at bedtime, or as required. Chew 1 - 2 tablets when required.

Storage: at room temperature.

Aluminium Hydroxide + Magnesium Hydroxide + Simethicone*

Suspension, 225mg +200 mg +25 mg/ 5 ml

Indications: hyperacidity associated with gas (for temporary relief); may also used for indications of other antacids.

Cautions, Drug interactions, Contraindications, Side effects and Storage: see under individual preparations and notes above.

Note: Simethicone, antiflatulent, has been added as an aid in those conditions in which the retention of gas may be a problem.

Dose and Administration: *Oral: Adult:* 10-20ml 4-6 times / day between meals and at bedtime; may be used every hour for severe symptoms.

Storage: at room temperature, avoid freezing

Magnesium Hydroxide

Tablet (chewable), 300 mg, 311 mg

Suspension, 375 mg/5ml, 7.75 %

Indications: ulcer and non-ulcer dyspepsia; gastro-esophageal reflux.

Cautions: severe renal impairment, hypermagnesemia, see notes above.

Drug interactions: as for Aluminum hydroxide, also see notes above.

Contraindications: see notes above

Side effects: diarrhoea, abdominal cramps, muscle weakness, respiratory depression, hypermagnesemia and hypotension.

Dose and Administration: *Tablet, Adult: Chew* 2-4 tablets repeated according to patients needs with maximum daily dose of 16 tablets.

Child (7-14 years): one tablet with maximum of 4 tablets per day.

Suspension, Adult: 5-15 ml repeated according to patient's needs with maximum daily dose of 60 ml. **Child:** 2.5-5ml as needed up to 4 times /day.

Storage: at room temperature, avoid freezing.

Magnesium Trisilicate

Tablet (Chewable), 500 mg

Indications, Cautions, Drug interactions, Contraindications,

Storage: see notes under magnesium hydroxide above.

Side effects: see notes above, silica renal stones on long term treatment; diarrhoea

Dose and Administration: *Oral*, Chew 2 tablets when required.

Note: the antacid action is exerted slowly, so it does not give such rapid symptomatic relief as magnesium hydroxide.

1.2. Antispasmodics /Spasmolytic Analgesics

Drugs in this section include antimuscarinic compounds and drugs believed to be direct relaxants of intestinal smooth muscle. The smooth muscle relaxant properties of antimuscarinics (formerly termed 'anticholinergics') and other antispasmodic drugs may be useful in some forms of dyspepsia, in irritable bowel syndrome and in diverticular disease.

Antimuscarinics that are used for gastro-intestinal smooth muscle spasm include the tertiary amines like **Hyoscine (Scopolamine) Hydrobromide** and the quaternary ammonium compounds **Hyoscine (Scopolamine) Butylbromide**.

The side effects frequently associated with the use of antimuscarinics include xerostoma (dry mouth), blurred vision, cycloplegia, mydriasis, photophobia, anhidrosis, urinary hesitancy and retention, tachycardia, palpitation, and constipation. Side effects that occur occasionally include confusion (particularly in elderly), nausea, vomiting and giddiness.

Antimuscarinics should be used with caution in geriatric-patients, and children, and also in patients with hyperthyroidism, hepatic or renal disease, or hypertension, tachyarrhythmias, congestive heart failure, or coronary artery disease; autonomic neuropathy, gastro-esophageal reflux, known or suspected gastro intestinal infections, diarrhea and mild to moderate ulcerative colitis, and in

patients who may be exposed to elevated environmental temperatures or in patients who are febrile.

The drugs are contraindicated in patients with severe ulcerative colitis, obstructive disease of the gastro intestinal tract, paralytic ileus, or intestinal atony, prostatic enlargement, known hypersensitivity to the drugs, angle-closure glaucoma, obstructive uropathy (caution for patients with partial obstructive uropathy) and myasthenia gravis (unless the antimuscarinic is used to reduce adverse muscarinic effects of an anticholinesterase agent).

Hyoscine (Scopolamine) Hydrobromide

Tablet, 0.6 mg

Injection, 0.4 mg/ml, 0.6 mg/ml in 1ml ampoule

Indications: prevention and control of motion sickness, and also used as an adjunct to anesthesia to inhibit salivation and excessive respiratory secretions and to produce sedative and amnesia (memory loss); see also notes above.

Cautions, Contraindications, Side effects; see notes above

Drug interactions: CNS depression - producing medications; see notes above.

Dose and Administration:

Adult: *Oral:* 0.3 mg 30 minutes before a journey to prevent motion sickness then 0.3 mg every 6 hours if required up to a maximum of 3 doses in 24 hours; *IM, IV, or SC,* 0.3 to 0.6 mg; if necessary, the dose may be repeated 3 or 4 times daily.

Child: *Oral:* aged 4 to 10 years, 75 to 150 microgram and those over 10 years, 150 to 300 microgram; *IM, IV, or SC,* 0.006 mg/Kg

Storage: Store in a light resistant container at room temperature, avoid refrigeration.

Hyoscine (Scopolamine) Butylbromide

Tablet, 10mg

Drops, 5mg/5ml

Injection, 20mg/ml

Suppository, 7.5mg, 10mg

Indications: symptomatic relief of visceral spasms of the gastrointestinal tract, painful spasm of the biliary and genito-urinary system.

Note: Hyoscine Butylbromide is preferable to Hyoscine Hydrobromide in the relief of visceral spasms of the gastrointestinal tract and pain associated with other smooth muscle spasm.

Cautions: pregnancy and lactation see notes above

Contraindications: Glaucoma, gastrointestinal obstruction, porphyria, see notes above

Side effect: dry mouth, visual disturbance and tachycardia, drowsiness and fatigue, see notes above

Drug interactions: CNS depressants see also notes above.

Dose and Administrations:

Adult: *Oral:* 20mg four times daily; *IM or IV,* 20 mg repeated after 30 minutes if necessary.

Child: *Oral:* 6-12 years, 10mg 3 times daily; parenteral use not recommended.

Storage: at room temperature, in a well-closed container.

1.3. Antiemetics

Antiemetics are a diverse group of drugs used to treat or prevent nausea and vomiting, including that associated with cancer therapy, anaesthesia and surgery, and motion sickness.

The choice of drug depends partly on the cause of nausea and vomiting. For example, hyoscine (see section 1.2.) or antihistamines are used in motion sickness whereas dopamine antagonists, which act selectively on the chemoreceptor trigger zone, are ineffective for the treatment of motion sickness. Conversely, nausea and vomiting associated with cancer chemotherapy is often hard to control and special regimens have been devised including the use of metoclopramide in high doses and more recently 5 HT₃ antagonist ondanesetron. The antihistamines may be slightly less effective than hyoscine against motion sickness but are often tolerated.

A popular choice of antiemetic is metoclopramide which is effective against nausea and vomiting following surgery and chemotherapy. Metoclopramide may cause acute dystonic reactions with facial and skeletal muscle spasms and oculogyric crises. These reactions are most common in the young (especially girls and young women) and the elderly; they occur shortly after the start of treatment and subside within 24 hours of drug withdrawal.

Antiemetics are unnecessary and sometimes harmful when the cause can be treated, e.g. as in diabetic ketoacidosis, or in excessive digoxin or antiepileptic drugs.

Pregnancy induced nausea and vomiting or “morning sickness” is common in the first trimester, but generally does not require drug therapy. Dietary modification such as taking of small frequent carbohydrate meals often helps.

Dimenhydrinate

Tablet, 50 mg

Indications: prevention and treatment of nausea, vomiting and/or vertigo associated with motion sickness.

Cautions: warn the patients not to perform hazardous activities requiring mental alertness or physical condition; patients with angle closure glaucoma or prostatic hypertrophy bladder neck obstruction, coma, jaundice; use with caution in hot weather and during exercise; elderly may be at risk for anticholinergic side effects; pregnant and nursing mothers.

Drug interactions: alcohol, CNS depressants including barbiturates, tranquillizers, drugs with anti cholinergic effects including tricyclic antidepressants; ototoxic drugs such as aminoglycoside antibiotics (dimenhydrinate may mask the early symptoms of ototoxicity)

Side effects: drowsiness, fatigue and rarely blurred vision, dryness of mouth, nose and throat, palpitations, thickening of bronchial secretions, increase appetite, weight gain, arthralgia, and pharyngitis also tinnitus.

Dose and Administration:

Adult: *Oral*, 50 to 100 mg every 4 to 6 hours.

Child: *Oral*, 6-12 Years of age, 25 to 50 mg every six to eight hours as needed, not to exceed 150 mg per day; 2-6 years of age, 12.5 to 25 mg every six to eight hours as needed, not to exceed 75 mg per day.

Note: Oral dosage forms used for motion sickness should be taken 30 minutes before travel.

Storage: at room temperature, in a well-closed container.

Metoclopramide Hydrochloride

Tablet, 10 mg

Syrup, 5mg/5ml

Drop, 0.2 mg/drop

Indications: nausea and vomiting in gastrointestinal disorders and treatment with cytotoxics or radiotherapy; gastro-oesophageal reflux; gastroparesis; premedication and postoperatively; aid to gastrointestinal intubation; nausea and vomiting in migraine.

Cautions: elderly, children and young patients are at increased risk of extrapyramidal reactions; hepatic and renal impairment; may mask underlying disorders such as cerebral irritation, avoid for 3 - 4 days after gastrointestinal surgery; pregnancy; breast feeding; parkinson disease; depression; porphyria; patients should be warned that the drug may impair their ability to perform activities requiring mental alertness or physical coordination.

Drug interactions: alcohol, barbiturates, CNS depressants; phenothiazines and butyrophenones, lithium, antidepressants, antiepileptics, and sympathomimetics; antimuscarinic agents and opioid analgesics; digoxin, aspirin or paracetamol, suxamethonium, bromocriptine.

Contraindications: epilepsy; gastrointestinal hemorrhage, mechanical obstruction or perforation; pheochromocytoma; hypersensitivity to the drug.

Side effects: extrapyramidal symptoms (especially in children and young adults), tardive dyskinesia on prolonged use; hyperprolactinaemia; drowsiness, restlessness, dizziness, headache, diarrhoea, depression, hypotension and hypertension; rarely, neuroleptic malignant syndrome; cardiac conduction abnormalities following IV administration.

Dose and Administration:

Nausea and vomiting, gastro-oesophageal reflux, gastroparesis:

Adult: *Oral:* 10 mg 3 times daily; **young adult:** 15 - 19 years (under 60 Kg) 5 mg 3 times daily;

Child: Oral: up to 1 year (up to 10 Kg) 1 mg twice daily, 1-3 years (10-14 Kg) 1 mg 2 - 3 times daily, 3 - 5 years (15 - 19 Kg) 2 mg 2 - 3 times daily, 5-9 years (20-28 Kg.) 2.5 mg 3 times daily, 9 - 14 years (30 Kg and over) 5 mg 3 times daily. (Usual maximum 500 micrograms/Kg daily, particularly for children and young adults)

Aid to gastrointestinal intubation, Oral: Adult: 10-20 mg as a single dose 5-10 minutes before examination; **Young Adult** (15-19 years) 10mg; **Child** under 3 years 1 mg, 3 - 5 years 2 mg, 5 - 9 years 2.5 mg, 9 - 14 years 5 mg.

Storage: at room temperature, protect from light, avoid refrigeration

1.4. Cathartics and Laxative

Laxatives (purgatives or cathartics) promote defecation and are used in the treatment of constipation and for bowel evacuation before investigational procedures, such as endoscopy or radiological examination, or before surgery. Constipation is the passage of hard stools less frequently than the patient's own normal pattern; this should be explained to the patient since misconceptions about bowel habits have led to excessive laxative use, which in turn has led to hypokalaemia.

There are many categories of laxatives. These includes the bulk forming laxatives (such as psyllium preparations) which relieve constipation by increasing faecal mass and stimulating peristalsis, stimulant laxatives (contact laxatives) that include anthraquinone-containing agents (such as senna and cascara), diphenylmethane derivatives (such as bisacodyl) and also osmotic laxatives such as glycerin and the saline laxatives such as magnesium sulphate are also included in this group; faecal softeners (emollient laxatives) include sodium salt of docusate and the lubricant laxative liquid paraffin.

Bulk forming laxatives relieve constipation by causing retention of fluid and an increase in faecal mass resulting in stimulation of peristalsis; the full effect may take some days to develop and patients should be told this. They are of particular value in those

with small hard stools, but should not be required unless fiber cannot be increased in the diet. They are useful in the management of patients with colostomy, ileostomy, haemorrhoids and fissure, chronic diarrhoea associated with diverticular disease, irritable bowel syndrome and as adjuncts in ulcerative colitis. Because they have hydrophilic nature, bulk laxatives may also be used to control acute diarrhoea and to regulate the consistency of effluent in colostomy patients. Adequate fluid intake must be maintained to avoid intestinal obstruction. Unprocessed wheat bran taken with food or fruit juice, is a most effective bulk forming preparation.

Stimulant laxatives which increase intestinal motility and often cause abdominal cramp; they should be avoided in intestinal obstruction. Prolonged use of stimulant laxatives can precipitate the onset of an atonic non-functioning colon and hypokalaemia; however, prolonged use may be justifiable in some circumstances. Glycerin suppositories act as a rectal stimulant by virtue of the mildly irritant action of glycerin. In general, use of stimulant laxatives should be avoided in children younger than 6-10 years of age unless prescribed by physician.

Faecal softeners such as liquid paraffin, which is the classical lubricant, lubricate and soften impacted faeces. Docusate sodium probably acts both as a stimulant and as a softening agent. Such drugs are useful for oral administration in the management of haemorrhoids and anal fissures.

Bisacodyl

Tablet, 5 mg, 10mg

Suppository 5 mg, 10 mg

Indications: constipation and for bowel evacuation.

Cautions: Inflammatory bowel disease, the suppositories should be used with caution in patients with rectal fissures or ulcerated haemorrhoids. it should be preferably avoided in children. See also notes above.

Contraindications: appendicitis, rectal bleeding, congestive heart failure, hypertension, diabetes mellitus, Intestinal obstruction or undiagnosed abdominal symptoms. See also notes above.

Side effects: abdominal discomfort (such as colic or cramp); gripping (tablets); local irritation (suppositories). Diarrhea with excessive loss of water and electrolytes may occur on prolonged use. See also notes above.

Dose and Administration:

Oral: **Adult and Child (>12 years):** 1-3 tablets daily as a single dose. **Child (> 3 years):** 1-2 tablets or 0.3 mg/kg daily as a single dose.

Rectal: **Adult and Child (>12 years):** 10mg daily as a single dose.

Child 2-11 years: 5-10mg daily given as a single dose.

Child (< 2 years of age): 5mg daily as a single dose.

Note: It is usually effective within 6 to 12 hours following oral administration and within 15 to 60 minutes following rectal administration. Oral bisacodyl should be administered the evening before a morning bowel-movement is desired. Swallowing the enteric-coated bisacodyl as a whole and do not crush to avoid gastric irritation. Take each dose with a full glass of water. Rectal bisacodyl suppositories and enemas may be administered at the time a bowel movement is desired.

Storage: at room temperature in a well-closed container.

Cascara Sagrada

Tablet, 125 mg

Indications: constipation

Cautions: care should be taken in patients with inflammatory bowel disease. Prolonged use should be avoided. It should be preferably avoided in children; avoid habitual use; See also notes above.

Contraindications: see notes under bisacodyl

Side effects: mild abdominal discomfort, diarrhoea (prolonged use), reversible melanosis coli, the urine may be coloured yellowish brown or red and also see notes above.

Dose and Administrations:

Adult and Child (>10 years): 0.3 -1g, usually at bedtime.

Note: A laxative effect usually occurs 6 to 8 hours after administration. As discussed above such laxatives have a limited role in the management of constipation.

Storage: at room temperature, in airtight container. Protect from light.

Glycerin (Glycerol)

Suppository, 1 g, 1.36 g, 2 g, 2.76 g

Indications: constipation, especially in children; see also notes above.

Cautions: avoid habitual use.

Contraindications: as for bisacodyl

Side effects: rectal discomfort such as irritation, burning and pain may occur rarely.

Dose and Administration: *Rectal:* **Adult:** 2 – 4g suppository; **Child:** 2g suppository; **Infant:** 1g suppository.

Note: The suppositories should be moistened with water before insertion.

Storage: In a cool place, in airtight containers.

Liquid paraffin, Heavy

Indication: constipation associated with stricture of colon.

Cautions: avoid prolonged use and caution should be taken in children, pregnant women, elderly patients; caution is also recommended with bedridden patients who may develop lipid pneumonia from aspiration of mineral oil.

Drug interactions: avoid concomitant administration of the oil with fat soluble vitamins (A, D, E, and K), carotene, oral

contraceptive, coumarine and indandione derivative anticoagulants.

Contraindications: as for bisacodyl; also colostomy, ileostomy.

Side effects: seepage of mineral oil that may cause soiling of the skin and clothing, anal irritation, pruritis, impair normal rectal reflex mechanism, granulomatous reaction caused by absorption of small quantities of liquid paraffin, lipoid pneumonia.

Dose and Administration: *Oral:* 5-20ml, when required.

Storage: at room temperature and protect from freezing.

Magnesium sulphate

Crystal, powder

Indications: rapid bowel evacuation in preparations for rectal and bowel examination, and selective colon surgery; to hasten excretion of poisonous substances, except acids or alkalis, from the gastro intestinal tract (GIT).

Cautions: care should be taken in patients with renal impairment, hepatic impairment, in elderly and debilitated patients.

Drug interactions: coumarin or indandione derivative anticoagulants, digitalis glycoside, chlorpromazine, sodium polystyrene sulfonate, and tetracycline.

Contraindications: as for bisacodyl; acute gastrointestinal conditions, colostomy, ileostomy,(increased risk of electrolyte or fluid imbalance); dehydration, renal impairment.

Side effects: colic, cramping, diarrhea, gas formation, increased thirst, electrolyte imbalance (confusion, irregular heartbeat, muscle cramp, unusual tiredness or weakness).

Dose and Administration: *Oral: Adult:* 5 – 10 gm in water preferably before breakfast (for rapid bowel evacuation).

Child (> 6 years): 5 – 10 gm dissolved in 120 ml of water.

Note: take each dose with a full glass of water. Dissolve or mix in water before taking.

Storage: at room temperature in a well-closed container.

Psyllium

Bulk Powder

Indications: Constipation, especially in diverticular disease and irritable bowel syndrome, and when excessive straining at stool must be avoided.

Cautions: avoid prolonged use; adequate fluid should be taken to avoid intestinal obstruction. Caution on dispensing the powder to avoid sensitization to air born particles of psyllium

Drug interactions: tetracyclines.

Contraindications: see under bisacodyl; pre-existing faecal impaction, intestinal obstruction or colonic atony.

Side effects: hypersensitivity reactions; esophageal blockage or intestinal impaction.

Dose and Administration: *Oral:* **Adult and Child (>12 years):** 30gm given daily in divided doses of 2.5 - 7.5gm per dose; **Child 6-11 years old:** 15gm daily given in divided doses of 2.5-3.75gm per dose.

Storage: at room temperature in a tight container and in a dry place.

Senna

Tablet (total sennosides), 7.5 mg

Indication: constipation and bowel evacuation.

Cautions, Contraindications: see under Cascara Sagrada

Side effects: abdominal discomfort; hypokalaemia (with prolonged use or over dosage), see notes above.

Dose and Administrations: *Oral:* **Adult:** 15 - 30 mg, as a single dose at bedtime. **Child (>6 years of age):** one half of the adult dose, and those aged 2 to 6 years are quarter the adult dose.

Note: - It is usually effective with in 6 to 12 hours.

Storage: at room temperature in a dry place. Protect from freezing

1.5. Medicines used in Diarrhoea

Acute diarrhoeal diseases are a leading cause of childhood morbidity and mortality; weak and elderly patients are also at risk. In adults, acute diarrhoea is the most frequent health problem of travelers. The priority in acute diarrhoea is the prevention or reversal of fluid and electrolyte depletion. Acute diarrhoea in children should always be treated with oral rehydration solution.

Antidiarrhoeal agents are used as adjuncts in the symptomatic treatment of diarrhea, although the main aim in the management of acute diarrhoea is the correction of fluid and electrolyte depletion with rehydration therapy; this is especially important in infants and young children and antidiarrhoeal agents are not generally recommended for this age group. Their use is also limited in chronic diarrhea (diarrhoea for longer than a month) for treatment aimed at the underlying disorder will often alleviate the diarrhoea.

The main groups of antidiarrhoeal agents are the drugs which reduce intestinal motility. Bulk laxatives may also be used in the symptomatic treatment of diarrhoea.

Antiperistaltic agents are also used for symptomatic treatment of mild or uncomplicated travelers' diarrhoea, including that occurring in adult travelers with HIV infection. The most important measure in the management of travelers' diarrhoea is replacement of lost fluids and electrolytes.

Antidiarrhoeal agents, especially the adsorbents may interfere with the absorption of other drugs from the gastro-intestinal tract if administered concomitantly. For this formulary purpose we will see only oral rehydration salt as follows.

Oral Rehydration Salt

Powder: each sachet for 1 liter contains:

	<i>Gram/letter</i>		<i>Mmol/L</i>
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<i>Sodium chloride</i>	<i>2.6</i>		<i>Sodium</i>	<i>75</i>
<i>Trisodium citrate Dihydrate</i>	<i>2.9</i>		<i>Chloride</i>	<i>65</i>
<i>Potassium chloride</i>	<i>1.5</i>		<i>Glucose anhydrase</i>	<i>75</i>
<i>Glucose anhydrase</i>	<i>13.5</i>		<i>Potassium</i>	<i>20</i>
			<i>Citrate</i>	<i>10</i>
			<i>Total osmolarity=</i>	<i>245</i>

NOTE. The solution may be prepared either from prepackaged sugar/salt mixtures or from bulk substances and water. Solutions must be freshly prepared, preferably with recently boiled and cooled water. Accurate weighing and thorough mixing and dissolution of ingredients in the correct volume of clean water are important.

Indications: replacement of fluid and electrolyte loss in diarrhoea.

Cautions: ORS is not appropriate for patients with gastrointestinal obstruction, inability to drink, oliguric or anuric renal failure (renal impairment), or when parenteral rehydration therapy is indicated as in severe dehydration or intractable vomiting.

Side effects: Vomiting can occur after administration of ORS (may indicate too rapid administration), hypernatraemia and hyperkalaemia (may result from overdose in renal impairment or administration of too concentrated a solution). The risk of hypernatremia or over hydration after administration of ORS is low in patients with normal renal function. Over dosage in patients with renal impairment may lead to hypernatremia and hyperkalaemia.

Dose and Administration: reconstitute one sachet by adding sufficient water to make 1 liter Oral Rehydration Solution. *By mouth*, Dose for **Adults** according to fluid loss, usually 200-400ml solution after every loose motion, **child:** 200ml after every loose motion, infant 1 - 1½ times usual feed volume.

Storage: at room temperature.

1.6. Antiflatulants

An antiflatulent agent is a drug used for the alleviation or prevention of excessive intestinal gas, i.e., flatulence

Activated Charcoal

Tablet, 125 mg, 250mg

Indications: flatulence, indigestion and intestinal distention.

Cautions: advice patients not to take other medications orally within two hours after taking activated charcoal, except when inactivation of the medication is desired.

Drug interactions: avoid simultaneous use of any other drugs with activated charcoal.

Side effects: vomiting, constipation, and pulmonary aspiration, intestinal obstruction

(With multiple dose administration); it colours the stool black.

Dose and Administration: *Oral:* with plenty of water chew a tablet every 8 hours daily after meals.

Note: Activated charcoal lacks substantial evidence of efficacy as an antiflatulent or digestive aid.

Storage: at room temperature, in airtight containers.

Simethicone

Tablet (chewable), 60mg, 80mg, 95mg

Capsule, 95mg, 125mg

Indications: Flatulence, functional gastric bloating, postoperative gas pains; immediate postprandial upper abdominal distress; intestinal distress

Cautions: infant colic, allergy, pregnancy

Side effects: constipation

Dose and Administration: *oral:* **Adults and Child (>12 years):** 40-125mg 4 times daily after meals and at bedtime. **Child (<2 years):** 20mg 4 times daily after meals and at bedtimes; and 40 mg 4

times daily after meals and at bed times for children 2-12 years of age.

Note: Chewable tablets should be chewed thoroughly before swallowing. Simethicone liquid filled capsules should not be chewed.

Storage: in a well closed containers at room temperature.

1.7. Antihæmorrhoidal Agents

Hæmorrhoids are enlarged or varicose veins of the tissues at the anus or rectal outlet. They are the most frequent cause of rectal bleeding. Anal and perianal pruritus, soreness and excoriation occur commonly in patient suffering from hæmorrhoids, fistulas and proctitis. Careful local toilet with attention to any minor, faecal soiling, adjustment of the diet to avoid hard stools, the use of bulk forming materials such as bran and a high residue diet are helpful.

Soothing preparations containing mild astringents such as bismuth subgallate, zinc oxide, peru balsam and hamamelis with lubricants, vasoconstrictors or mild antiseptics, in the form of topical ointments, creams and suppositories, are used to provide symptomatic relief. Local anesthetics may be included to relieve pain, and corticosteroids may be used when infection is not present; preparations containing either group of drugs are intended only for short term use after exclusion of infections, such as herpes simplex; prolonged use can cause atrophy of the anal skin.

Hæmorrhoids in children are rare. Treatment is usually symptomatic and the use of locally applied cream is appropriate for short periods; however, local anaesthetics can cause stinging initially and this may aggravate the child's fear of defecation.

Bismuth Subgallate Compound (*Bismuth Subgallate + Bismuth Oxide + Peru Balsam + Zinc Oxide*)[†]
Ointment, 2.25% + 0.875% + 1.875% + 10.75%

[†] Any antihæmorrhoidal preparation proven to be therapeutically effective can be used.

Suppository, 59mg + 24mg + 49mg + 296mg

Indications: to relieve anal and perianal pain, itching and soreness associated with hemorrhoids, anal fissures.

Cautions: advise patients to regulate their diet to produce soft stools that pass through the anus with a minimum irritation. Patients should be instructed to take hygienic measures after defecation. See also notes above.

Dose and Administration: *Rectal:* wash and dry the anal area before application.

Unless otherwise indicated; *Ointment:* Apply *rectally* night and morning and after defecation. *Suppositories:* Insert in to the *rectum* night and morning and after defecation.

Storage: in a cool place.

Bismuth Subgallate Compound with Hydrocortisone (Bismuth Subgallate + Bismuth Oxide + Peru Balsam + Zinc Oxide + Hydrocortisone acetate + Benzyl Benzoate)†

Ointment, 2.25% + 0.875% + 1.875% + 10.75% + 0.25% + 1.25%

Suppository, 59mg + 24mg + 49mg + 296mg + 10mg + 33mg

Indications: same as Bismuth Subgallate Compound, and anal inflammation in the absence of infection, see notes above.

Cautions: Same as Bismuth Subgallate Compound. Avoid this preparation in the presence of an infection in the rectal area.

Contraindications: known hypersensitivity to the preparation, untreated infection.

Side effects: worsening of untreated infection, and thinning of the skin structure on prolonged use.

Dose and Administration: *Rectal:* Wash and dry the rectal area before application. Unless otherwise indicated, *Ointments:* Apply *rectally* night and morning and after defecation. *Suppositories:* Insert into the *rectum* night and morning and after defecation.

Storage: in a cool place.

Any antihemorrhoidal preparation proven to be therapeutically effective can be used.

2. RESPIRATORY MEDICINE

2.1. Antitussives /Expectorants/Mucolytics

Cough is an important physiological protective mechanism, but may also occur as a symptom of an underlying disorder such as asthma, gastro-oesophageal reflux disease, and postnasal drip. Treatment of the disorder often alleviates the cough, but there are times when symptomatic treatment is appropriate. The treatment chosen depends on whether the cough is productive or non-productive.

A non-productive cough such as that often seen with the common cold serves no useful purpose for the patient, and cough suppressants, such as dextromethorphan, may provide some relief, particularly if given at night.

A productive cough is characterized by the presence of sputum and may be associated with conditions such as chronic bronchitis, bronchiectasis, or cystic fibrosis. Cough suppressants are inappropriate, since the cough serves the purpose of clearing the airways; expectorants such as guaifenesin have been used on the grounds that increasing the volume of secretions in the respiratory tract facilitates removal by ciliary action and coughing. Mucolytics such as carbocysteine have been shown to affect sputum viscosity and structure and patients with productive cough have reported alleviation of their symptoms, but no consistent improvement has been demonstrated in lung function.

Note: - The dose of medicines for patients under age of 2 years old are not established or not recommended.

Bromhexine Hydrochloride

Elixir, 4mg/ml

Indications: acute and chronic bronchopulmonary diseases associated with abnormal mucous secretion and impaired mucous transport.

Cautions: history or symptoms of peptic ulceration

Side effect: gastrointestinal effects may occur; and transient elevation in serum aminotransferase has been reported.

Dose and administration: *Oral:* **Child (<2 years):** 1mg 3 times/ day; **Child (2-6 years):** 4mg twice daily or 2mg 3 times/ day; **Child (6-12 years):** 4 mg 3 times/day; **Child (>12 years) and Adults:** 8mg 3 times/day.

Storage: kept in a cool dry place where the temperature stays below 30°C.

Carbocisteine

Syrup, 2%, 5%

Indications: for its mucolytic activity in respiratory disorders associated with productive cough.

Cautions: history of peptic ulcer disease.

Contraindications: active peptic ulceration.

Side effects: headache, gastro intestinal tract (GIT) disturbances such as nausea, diarrhoea and gastrointestinal bleeding, and skin rashes.

Dose and Administration: *Oral:*

Adult: initially 750 mg 3 times daily, reduced to 1.5 g/day in divided doses, as soon as a response is obtained.

Child: 6-12 years, 250 mg 3 times daily; 2-5 years, 62.5-125 mg 4 times daily.

Storage: at room temperature.

Note: - **If dose is calculated based on 5% strength of syrup:** 750mg = 15ml; 1.5g = 30ml; 250mg = 5ml; 62.5-125 = 1.25-2.5ml

Dexchlorpheniramin

Syrup, 2mg/5ml

Tablet, 2mg, 4mg, 6mg

Indication: perennial and seasonal allergic rhinitis and other allergic symptoms including urticaria

Cautions: history of bronchial asthma; glaucoma or increased intraocular pressure; a stomach ulcer; an enlarged prostate, bladder problems, or difficulty urinating; hyperthyroidism; cardiovascular disease; hypertension;

Drug interaction: monoamine oxidase inhibitor such as isocarboxazid, phenelzine, or tranylcypromine, alcohol and other sedatives.

Contraindications: pregnancy; breast feeding; Lower Respiratory Disease; Hypersensitivity to Dexchlorpheniramin or other antihistamines; Monoamine oxidase inhibitor therapy

Side effect: allergic reactions; dryness of mouth, nose, and throat; anorexia; nausea; vomiting; diarrhea; constipation; dizziness or drowsiness, tachycardia; hypotension, thickening of bronchial secretions, tightness of chest and wheezing, Hemolytic anemia, thrombocytopenia, agranulocytosis; change in vision

Dose and administration: *Oral:* Adult 2mg 3-4 times daily; Child (6-12 years) 1mg 3-4 times/day, Child (2-5 years) 0.5mg 3-4 times/day

Storage: Store at room temperature between 15 and 30 degrees. Protect from light and moisture

Dexchlorpheniramine + Guaiifenesin + Pseudoephedrine

Syrup, 2mg +100mg + 20mg/5ml

Dextromethorphan Hydrobromide

Tablet, 15mg

Syrups, 5mg/5ml, 7.5mg/5ml, 15mg/5ml

Drops, 15mg/ml

Indications: symptomatic relief of non-productive cough due to minor throat and bronchial irritation occurring with colds or inhales irritants.

Cautions: hepatic disorders, decreased respiratory reserve, severe asthma

Drug interactions: CNS depressants, monoamine oxidase inhibitors including furazolidine and procarbazine, amiodarone, fluoxetine, haloperidol, quinidine, thioridazine.

Contraindications: respiratory failure, acute asthma, in children up to two years of age.

Side effects: mild dizziness, mild drowsiness, nausea or vomiting, stomach pain.

Dose and Administration: *Oral:*

Adult: 10 to 20 mg every 4 hours, or 30 mg every 6 to 8 hours, to a usual maximum of 120 mg in 24 hours;

Child (6-12 years): 5 to 10 mg every 4 hours or 15 mg every 6 to 8 hours to a maximum of 60mg in 24 hours, and **Child (2 to 6 years):** 2.5 to 5 mg every 4 hours, or 7.5 every 6 to 8 hours, to a maximum of 30 mg in 24 hours.

Storage: at room temperature in a well-closed container.

Dextromethorphanhydrobromide + Guaicol sulphonate

Syrup, 0.3mg + 7.6mg/100ml

Diphenhydramine + Sodium Citrate + Ammonium chloride

Syrup, 12.5mg + 60mg +130mg/5ml

Guaifenesin

Tablet, 100mg, 200mg

Capsules, 200mg

Syrup, 100mg/5ml

Indications: symptomatic relief of productive cough due to colds and minor upper respiratory infections.

Cautions: persistent or chronic cough such as that occurring with smoking, asthma, chronic bronchitis, or emphysema, or for cough accompanied by excessive phlegm.

Drug interaction: heparin

Contraindications: sensitive to Guaifenesin.

Side effects: diarrhoea, drowsiness, nausea or vomiting, stomach pain.

Dose and Administration: *Oral:*

Adult: 200-400mg every 4 hours.

Child (6-12 years): 100-200mg every 4 hours, and **Child (2- 6 years):** 50-100mg every 4 hours.

Storage: at room temperature in a tight container

2.2. Bronchodilators /Antiasthmatics

Asthma is a chronic inflammatory disease in which the patient suffers episodes of reversible airways obstruction due to bronchial hyperresponsiveness; in a few patients, inflammation may lead to irreversible obstruction.

Common precipitating factors include exposures to cold weather, upper respiratory tract infections, bad smells, exercise, ingestion of drugs like aspirin and beta blockers e.t.c.

Management of asthma involves prophylactic measures to reduce inflammation and airway resistance and to maintain airflow as well as specific regimens for the treatment of acute attacks.

Bronchodilators with B₂-receptor stimulant action like adrenaline and methylxanthines including theophylline are used to maintain airflow

Adrenaline (Epinephrine)

Injection, 0.1 % in 1 ml ampoule, 1:1000 (1mg/ml)

Indications: for acute bronchial asthma, and acute anaphylactic reactions.

Cautions: hyperthyroidism, hypertension, diabetes mellitus, ischaemic heart disease, arrhythmias, cerebrovascular disease, elderly, cerebral arteriosclerosis, parkinson's and rapid IV infusion may cause death from cerebrovascular hemorrhage or cardiac arrhythmias.

Drug interactions: other sympathomimetic agents (additive effects), alpha-adrenergic blocking agents, anaesthetics (volatile), beta blockers, digoxin, theophylline, tricyclic antidepressants, monoamine oxidase inhibitors.

Contraindications: asymmetric septal hypertrophy, pheochromocytoma, tachyarrhythmias.

Side effects: tachycardia and arrhythmia, hypertension, hypotension, tremor, anxiety, sweating, nausea, vomiting,

weakness, dizziness, pulmonary oedema, headache, peripheral vasoconstriction.

Dose and Administration: Acute bronchial asthma: *S.C or I.M:*

Adult: *S.C.* initially, 0.2– 0.5mg (0.2—0.5ml), repeated every 20 minutes as necessary up to 3 doses or IV (slow & cautions), 0.1 to 0.25mg;

Child: *S.C.* 0.01mg (0.01ml)/ kg of body weight, up to a maximum of 0.3mg (0.3ml)/dose. The dose may be repeated every 15 minutes for 3 or 4 doses as necessary.

Note: only a 1:10,000 epinephrine solution should be used for intravenous administration.

Storage: at room temperature, in a light – resistant container.

Aminophylline

Tablet, 100mg, 200mg

Tablet (m/r), 100mg, 225mg, 350mg

Injection, 250mg/10ml, in 10 and 20ml

Indications: reversible airways obstruction, acute severe asthma.

Cautions: peptic ulcer, hyperthyroidism, hypertension, cardiac arrhythmias or other cardiovascular disease, or epilepsy; heart failure, hepatic dysfunction or chronic alcoholism, acute febrile illness, and to neonates and the elderly (since in all of these circumstances theophylline clearance may be decreased), and also, IV injection must be administered very slowly to prevent dangerous CNS and cardiovascular side effects.

Drug interactions: other xanthine medications, allopurinol, antiarrhythmics, cimetidine, disulfiram, fluvoxamine, interferon- α , macrolide antibacterials and quinolones, oral contraceptives, phenytoin, alcohol, ritonavir, rifampicin, sulfinpyrazone, smoking, sympathomimetic agents, corticosteroids, diuretics, halothane or ketamine, lithium, beta blockers.

Contraindications: hypersensitivity to theophylline or xanthine derivatives; coronary artery disease (when, in the physician's judgment, myocardial stimulation might prove harmful).

Side effects: tachycardia, palpitations, nausea, gastro-intestinal disturbances, headache, insomnia, arrhythmias; also allergy to Ethylenediamine can cause urticaria, erythema, and exfoliative dermatitis.

Dose and Administration:

Tablet, Oral:

Adult, 100-300mg, 3-4 times daily, after food. (m/r, 225mg), 1 tablet twice daily initially, increased after 1 week to 2 tablets twice daily. Tablet (m/r, 350mg) is for smokers and other patients with decreased

theophylline half-life. Tablet (m/r, 100mg),

Child (>3 years): 6mg/kg twice daily initially, increased after 1 week to

12mg/kg twice daily; some children with chronic asthma may require 13-20mg/kg every 12 hours.

Slow I.V injection or preferably by slow I.V infusion, Avoid rapid intravenous injection. It should be given cautiously, particularly in patients who have previously been taking theophylline and/or ephedrine.

Adult: *Slow, I.V.,* 250—500mg (5mg/kg) over 20 minutes, or diluted with 10ml of water for injection. Maintenance: If required, 0.5mg/kg of body weight per hour *by slow I.V. infusion* for a period of 24 hours only.

Child: *Slow I.V.* 5mg/kg of body weight

Maintenance: If required, 6 months-9 years: 1mg/kg of body weight per hour by slow I.V. infusion. (10 -16 years) - 0.8mg/kg of body weight per hour by slow intravenous infusion.

Storage: at room temperature protect from light.

Ephedrine + Theophylline

Tablet, 11mg + 120mg

Elixir, 6mg + 30mg in each 5ml

Syrup, 2.24% + 0.30%

Indications: symptomatic relief of chronic bronchial asthma; asthmatic bronchitis; and other bronchospastic disorders; prophylactically use to stop or decrease asthmatic attacks.

Drug interactions, Contraindications, Side effects: See Ephedrine and Theophylline

Dose and Administration:

Child (> 25kg): ½ to 1 regular release tablet 3-4 times/day or at first sign of an asthmatic attack

Adult: 1-2 regular release tablet 3-4 times/ day or at first sign of an asthmatic attack.

Storage: at room temperature

Salbutamol (Albuterol)

Tablet, 2mg, 4mg, 4mg (s/r)

Syrup, 2mg/5ml

Oral inhalation (aerosol), 0.1mg/ dose

Indications: prophylaxis and treatment of asthma and other conditions associated with reversible airways obstruction.

Cautions: hyperthyroidism, myocardial insufficiency, arrhythmias, susceptibility to QT-interval prolongation, hypertension, elderly.

Note: it is important that asthma be well controlled throughout pregnancy. Inhaled administration is particularly advantageous as therapeutic action can be achieved at lower plasma levels with very little risk to the fetus.

Drug interactions: corticosteroids, cardiacglycosides, diuretics, xanthines and antidepressants.

Contraindications: eclampsia and severe pre-eclampsia, intra-uterine infection, intra-uterine fetal death, antepartum haemorrhage (which requires immediate delivery), placenta praevia, and cord compression; threatened miscarriage.

Side effects: fine tremor, nervousness, headache, dizziness, cardiac stimulation with tachycardia & palpitations (infrequent with aerosol inhalation) are usually dose-related. High doses may cause nausea & vomiting, and prolonged use has led to reversible hypertrichosis. Hypersensitivity reactions are rare.

Dose and Administration:

Chronic asthma, Oral:

ADULT: 2–4 mg, 3–4 times daily; in some patients up to a maximum of 8 mg 3–4 times daily;

CHILD under 2 years, 100 micrograms/kg 4 times daily; **CHILD** 2–6 years, 1–2 mg 3–4 times daily; **CHILD** 6–12 years, 2 mg 3–4 times daily.

Severe acute bronchospasm, by slow I.V. injection:

ADULT, 250 micrograms, repeated if necessary.

Relief of acute bronchospasm, by aerosol inhalation:

ADULT, 100–200 micrograms (1–2 puffs);

CHILD, 100 micrograms (1 puff) increased to 200 micrograms (2 puffs) if necessary;

IM or SC injection:

ADULT, 500 micrograms repeated every 4 hours if necessary.

Prophylaxis of exercise-induced bronchospasm, Aerosol inhalation:

ADULT, 200 micrograms (2 puffs);

CHILD, 100 micrograms (1 puff) increased to 200 micrograms (2 puffs) if required.

Chronic asthma (as adjunct in stepped treatment), by aerosol inhalation:

ADULT, 100–200 micrograms (1–2 puffs) up to 3–4 times daily;

CHILD, 100 micrograms (1 puff) 3–4 times daily, increased to 200 micrograms

(2 puffs) 3–4 times daily if necessary.

Note: Shake well before use.

Storage: Aerosol: store at room temperature away from heat and direct sunlight. Syrup, Tablet: store between 2 and 30°C, in a well-closed container, protect from light and from freezing.

Salbutamol + Bromhexine + Guaifenesine + Menthol

Syrup, 2mg + 4mg + 100mg + 1mg

Indications: for symptomatic management of all productive – including asthmatic – coughs.

Cautions: cardiovascular disorders like ischemic heart disease, hypertension and cardiac arrhythmias; hyperthyroidism, diabetes, those who are unusually responsive to sympathomimetics or who have convulsive disorders. Pregnancy and lactation. Peptic ulceration, severe hepatic and renal dysfunction. Menthol

containing products should be avoided in those with hiatal hernia, gallstones and in near-term pregnant females.

Drug interactions: sympathomimetics, beta blockers, monoamine oxidase inhibitors (MAOIs), nonpotassium-sparing diuretics, digoxin tricyclic antidepressants to cause untoward reactions.

Contraindications: hypersensitivity reaction.

Side effects: nausea, vomiting, skin rashes, headache, and dizziness may rarely occur.

Storage: store below 25°C in a dry place, protected from light.

Theophylline + Guaifenesin

Tablet 150mg + 90mg

Capsule, 150mg + 90mg; 300mg + 180mg

Elixir, 150mg + 90mg/15ml

Indications: for relief and/or prevention of symptoms of bronchial asthma and reversible bronchospasm associated with chronic bronchitis and pulmonary emphysema.

Cautions: peptic ulcer, hyperthyroidism, hypertension, cardiac arrhythmias or other cardiovascular disease, or epilepsy; heart failure, hepatic dysfunction or chronic alcoholism, acute febrile illness, and to neonates and the elderly (since in all of these circumstances theophylline clearance may be decreased), persistent or chronic cough such as that occurring with smoking, asthma, chronic bronchitis, or emphysema, or for cough accompanied by excessive phlegm.

Drug interactions: other xanthine medications, allopurinol, antiarrhythmics, cimetidine, disulfiram, fluvoxamine, interferon- α , macrolide antibacterials and quinolones, oral contraceptives, phenytoin, alcohol, ritonavir, rifampicin, sulfinpyrazone, smoking, sympathomimetic agents, corticosteroids, diuretics, halothane or ketamine, lithium, beta blockers, heparin

Contraindications: sensitive to Guaifenesin, hypersensitivity to theophylline or xanthine derivatives; coronary artery disease (when, in the physician's judgment, myocardial stimulation might prove harmful).

Side effects: gastroesophageal reflux; gastrointestinal irritation and stimulation of the CNS. Nausea, vomiting, abdominal pain,

diarrhoea, and other gastrointestinal disturbances, insomnia, headache, anxiety, irritability, restlessness, tremor, and palpitations.

Over dosage (agitation, diuresis and repeated vomiting (sometimes haematemesis) and consequent dehydration, cardiac arrhythmias including tachycardia, hypotension, electrolyte disturbances)

Dose and Administration:

Adult: *Oral:* 16mg/kg/day or 400mg theophylline/day, in divided doses, every 6-8 hours.

Storage: Guaifenesin preparations should be stored in tight containers at room temperature.

3. CENTRAL NERVOUS SYSTEM MEDICINES

3.1. Analgesics / Antipyretics

Pain is not only associated with physical suffering or hurting but has an emotional or mental component, hence it is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.

Pain can be classified as acute or chronic. Acute pain is usually of short duration and the cause often identifiable (disease trauma). Chronic pain persists after healing is expected to be complete, or is caused by a chronic disease. Pain may be modified by psychological factors and attention to these is essential in pain management. Drug treatment aims to modify the peripheral and central mechanisms involved in the development of pain.

Non steroidal anti-inflammation drugs (NSAIDs) are suitable for mild or moderate pain in musculoskeletal conditions though sometimes they may not be suitable for severe pain associated with visceral organs. NSAIDs also have anti-inflammatory actions. They reduce both pain and inflammation of chronic inflammatory disorders such as rheumatoid arthritis, but they do not alter or modify the disease process itself.

Fever (pyrexia) is defined as an increase in body temperature due to an elevated thermoregulatory set-point temperature. Common causes of fever include infections, inflammatory disorders, neoplastic disease, and some drug treatment. Methods for reducing body temperature in fever include the use of antipyretic drugs and/or physical means. Antipyretic agents used include paracetamol, salicylates and some other NSAIDs.

Acetylsalicylic acid

Acetylsalicylic acid (aspirin) is indicated for headache, transient musculoskeletal pain, dysmenorrhoea (pain associated with menstruation) and pyrexia (fever). Acetylsalicylic acid is also used for its anti platelet properties.

Adverse effects with analgesic doses are generally mild but include a high incidence of gastro-intestinal irritation with slight blood loss (minimized by taking the dose after food, or enteric coated preparations), bronchospasm and skin reactions in hypersensitive patients, and increased bleeding time. Anti-inflammatory doses are associated with a much higher incidence of adverse reactions, and they also cause mild chronic salicylism which is characterized by tinnitus (perception of sound within the human ear in the absence of corresponding external sound) and deafness. Its use is not advisable in the latter stage of pregnancy, or in children because of an association with Reye syndrome (encephalopathy and liver damage).

Ibuprofen is used for relief of symptoms of arthritis, primary dysmenorrhoea, fever, and as an analgesic, especially where there is an inflammatory component. Ibuprofen is also known to have an antiplatelet effect, though it is relatively mild and short-lived when compared with aspirin or other better-known antiplatelet drugs.

Paracetamol is similar in analgesic and antipyretic efficacy to acetylsalicylic acid. Unlike acetyl salicylic acid and other NSAIDs, it lacks anti-inflammatory activity which limits its

usefulness for long-term treatment of pain associated with inflammation.

Since paracetamol does not have aspirin's hypersensitivity hematological or gastro-intestinal adverse effects, it is particularly useful in patients in whom salicylates or other NSAIDs are contraindicated, such as asthmatics and those with a history of peptic ulcer, or for children under the age of 12 years in whom salicylates are contraindicated because of the risk of Reye syndrome. However large doses of paracetamol can produce severe or sometimes fatal hepatotoxicity; patients with cachexia or those with existing liver disease may be more susceptible.

Acetylsalicylic acid

Tablet, 75mg, 100mg, (Soluble);

300mg, 324mg, (micro fined);

75mg, 81mg, 100mg, 500mg (enteric coated)

Indications: relief of mild to moderate pain, pyrexia; prophylaxis of platelet aggregation; treatment of rheumatic fever, and acute and chronic inflammatory disorders.

Cautions: caution in patients with gastritis, peptic ulcer, elderly, lactation (high dose)

Drug interactions: antidiabetic agents, including insulin; agents inhibiting platelet aggregation (e.g. penicillins, dipyridamole and valproic acid); thrombolytic agents and heparin; agents causing gastric irritation; methotrexate, probenecid; zidovudine.

Contraindications: history of severe sensitivity reaction to acetylsalicylic acid, bleeding ulcers or other hemorrhagic states, nasal polyps associated with asthma, febrile and dehydrated children (especially with viral infections).

Side effects: gastrointestinal irritation, nausea, vomiting and occult or overt mucosal bleeding. Chronic administration of high doses may cause gastric erosion and acute haemorrhage, potentiated by alcohol.

Pseudo-allergic reactions such as bronchospasm, rhinitis, urticaria, angioedema and anaphylaxis like shock may occur, most frequently in asthmatics, or in patients with nasal polyps or severe atopy. True hypersensitivity reactions may also occur.

Tinnitus and decreased hearing, impaired renal function, decreased prothrombin time and hepatotoxicity are more likely when serum levels are > 200mcg/ml, but may be caused by low doses, especially in the elderly.

Dose and Administration: *Oral:*

Adult:

Analgesic and antipyretic: 325-650mg every 4-6 hours up to 4g/day.

Anti-inflammatory: initial: 2.4-3.6g/day in divided doses; usual maintenance: 3.6-5.4 g/day

Child:

Analgesic and antipyretic: 10-15mg/kg/dose every 4-6 hours, up to a total of 4g/day orally, preferably with or after food with a full glass of water. Children should not take more than 5 doses/day or for longer than 10 days at a time, and adults should not take for longer than 10 days at time.

Note: - Aspirin tablets or dispersible aspirin tablets are adequate for most purposes as they act rapidly. Enteric-coated tablets are beneficial in minimizing gastric irritation effect of aspirin, but have a slow onset of action and are therefore unsuitable for single-dose analgesic use (though their prolonged action may be useful for night pain).

Acetylsalicylic acid preparations should not be used if a strong vinegar-like odor is present.

Storage: at room temperature, in a tight container. Protect from heat.

Diclofenac sodium

Capsule (S/R), 75 mg

Tablet (e/c), 25mg, 50mg, 75mg(s/r), 100mg(s/r)

Suppository, 12.5mg, 25mg, 50mg, 100mg

Indications: pain and inflammation in rheumatic disease (including juvenile idiopathic arthritis) and other musculoskeletal disorders; acute gout; post operative pain

Cautions: should be used with caution in the elderly (risk of serious side effects and fatalities) during pregnancy and breast-feeding and in coagulation defects. Long-term use of some NSAIDs

is associated with reduced female fertility, which is reversible on stopping treatment. In patients with renal, cardiac, or hepatic impairment caution is required since NSAIDs may impair renal function; the dose should be kept as low as possible and renal function should be monitored.

Drug interactions: Alendronate, lithium, methotrexate, increased risk of methotrexate toxicity), rifampin, timolol, warfarin, coumarin or indandione derivative anticoagulants, heparin, or thrombolytic agents, antihypertensives or diuretics, especially triamterene; aspirin and anti-inflammatory, blood dyscrasia causing medications and bone marrow depressants, radiation therapy, colchicine, probenecid

Contraindications:

It's contra-indicated in patients with a history of hypersensitivity to aspirin or any other NSAID—which includes those in whom attacks of asthma, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other NSAID. All NSAIDs are contra-indicated in severe heart failure.

Side effects:

Gastro-intestinal discomfort, nausea, diarrhoea, and occasionally bleeding and ulceration occur, hypersensitivity reactions, headache, dizziness, nervousness, depression, drowsiness, insomnia, vertigo, hearing disturbances such as tinnitus, photosensitivity, and haematuria, blood disorders, fluid retention, increased blood pressure, hepatic damage, alveolitis, pulmonary eosinophilia, pancreatitis, eye changes, Stevens-Johnson syndrome and toxic epidermal necrolysis are other rare side effects.

Dose and Administration:

Oral: 75–150 mg daily in 2–3 divided doses

Rectal: suppositories, 75–150 mg daily in divided doses

Children 1–12 years, juvenile arthritis, orally or rectal, 1–3 mg/kg (max. 150 mg) daily in divided doses (25 mg e/c tablets, 12.5 mg and 25 mg suppositories only)

Children 6–12 years, postoperative pain, rectally, 1–2 mg/kg (max. 150 mg) daily in divided doses (12.5 mg and 25 mg suppositories only) for max. 4 days

Storage: store at room temperature in a well-closed, light resistant container. Protect from freezing.

Ibuprofen

Capsule, 300mg

Tablet, 200mg, 400mg (enteric coated, optional)

Syrup, 100mg/5ml

Indications: pain and inflammation in rheumatic disease (including juvenile arthritis) and other musculoskeletal disorders; mild to moderate pain including dysmenorrhoea, postoperative analgesia; migraine; fever and pain in children.

Cautions: see notes under diclofenac

Drug interactions: see notes under diclofenac

Contraindications: see notes under diclofenac

Side effects: see notes under diclofenac

Dose and Administration:

Adult: Antirheumatic: Oral: 1.2 to 3.2gms a day in three or four divided doses.

After a satisfactory response has been obtained, the dosage should be reduced to the lowest maintenance dose that provides continuing control of symptoms.

Note - Higher doses are generally required in rheumatoid arthritis than in osteoarthritis.

Analgesia/pain/fever/dysmenorrhea: 200-400 mg/dose every 4-6 hours (maximum daily dose: 1.2g, unless directed by physician)

OTC labeling (analgesic, antipyretic): 200mg every 4-6 hours as needed (maximum: 1200 mg/24 hours)

Child: Antirheumatics: (1-12 years of age): Oral: initially 30 to 40mg per kg of body weight a day in three or four divided doses then reduced to the lowest dose needed to control disease activity.

Storage: store at room temperature in a well-closed, light resistant container. Protect from freezing.

Paracetamol

Tablet, 100mg, 500mg

Suppository, 125mg, 250mg

Syrup, 120mg/5ml, 250mg/5ml

Drops, 100mg/ml

Injection, 1g in 100ml

Indications: mild to moderate pain or pyrexia.

Cautions: caution in alcoholics, and in patients with hepatic diseases, and severe renal function impairment, anaemia and other disorders of the haemopoietic system.

Drug interactions: avoid simultaneous use of single toxic doses or long-term high doses of paracetamol with alcohol, or phenobarbitone; oral anticoagulants.

Contraindications: severe hepatic or renal disease.

Side effects: rare in therapeutic doses. Allergic reactions such as skin rashes, neutropenia and thrombocytopenia may occur rarely.

Dose and Administration:

Mild to moderate pain, pyrexia,

Oral: Adult: 0.5 - 1g every 4-6 hours, maximum 4g daily;

Child: 3 months-1 year 60-125mg, 1-5 years 120 - 250mg, 6-12 years 250 - 500mg these doses may be repeated every 4 - 6 hours if necessary (maximum 4 doses in 24 hours).

Rectum: Adult: 0.5 - 1g, every 4-6 hours, maximum 4g daily.

Child: 1 - 5 years 125 - 250mg, 6 - 12 years 250 - 500mg; doses inserted every 4 - 6 hours if necessary, maximum 4 doses in 24 hours.

Post - immunization pyrexia: **Oral:** infant 2-3 months, 60mg followed by a second dose if necessary 4-6 hours later; warn parents to seek medical advice if pyrexia persists after second dose.

Injection:

Adult and Adolescents > 50 kg: 1g per administration (100ml vial), up to 4 times a day. Maximum daily dose not exceed 4g.

Child weighing more than 33 kg (approximately 11 years old), adolescents and adults weighing less than 50 kg: 15 mg/kg per administration, i.e. 1.5 ml solution per kg up to 4 times a day. The minimum interval between each administration must be 4 hours. The maximum daily dose must not exceed 60 mg/kg (without exceeding 3 g).

Children weighing more than 10 kg (approximately 1 year old) and less than 33 kg: 15 mg/kg per administration, i.e. 1.5 ml

solution per kg up to 4 times a day. The minimum interval between each administration must be 4 hours. The maximum daily dose must not exceed 60mg/kg (without exceeding 2 g).

Storage: at room temperature

3.2. Antimigraine Headache Medicine

Migraine is characterized by recurrent attacks of headache which may take up to 72 hours to resolve. Treatment of migraine attacks may be successfully carried out with analgesics such as NSAIDs, or paracetamol. Attacks which do not respond to NSAIDs or paracetamol should be referred.

Paracetamol +Acetylsalicylic acid +Caffeine

Tablet, 250mg+250mg+65mg

Indications: relief of mild to moderate pain; mild to moderate pain associated with migraine headache.

Dose and Administration: Oral: **Adult:**

Based on acetaminophen component:

Mild to moderate pain: 325-650mg every 4-6 hours as needed; do not exceed 4 g/day

Mild to moderate pain associated with migraine headache: 500mg/dose (in combination with 500mg aspirin and 130mg caffeine) every 6 hours while symptoms persist; do not use for longer than 48 hours

Based on aspirin component:

Mild to moderate pain: 325-650mg every 4-6 hours as needed; do not exceed 4 g/day

Mild to moderate pain associated with migraine headache: 500mg/dose (in combination with 500mg acetaminophen and 130mg caffeine) every 6 hours; do not use for longer than 48 hours.

4. MEDICINES USED IN MUSCULOSKELETAL AND JOINT DISEASES

4.1. Antirheumatics

Many different drugs have been used for rheumatoid arthritis. The choice of drugs for relief of pain depends up on the severity of

symptoms. In mild cases an analgesic alone may be all that is required but most patients need the additional anti-inflammatory effect provided by a non steroidal anti-inflammatory drug (NSAID).

Non-steroidal anti-inflammatory drugs (NSAIDs)

Many of the effects of non-steroidal anti-inflammatory drugs (NSAIDs) appear to be due to their inhibitory action on cyclo-oxygenases which are involved in the biosynthesis of prostaglandins. Prostaglandins have an important role in the production of pain, inflammation, and fever and NSAIDs therefore find their main use as analgesics, anti-inflammatory agents, and antipyretics. Administered as single doses or in short-term intermittent therapy they provide adequate analgesia to relieve mild to moderate pain. However, it may take several days to two weeks of use before their anti-inflammatory effects become evident.

The combined analgesic and anti-inflammatory effects of NSAIDs make them particularly useful for the symptomatic relief of painful and/or inflammatory conditions including musculoskeletal and joint disorders.

Differences in anti-inflammatory activity between different NSAIDs are small, but there is considerable variation in individual patient tolerance and response. The main differences between NSAIDs are in the incidence and type of side effects. Before treatment is started the prescriber should weigh efficacy against possible side effects.

Side effects:

The commonest side-effects occurring during therapy with NSAIDs are generally gastrointestinal disturbances; these are usually mild and reversible but in some patients peptic ulcer and severe gastro-intestinal bleeding have been reported; CNS related side effects include headache, dizziness, nervousness, tinnitus, depression, drowsiness, and insomnia; hypersensitivity reactions may occur occasionally and include fever, asthma, and rashes. Hematological adverse effects of NSAIDs include anaemias, thrombocytopenia, neutropenia, eosinophilia, and agranulocytosis. Fluid retention may occur (rarely precipitating congestive heart

failure in elderly patients). Renal failure may be provoked by NSAIDs especially in patients with pre-existing renal impairment. Rarely, papillary necrosis or interstitial fibrosis associated with NSAIDs may lead to renal failure. Hepatic damage alveolitis, pulmonary eosinophilia, pancreatitis, eye changes, Stevens – Johnson syndrome and toxic epidermal necrolysis are other rare side effects. Induction of or exacerbation of colitis has been reported. Aseptic meningitis has been reported rarely with NSAIDs. Patients with connective tissue disorders such as systemic lupus erythematosus may be especially susceptible.

Cautions and contraindications:

NSAIDs should be used with caution in the elderly (risk of serious side effects and fatalities), in allergic disorders (they are contraindicated in patients with a history of hypersensitivity to aspirin or any other NSAID. Which include those in whom attacks of asthmas, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other NSAID), during breast-feeding and pregnancy and in coagulation.

In patients with renal, cardiac, or hepatic impairment caution is required since the use of NSAIDs may result in deterioration of renal function; the dose should be kept as low as possible and renal function should be monitored.

NSAIDs should not be given to patients with active peptic ulceration. While it is preferable to avoid them in patients with current or previous gastro-intestinal ulceration or bleeding, and to withdraw them if gastro-intestinal lesions develop, nevertheless patients with serious rheumatic diseases (e.g. rheumatoid arthritis) are usually dependent on NSAIDs for effective relief of pain and stiffness.

Acetylsalicylic acid

Tablet, 75mg, 100mg (soluble), 300mg, 324mg (microfined), 500mg (enteric coated).

See notes on section under 3.1 Analgesics / Antipyretics above

Diclofenac Diethylamine

Gel, 1%, 30gm

Indications: - For the relief of aches and pain associated with acute, localized muscle or joint injuries such as sprains, strains or sports injuries (e.g. sprain of ankle, strain of shoulder or back muscles). Rest may also be helpful to assist the relief of associated discomfort.

Cautions and Contraindications: - see notes above.

Drug interactions: -anticoagulants (blood thinners), or heparin or thrombolytic agents, antihypertensives, oral antidiabetic agents, fluoroquinolone antibiotics (ofloxacin) aspirin and anti-inflammatory, colchicine, lithium, methotrexate, probenecid.

Side effects: see notes above.

Dose and Administration:

For adults and adolescents 16 years and older: apply diclofenac diethylamine gel 3 to 4 times a day. Gently rub a small amount of diclofenac diethylamine gel into the skin where you have pain or swelling. The amount needed will vary depending upon the size of the painful or swollen area. Usually, a strip approximately 2 cm long will be sufficient to cover a 200cm² area. Wash your hands after rubbing in diclofenac diethylamine gel, unless of course they are the site being treated. The gel should not be used for more than 7 days for muscle and joint injuries, unless recommended.

Diclofenac sodium

Capsule (S/R), 75 mg

Tablet (e/c), 25mg, 50mg, 75mg(s/r), 100mg(s/r)

Suppository, 12.5mg, 25mg, 50mg, 100mg

Sachet (as potassium salt), 50mg

Indications: pain and inflammation in rheumatic disease (including juvenile arthritis) and other musculoskeletal disorders; acute gout; postoperative pain.

Cautions: see notes above.

Drug interactions: coumarine or indandione derivative anticoagulants, or heparin or thrombolytic agents, antihypertensives or diuretics, especially triamterene, aspirin and anti-inflammatory, blood dyscrasia causing medications and bone marrow depressants, radiation therapy, colchicine, lithium, methotrexate, probenecid.

Contraindications: see notes above, porphyria.

Side effects: see notes above; suppositories may cause rectal irritation, injection site reactions.

Dose and Administration:

Adult:

Oral: Rheumatoid arthritis: 150-200mg per day in three or four divided doses, initially. After a satisfactory response has been obtained, dosage should be reduced to the minimum dose that provides continuing control of symptoms, usually 75 – 100 mg a day in 3 divided doses.

Deep IM injection into the gluteal muscle: acute exacerbations and post-operative: 75 mg once daily (twice daily in severe cases) for maximum of 2 days.

Ureteric colic: 75 mg then a further 75 mg after 30 minutes if necessary.

IV infusion (in hospital setting), 75 mg repeated if necessary after 4 – 6 hours for maximum 2 days.

Prevention of postoperative pain, initially after surgery 25 – 50 mg over 15 – 60 minutes then 5 mg/hour for maximum 2 days.

Rectum in suppositories, 75 – 150 mg daily in divided doses.

Maximum total daily dose by any route 150 mg.

Child 1 – 12 years, juvenile arthritis, Oral or rectum: 1 – 3 mg/kg daily in divided doses (25 mg e/c tablets, 12.5 mg and 25 mg suppositories only).

Storage: at room temperature in a tight container, protect from moisture

Ibuprofen

Capsule, 300mg

Tablet, 200mg, 400mg (enteric coated, optional)

Syrup, 100mg/5ml

Indications: pain and inflammation in rheumatic disease (including juvenile arthritis) and other musculoskeletal disorders; mild to moderate pain including dysmenorrhoea, postoperative analgesia; migraine; fever and pain in children.

Cautions: see notes above

Drug interactions: coumarin or indandione derivative anticoagulants, heparin, or thrombolytic agents,

antihypertensives or diuretics, especially triamterene; aspirin and anti-inflammatory, blood dyscrasia causing medications and bone marrow depressants, radiation therapy, colchicine, lithium, methotrexate, probenecid.

Contraindications: see notes above

Side effects: see notes above

Dose and Administration:

Adult: Antirheumatic: *Oral:* 1.2 to 3.2gms a day in three or four divided doses.

After a satisfactory response has been obtained, the dosage should be reduced to the lowest maintenance dose that provides continuing control of symptoms.

Note - Higher doses are generally required in rheumatoid arthritis than in osteoarthritis.

Analgesia/pain/fever/dysmenorrhea: 200-400 mg/dose every 4-6 hours (maximum daily dose: 1.2g, unless directed by physician)

OTC labeling (analgesic, antipyretic): 200mg every 4-6 hours as needed (maximum: 1200 mg/24 hours)

Child: Antirheumatics: (1-12 years of age): *Oral:* initially 30 to 40mg per kg of body weight a day in three or four divided doses then reduced to the lowest dose needed to control disease activity.

Storage: store at room temperature in a well-closed, light resistant container. Protect from freezing.

5. Anti-Infectives

5.1. Antibacterials

5.1.1 Penicillins

Penicillins can be classified into four broad categories, each covering a different spectrum of activity. The natural penicillins (penicillin G and penicillin V) have activity against many gram-positive organisms, gram-negative cocci and some other gram-negative organisms. The aminopenicillins (ampicillin, amoxicilline, bacampicillin, and pivampicillin) have activity against penicillin-sensitive gram-positive bacteria, as well as

Escherichia coli, *Proteus mirabilis*, *Salmonella* sp., *Shigella* sp. and *Haemophilus influenzae*. The antistaphylococcal penicillins (cloxacillin, dicloxacillin, etc) are also active against beta – lactamase – producing staphylococci. The antipseudomonal penicillins have less activity against gram-positive organisms than the natural penicillins or aminopenicillins.

Benzylpenicillin can be considered the parent compound of the penicillins and is inactivated by penicillinase – producing bacteria and because of its instability in gastric acid it is usually injected. Long-acting preparations include procaine penicillin and benzathine penicillin which slowly release benzylpenicillin after injection. Phenoxymethyl penicillin is acid – stable and therefore given by mouth but it is also inactivated by penicillinase. It is generally used for relatively mild infections.

The isoxazolyl penicillins such as cloxacillin are resistant to penicillinase and gastric acid.

Ampicillin has a broader spectrum of activity than benzylpenicillin; although generally less active against gram-positive bacteria, some gram-negative organisms including *Escherichia coli*, *Haemophilus influenzae*, and *Salmonella* spp. are sensitive although resistance is being reported increasingly, *Pseudomonas* spp are not sensitive. Ampicillin is acid stable and can be given by mouth but is destroyed by penicillinase. Amoxicillin, only differs from ampicillin by the addition of a hydroxyl group, but is better absorbed from the gastro-intestinal tract.

The most important side effect of the penicillins is hypersensitivity which cause rashes and anaphylaxis, which can be fatal. Individuals who have experienced anaphylaxis, urticaria, or rash immediately after penicillin administration are at increased risk of immediate hypersensitivity to penicillin; these individuals should not receive a beta-lactam antibiotic. Patients who are allergic to one penicillin will be allergic to all because the hypersensitivity is related to the basic penicillin structure.

Individuals who develop a minor rash or a rash that occurs more than 72 hours after penicillin administration are probably not allergic to penicillin and in these individuals a penicillin should not be withheld unnecessarily on serious infections ; the possibility of an allergic reaction should, however, be borne in mind.

A rare but serious toxic effect of the penicillins is encephalopathy due to cerebral irritation. This may result from excessively high doses or in patients with severe renal failure. The penicillins should not be given by intrathecal injection because they can cause encephalopathy which may be fatal.

Another problem relating to high doses of penicillin, or normal dose given to patients with renal failure, is the accumulation of electrolyte since most injectable penicillins contain either sodium or potassium.

Diarrhea frequently occurs during oral penicillin therapy. It is most common with broad-spectrum penicillins, which can also cause antibiotic associated colitis.

Amoxicillin

Capsule, 250mg, 500mg

Syrup, 125mg/5ml, 250mg/5ml

Tablet, 500mg

Indications: urinary tract infections, upper respiratory tract infections, bronchitis; pneumonia; otitis media; dental abscess; osteomyelitis; Lyme disease in children; endocarditis prophylaxis; post-splenectomy prophylaxis; gynaecological infections; gonorrhoea; Helicobacter pylori eradication (section 1.2)

Cautions, Drug interactions, Contraindications and Side effects: see under Ampicillin

Dose and Administrations:

Infections due to sensitive organisms: *Oral:*

Adult and Child over 10 years, 250 mg every 8 hours, doubled in severe infections; **Child** up to 10 years, 125mg every 8 hours, doubled in severe infections.

Severe or recurrent purulent respiratory-tract infections: *Oral:*

Adult: 3 g every 12 hours

Pneumonia: Oral: **Adult:** 0.5 – 1 g every 8 hours
Short Course Oral therapy
Dental abscess: **Adult:** 3 g repeated after 8 hours
Urinary tract infections: **Adult:** 3 g repeated after 10 – 12 hours.
Otitis media: **Child** 3 – 10 years, 750 mg twice daily for 2 days.
IM: 500 mg every 8 hours; **Child**, 50 – 10 mg/kg daily in divided doses
IV injection or infusion: 500 mg every 8 hours increased to 1g every 6 hours;
Child, 50 – 100 mg/kg daily in divided doses
Meningitis (in combination with another antibiotic if necessary):
IV infusion: 2 g every 4 hours for at least 5 days in meningococcal disease or for 10 – 14 days in listerial meningitis.
Enterococcal endocarditis (in combination with another antibiotic if necessary): IV infusion: 2 g every 4 hours.
Storage: at room temperature in a tight container; oral suspension remains stable for 14 days at room temperature or if refrigerated.
Note: Reconstitution and Administration: According to manufacturer's directions

Ampicillin

Drop, 100mg/ml

Capsule, 250mg, 500mg

Injection, (Sodium), 250mg, 500mg, 1gm

Oral Suspension, 125mg/5ml, 250mg/5ml

Indications: broad-spectrum activity against several Gram-positive organisms, Gram-negative cocci and some bacilli. Used in respiratory tract infections, cholecystitis and gastrointestinal tract infections, including typhoid.

Cautions: history of allergy, renal impairment, erythematous rashes common in glandular fever, chronic lymphatic leukaemia, and possibly HIV infection.

Drug interactions: probenecid (except in cases of gonorrhoea and other STD), allopurinol, oral contraceptives, methotrexate, warfarin.

Contraindications: known hypersensitivity (allergy) to any penicillines.

Side effects: allergic reaction, specifically anaphylaxis (bronchospasm, sudden or severe decrease in blood pressure), skin rash, joint pain, fever, GIT reaction (mild diarrhoea, nausea, vomiting), oral candidiasis (sore mouth or tongue), pseudomembranous colitis (severe abdominal or stomach cramps and pain, abdominal tenderness, watery and severe diarrhoea).

Dose and Administration:

Adult: Oral: 250-500mg 6 hourly (up to 1g 6 hourly for severe infections).

IM: 500mg 6 hourly

IV: by slow injection or infusion over 30-60 minutes, 500mg 4-6 hourly (up to 12g daily for severe infections).

Meningitis/septicaemia: IV: 1-2g 3-4 hourly; maximum 300 mg/kg/day or 16g.

Renal impairment: GFR 10-50ml/min, dose interval 6-12 hours;
GFR

<10ml/min, 12-24 hours.

Child: Oral, IM or IV: under 20kg, 10-25 mg/kg/dose 6 hourly; over 20kg, as for adults.

Meningitis or severe infections: IV: 50mg/kg dose 6 hourly

Neonates: IM or IV: 50mg/kg/dose (meningitis 100mg/kg/dose) 12 hourly in the first week of life, 8 hourly from 1-3 weeks old, 6 hourly thereafter.

Storage: at room temperature; after reconstitution oral suspension is stable for 7 days at room temperature or for 14 days under refrigeration.

Note: Reconstitution and Administration: According to manufacturer's directions.

Cloxacillin sodium

Capsule, 250mg, 500mg

Syrup, 125mg, 250mg in each 5ml

Indications: infections due to beta-lactamase-producing staphylococci including impetigo, cellulitis and other soft-tissue

infections; staphylococcal endocarditis, septicaemia, pneumonia and osteomyelitis.

Cautions: history of allergy, renal and hepatic function impairment, GIT disease especially ulcerative colitis, regional enteritis, antibiotic associated colitis, heart failure; pregnancy and breastfeeding.

Drug interactions: probenecid, chloramphenicol, erythromycin, sulfonamide, and tetracyclines.

Contraindications: known hypersensitivity or allergy to penicillines.

Side effects: nausea and vomiting, diarrhea, hypersensitivity reactions including urticaria, fever, joint pain, rashes, angioedema, anaphylaxis, serum sickness-like reactions, haemolytic anaemia, interstitial nephritis; neutropenia, thrombocytopenia, coagulation disorders; antibiotic-associated colitis; hepatitis and cholestatic jaundice - may be delayed in onset; electrolyte disturbances; pain, inflammation, phlebitis or thrombophlebitis at injection sites.

Dose and Administration:

Adult: Oral: 250 to 500mg (base) every six hours. Maximum dose up to 6 gm (base) a day.

IV - 250 to 500mg (base) every six hours maximum - 6gms (base) daily

Child: Infants and children up to 20kg of body weights: Oral: 6.25 to 12.5mg (base) per kg of body weights every six hours or IV: 6.25 to 12.5mg (base) per kg of body weight every six hours.

Note: - continue medicines for full time of treatment and take on empty stomach.

Storage: store at room temperature. After reconstitution, solutions retain their potency for 14 days if refrigerated.

Penicillin G, Benzathine

Injection, 0.6, 1.2, 2.4 million IU in vial

Indications: streptococcal pharyngitis; diphtheria carrier state; syphilis and other treponemal infections (yaws, pinta, bejel); rheumatic fever prophylaxis.

Cautions: history of allergy (see notes above); renal failure; pregnancy and breast feeding

Drug interactions: methotrexate

Contra indications: see under penicillin G, sodium crystalline; and neurosyphilis

Side effects: hypersensitivity reactions including urticaria, fever, joint pains, rashes, angioedema, anaphylaxis, serum sickness – like reactions, hemolytic anemia and interstitial nephritis; neutropenia, thrombocytopenia, coagulation disorders and central nervous system

Dose and Administrations: deep IM injection:

Streptococcal pharyngitis; primary prophylaxis of rheumatic fever:

Adult and Child over 30 Kg body-weight, 900 mg as a single dose;

Child under 30 Kg body – weight, 450 – 675 mg as a single dose.

Secondary prophylaxis of rheumatic fever:

Adult and Child over 30 Kg body-weight, 900 mg once every 3 – 4 weeks; **Child** under 30 Kg body-weight, 450 mg once every 3 – 4 weeks.

Early syphilis: **Adult** 1.8 g as a single dose, divided between 2 sites.

Late syphilis: **Adult** 1.8 g divided between two sites, once weekly for 3 consecutive weeks.

Congenital syphilis (where no evidence of CSF involvement): **Child** up to 2 years, 37.5 mg/kg as a single dose.

Yaws, Pinta, and bejel: **Adult:** 900 mg as a single dose; **Child** 450 mg as a single dose.

Reconstitution and Administration: According to manufacturer's directions.

Storage: store between 2 and 8°C.

Phenoxymethyl Penicillin

Oral Suspension, 125mg/5ml, 50,000 IU/ml

Tablet, 125mg, 250mg, 500,000IU

250mg = 400,000IU

Indications: streptococcal pharyngitis; otitis media; erysipelas; mouth infection; secondary prophylaxis of rheumatic fever; post-splenectomy prophylaxis.

Cautions, Contraindications, Drug interactions, Side effects: see under penicillin G, sodium crystalline

Dose and Administration:

Infections due to sensitive organisms: Oral:

Adult: 500 mg every 6 hours increased up to 1 g every 6 hours in severe infections;

Child up to 1 year, 62.5 mg every 6 hours; **Child** 1 – 5 years, 125 mg every 6 hours; **Child** 6 – 12 years, 250 mg every 6 hours.

Secondary prophylaxis of rheumatic fever: Oral: **Adult:** 500 mg twice daily; **Child** 1 – 5 years, 125 mg twice daily; **Child** 6 – 12 years, 250 mg twice daily.

Patient advice. Phenoxymethyl penicillin should be taken at least 30 minutes before or 2 hours after food.

Storage: at room temperature in a tight container.

Phenoxymethyl penicillin, potassium

Suspension, 195mg/5ml

Tablet, 390mg

See under Phenoxymethyl Penicillin

Procaine Penicillin, Fortified

Injection (Buffered), 4,000,000 IU

Indications: for the treatment of respiratory infections (e.g. pneumonia), acute otitis media, skin structure infections, uncomplicated urogenital gonorrhoea, and syphilis.

Cautions: same as penicillin G benzathine and also caution in the treatment of gonococcal infections during pregnancy and in children.

Drug interactions: methotrexate, probenecid (decrease renal tubular secretion of the penicillins), aminoglycosides (inactivated by high doses of IV benzylpenicillin; should not be administered in same giving set).

Contraindications: known hypersensitivity to any penicillin and/or procaine.

Side effects: hypersensitivity reactions such as skin rash, fever, joint pains, edema and anaphylaxis may occur.

Dose and Administration: IM injection only.

Adult:

Gonorrhoea (acute, uncomplicated): 4,800,000 IU (2,400,000 IU in each buttock). Repeat the same dose next day.

Syphilis— Primary, secondary, or latent (of not more than 2 years duration): 600,000 IU daily for 8 days. Tertiary (2 year and more)- 600,000 IU daily for 10-15 days.

Note: Remember to treat always the sexual partner.

Pneumonia, acute otitis media, skin or skin structure infections:

Adult and Child (12 years and over): 600,000-1,200,000 IU daily for 5- 7days. Maximum dose –100,000 IU of penicillin G /kg of body weight in divided doses.

Child (below 12 years): Treatment is given daily for 5 –7 days, 1-5 months (3-5kg) –100,000 IU daily, 6-12 months (6-10kg) –200,000 IU daily, 1- 6 years (11-20kg) –300,000 IU daily, 1-5 years (21-30kg) – 400,000 IU daily.

Storage: At room temperature. After reconstitution, it should be used within 14 days provided it is stored between 2-4°C or within 4 days at about 20°C.

5.1.2. Other Antibacterials

Chloramphenicol

Chloramphenicol was the first broad-spectrum antibacterial to be discovered; it acts by interfering with bacterial protein synthesis and is mainly bacteriostatic. Its range of activity is similar to that of tetracycline and includes Gram-positive and Gram-negative bacteria, *Rickettsia* spp., and *Chlamydiae*.

It is associated with serious haematological adverse effects and should be reserved for the treatment of severe infections, particularly those caused by *Haemophilus influenzae* and typhoid fever.

Chloramphenicol

Capsule, 250mg

Oral suspension, 125 mg/5ml

Indications: severe life-threatening infections, particularly those caused by *Haemophilus influenzae* and typhoid fever; also, cerebral abscess; mastoiditis; relapsing fever; gangrene; granuloma inguinale; listeriosis; severe melioidosis; plague; psitticosis; tularaemia; Whipple disease; septicaemia; empirical treatment of meningitis

Cautions: it should not be used for the treatment of minor and undefined infections, or as a prophylaxis. Caution in patients with hepatic function impairment, blood disorder, in neonates and infants, in pregnant women, particularly those near term or in labour, and in nursing women.

Drug interactions: phenobarbital, oral contraceptives (estrogen containing), tolbutamide, chlorpropamide, penicillines, or streptomycin.

Contraindications: known hypersensitivity and/or toxic reactions to chloramphenicol.

Side effects: nausea, vomiting diarrhoea, and bone-marrow depression may occur.

Dose and Administration:

Note: A high initial dosage should not be given in the treatment of typhoid fever as sensitivity like reaction occurs. Reduce dose in hepatic and/or renal impairment.

Typhoid Fever: Adult: 500mg every 6 hours daily for 14 days.

Child: 11-30kg, 250mg every 6 hours daily for 14 days. 6-10kg, 125mg every 8 hours daily for 14 days.

Typhus: Adult: 500mg every 6 hours for 10 days. **Child:** 50 – 75 mg/kg of body weight daily in divided doses every 6 hours for 10 days.

Meningitis: I.V: infants > 30 days and **Child:** 50 - 100 mg/kg/day divided every 6 hours.

Other infections: I.V:

Adult: 50 - 100 mg/kg/day in divided doses every 6 hours; maximum daily dose: 4 g/day.

Infant > 30 days and **Child:** 50 - 75 mg/kg/day divided every 6 hours; maximum daily dose: 4 g/day.

Storage: at room temperature, in a tight container.

Sulphamethoxazole and Trimethoprim

Tablet (pediatric), 100mg + 20mg; (adult), 400mg + 80mg, 800mg+160mg

Mixture, 200mg + 40mg in each 5ml

Injection, 400mg + 80mg in each 5ml ampoule

Indications: prophylaxis and treatment of *Pneumocystis carinii* infections. Treatment of nocardiosis, and of urinary tract, respiratory tract and prostatic infections caused by susceptible organisms. Also used in treatment of typhoid/paratyphoid fevers, and in the treatment and prophylaxis of toxoplasmosis and *Isospora belli* diarrhea.

Cautions: elderly, renal and hepatic function impairment, photosensitivity, Glucose-6-phosphate dehydrogenase (G6PD) deficiency; maintain adequate fluid intake (to avoid crystalluria); avoid in blood disorders (unless under specialist supervision); monitor blood counts and discontinue immediately if blood disorder develops; rash – discontinue immediately; predisposition to folate deficiency; asthma; pregnancy; breastfeeding.

Drug interactions: coumarin or indandione derivative anticoagulant, hydantoin, oral hypoglycemics, hemolytics, hepatotoxic medication, methenamine, methotrexate, folate antagonists.

Contraindications: infants up to two months of age, in patients who are allergy to sulfonamide, furosemide, thiazide diuretics, sulfonylureas, carbonic anhydrase inhibitors or trimethoprim.

Side effects: hypersensitivity (fever, itching, skin rash), photosensitivity (increased sensitivity of skin to sunlight), blood disorder (sore throat, fever, pale skin), unusual bleeding or

bruising, unusual tiredness or weakness), hepatitis (yellow eyes or skin), Steven's Johnson syndrome, aching joints and muscles, redness, blistering, peeling, or loosening of the skin, unusual tiredness or weakness, toxic epidermal necrosis (difficulty in swallowing, redness, blistering, peeling, loosening of the skin), dizziness, headache, GIT disturbance, loss of appetite, nausea or vomiting.

Dose and Administration:

Adult:

Oral: 160mg of trimethoprim and 800mg of sulphamethoxazole every 12 hours may be increased to 320/1600 mg 12 hourly in severe infections.

IV infusion: 160/800 mg 12 hourly. Each 80/400mg (5ml) to be diluted in 125ml 5% glucose or 0.9% sodium chloride solution or infused over 1-1.5 hours.

Cerebral toxoplasmosis: 320/1600mg twice daily for 4 weeks, then 160/800 mg twice daily for 3 months.

Isospora belli: 160/800 mg 6 hourly for 10 days.

Primary prophylaxis in HIV-infection: Oral: 160/800 mg daily. Lower doses (80/400 mg daily or 160/800 mg 3 times a week) have been shown to be effective for Pneumocystis pneumonia and are better tolerated.

Child:

Oral: 2 months to 5 months, 20/100mg; 6months -5 years, 40/200 mg; 6-12 years, 80/400mg, 12 hourly.

IV infusion: 6/30 mg/kg/day in 2 divided doses, increased to 9/45 mg/kg/day in severe infections.

Pneumocystis carinii pneumonia:

Treatment: Oral or IV infusion: **Adult and Child:** sulphamethoxazole up to 100mg/kg daily with trimethoprim up to 20mg/kg daily in 2-4 divided doses for 14-21 days.

Prophylaxis: Oral: **Adult and Child:** sulphamethoxazole 25mg/kg with trimethoprim 5 mg/kg in 2 divided doses on alternate days (3 times a week).

Note: - For oral, continue medicine for full time of treatment, avoid too much sun or use of sun lamp. Avoid IM administration.

Storage: at room temperature, in a tight, light-resistant container, protect from freezing.

Tetracyclines

Tetracyclines all have a broad spectrum of activity which includes Gram-positive and Gram-negative bacteria. Unlike the penicillins they are usually bacteriostatic at the concentrations achieved in the body but interfering with protein synthesis in susceptible organisms.

Tetracycline hydrochloride

Capsule, 250mg, 500mg

Tablet, 250mg, 500mg (coated)

Indications: exacerbations of chronic bronchitis; brucellosis, chlamydia, mycoplasma, and rickettsia; acne vulgaris, rosacea, typhus, gonorrhoea, chancroid, syphilis, and cholera.

Cautions: caution in patients with renal function impairment.

Drug interactions: aluminum and/or magnesium containing antacids, laxatives, calcium (e.g. milk or other dairy products, eggs) and/or iron supplements, penicillins, or streptomycin.

Contraindications: pregnant or nursing women, infants and children under 8 years of age (it may also depress bone growth and cause permanent discoloration of the teeth).

Side effects: nausea, vomiting, epigastric burning and distress, flatulence and diarrhoea occur most frequently due to gastric irritation. Rarely photosensitivity, skin discoloration, blood dyscrasias may occur.

Dose and Administration: Orally, given 1 hour before or 2 hours after meals with adequate amounts of fluid.

Reduce dosage in renal and hepatic function impairment.

Adult:

Rickettsial infection (e.g. typhus): 1-2g daily in 2-4 divided doses for 7-10 days.

Gonorrhoea (uncomplicated or disseminated) in penicillin allergies: 500mg every 6 hours daily for at least 7 days.

Chancroid: 1-2g daily in 2-4 divided doses for 7 days.

Syphilis (in penicillin allergies):

Early syphilis (of not more than 2 years duration) and Late syphilis (2 years and more): 500mg every 6 hours daily for 15 days.

Cholera: 1-2g daily in 2-4 divided doses for 48 – 72 hours.

Child (8 years and over): usually, oral, 25 –50mg/ml of body weight daily in 2-4 divided doses.

Relapsing fever-

Adult: 500mg – 1g every twelve hours.

Child (8 years and over): 6.25 –12.5mg/kg of body weight every six hours.

Adult and Child: IV or IM: administration given in two to four divided doses at dose levels of 2.5 to 5 mg/kg/day for patients with normal renal function depending on the severity of the infection.

Storage: at room temperature, in a tight, light-resistant container.

Note: outdated and decomposed tetracycline are toxic and may cause nephrotoxicity and skin lesion.

5.2. Antiprotozoals

5.2.1. Antimalarials

Malaria is one of the most serious protozoal infections, which is transmitted by anopheline mosquitoes and rarely by congenital transmission, transfusion of infected blood or use of contaminated syringes among drug addicts. It is caused by infection by any of four species of plasmodium. Plasmodium vivax is the most extensively distributed and cause much debilitating disease. P falciparum is also widespread, and causes the most severe infections, which are responsible for nearly all malarial - related deaths. P. Ovale is mainly confined to Africa and is less prevalent, while P.malariae, which causes the least severe but most persistent infections also occur widely.

Certain tissue forms of P. vivax and P. ovale which persist in the liver for many months and even years are responsible for the relapses characteristic of malaria such latent forms are not

generated by *P. falciparum* or *P. malaria*. Recrudescence of these infections results from persistent blood forms in inadequately treated or untreated patients.

Management of malaria involves vector control, protection from bites, prophylaxis with drugs, and treatment of any infection that develops

Artemether + Lumfantrine is an antimalarial agent used to treat acute uncomplicated malaria. It is combination of lumfantrine with artemether for improved efficacy. This combination therapy exerts its effects against the erythrocytic stages of *Plasmodium* spp. and may be used to treat infections caused by *P. falciparum* and unidentified *Plasmodium* species, including infections acquired in chloroquine-resistant areas.

Prophylaxis against malaria

No drug regimen gives assured protection to everybody, and indiscriminate use of existing antimalarials increases the risk of inducing resistance.

Chloroquine, which is usually well tolerated at the required dosage, is preferred where *p.falciparum* remains fully sensitive. The recommended prophylactic regimen has been employed effectively even in areas of marginal resistance. However, it must be started 1 week before exposure, and be maintained in pregnant women until after delivery and for at least 4 weeks after the last risk of exposure in the case of non-immune individuals. This is sufficient to ensure elimination of *P.falciparum* and *P.malaria*, but not of *P.vivax* and *P.ovale* whose residual hepatic forms survive.

Proguanil, a predominantly tissue schizontocide with little blood schizontocidal activity, is a causal prophylactic agent since it is active against pre-erythrocytic intrahepatic forms, particularly of *P.falciparum*. The latent persistent liver forms of *P.ovale* and *P.vivax* are unresponsive. However, there is evidence that it may be effective against *P.vivax* only immediately after the initial infection. *P.falciparum* resistance to proguanil and related compounds may occur in malaria endemic areas and particularly where it has been employed in mass prophylaxis.

Pregnancy: travel to malarious areas should be avoided during pregnancy; if travel is unavoidable, effective prophylaxis must be used. Chloroquine and proguanil may be given in usual doses in areas where *P.falciparum* strains are sensitive; in the case of proguanil, folic acid 5mg daily should be given.

Artemether + Lumfantrine

Tablet, 20mg +120mg (Dipersable)

Indications: treatment of acute uncomplicated malaria caused by *p.falciparum* and acute *p.vivax* including malaria acquired in chloroquine-resistant areas. It may also be used to treat uncomplicated malaria when the *Plasmodium* species has not been identified. Indicated for use in adults and children greater than 5 kg.

Cautions: electrolyte disturbances, concomitant administration of drugs that prolong QT interval; severe renal or hepatic impairment.

Drug interactions: amiloride, amitriptyline, azithromycin, chloroquine, chlorpromazine, ciprofloxacin, clomipramine, erythromycin, fluconazole, fluphenazine, furosemide, grapefruit juice, hydrochlorothiazide, mefloquine, naldixic acid, ofloxacin, procainamide, pyrimethamine, quinidine, quinine, spironolactone, sulfadoxine + pyrimethamine.

Contraindications: pregnancy, breastfeeding, history of arrhythmias, of clinically relevant bradycardia, and congestive heart failure accompanied by reduced left ventricular ejection fraction.

Side effects: abdominal pain, anorexia, diarrhoea, nausea and vomiting; headache, dizziness, sleep disorders; palpitations; arthralgia, myalgia; cough; asthenia; fatigue; pruritus, rash.

Dose and Administration: Oral:

Adult: 35-65kg, artemether 80mg and lumefantrine 480mg, repeated after 8 hours, then twice daily on the following 2 days (i.e. 3-day course of 6 doses). Over 65 kg, as for 35-65 kg, but with closer monitoring for treatment failure / recrudescence.

Child: 5 - < 15kg, 1 tablet; 15 - < 25kg, 2 tablets; 25 - < 35kg, 3 tablets; 35 – 65 kg, 4 tablets, repeated after 8 hours, then twice daily on the following 2 days (i.e. a 3-day course of 6 doses).

Storage: store at room temperature

Chloroquine Phosphate

Tablet, 250mg, 500mg (equivalent to 150mg, 300mg base)

Syrup, 50mg base/5ml

Injection, 250mg/5ml; 5ml (equivalent to 150 mg chloroquine base)

Indications: prophylaxis and treatment of acute attacks of malaria.

Cautions: patients should avoid alcoholic beverages while taking chloroquine.

Side effects: gastro-intestinal disturbances, headache, also convulsions, visual disturbances, depigmentation or loss of hair, skin reactions (rashes, pruritus); rarely, bone-marrow suppression; other side effects (not usually associated with malaria prophylaxis or treatment).

Drug interactions: carbamazepine, ciclosporin, digoxin, ethosuximide, mefloquine, phenytoin and valproic acid.

Dose and administration: Orally with meals or milk and intramuscularly. Where chloroquine syrup is not available the tablets can be given to children by crushing and mixing with sweetened milk on spoon. Chloroquine phosphate injection is very dangerous and should be used only in severe malaria and in comatose or vomiting patients. Always check if patients have not taken chloroquine tablet before giving the injection.

For prophylaxis –

Adult: Oral, 500mg (300mg base) once weekly.

Child: Oral, 8.3mg/kg (5mg/kg base) of body weight once weekly, not to exceed 500mg/week (300mg base) regardless of weight.

The tablets are taken on the same day of the week, beginning 1 –2 weeks before travel into a malarious area until 6 weeks after leaving it. If therapy has not been started 2 weeks prior to exposure -

Adult: Initially, 1g (600mg base).

Child: Initially, 16.7mg/kg (10mg base/kg) of body weight.

Note: The initial dose is given in 2 equally divided doses 6 hrs apart followed by the usual dosage.

Counselling. Warn travellers about importance of avoiding mosquito bites, importance of taking prophylaxis regularly, and importance of immediate visit to doctor if ill within 1 year and especially within 3 months of return.

For treatment –

Oral treatment of cases with chloroquine dose table for 150mg base/tablet or 50mg base/5ml syrup—

Age group in year	Chloroquine Dosage (Expressed in mg base and in tablets)	
Under 1 year	75mg ½ tab 40 mg ¼ tab 75mg ½ tab 75mg ½ tab	STAT 6 hours later 2 nd . Day 3 rd . day
1 -5 years	150mg 1 tab 75mg ½ tab 75mg ½ tab 75mg ½ tab	STAT 6 hours later 2 nd . Day 3 rd . day
6 – 9 years	300mg 2 tab 150mg 1 tab 150mg 1 tab 150mg 1 tab	STAT 6 hours later 2 nd . Day 3 rd . day
10 -15 years	450mg 3 tab 225 mg 1 ½ tab 225 mg 1 ½ tab 225 mg 1 ½ tab	STAT 6 hours later 2 nd . Day 3 rd . day
ADULT (16 years and over)	600mg 4 tab 300 mg 2 tab 300 mg 2 tab 300 mg 2 tab	STAT 6 hours later 2 nd . Day 3 rd . day

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For the treatment of comatose or vomiting patient and severe malaria, intramuscular injection, 5.8mg (3.5mg base)/kg of body weight. May be repeated if necessary after 6 hours. Continue treatment with tablet or syrup as soon as the patient can swallow until a total dose of 25mg/kg of chloroquine base.

Note: resistance should be considered if a good response is not noted in 2 or 3 days.

Storage: at room temperature.

Proguanil Hydrochloride

Tablet, 100mg (scored)

Indications: chemoprophylaxis of malaria.

Cautions: pregnancy and in renal impairment.

Drug interaction: - anticoagulants.

Side effects: mild gastric intolerance and diarrhoea, occasional mouth ulcers and stomatitis, skin reaction and hair loss.

Dose and Administration: Prophylaxis of malaria: Oral:

Adult: 200mg daily, after food;

Child under 1 year, 25mg daily; 1-4 years, 50mg daily; 5-8 years, 100mg daily; 9-14 years, 150mg daily.

Note: warn travelers about importance of avoiding mosquito bites, importance of immediate visit to doctor if ill within 1 year and especially within 3 months of return.

5.2.2. Amoebicides

Metronidazole is a 5-nitroimidazole derivative with activity against protozoa and anaerobic bacteria. In amoebiasis, metronidazole acts as an amoebicide at all sites of infection with *Entamoeba histolytica*. Because of its rapid absorption it is probably less effective against parasites in the bowel lumen and is

therefore used in conjunction with a luminal amoebicide such as **diloxanide furoate** or di-iodohydroxyquinoline in the treatment of amoebic dysentery and in extra-intestinal amoebiasis, including hepatic amoebiasis.

Tinidazole has the antimicrobial actions of metronidazole and usually administered as a single dose by mouth with or without food.

Metronidazole

Suspension (Oral), 125mg/5ml, 200mg/5ml, 250mg/5ml

Indications: invasive amoebiasis

Cautions: disulfiram like reaction with alcohol; hepatic impairment and hepatic encephalopathy, pregnancy; breastfeeding; clinical and laboratory monitoring in courses lasting longer than 10 days; see also interactions.

Note: - Avoid Alcohol. The drug may cause dizziness.

Drug interactions: phenytoin, coumarin or indandion derivative anticoagulant, warfarin, disulfiram, alcohol, cimetidine, fluorouracil, lithium, phenobarbitone.

Contraindications: chronic alcohol dependence

Side effects: nausea, vomiting, unpleasant metallic taste, furred tongue and gastrointestinal disturbances; rarely headache, drowsiness, dizziness, ataxia, darkening of urine, erythema multiform, pruritus, urticaria, angioedema, and anaphylaxis; abnormal liver function tests, hepatitis, jaundice, thrombocytopenia, aplastic anaemia, myalgia, arthralgia, peripheral neuropathy, epileptiform seizures, leucopenia, on prolonged or high dosage regimens

Dose and Administration:

Oral: Adult and Child:

Child: 15mg/kg daily in divided doses for 5 - 10 days.

Urogenital trichomoniasis: **Oral: Adult:** 2g as a single dose or 400 – 500 mg twice daily for 7 days; sexual partners should be treated concomitantly.

Patient Advice: Metronidazole tablets should be swallowed whole with water, during or after a meal; metronidazole suspension should be taken one hour before a meal.

Storage: at room temperature, in a well closed, light resistant container.

Tinidazole

Tablet, 250mg, 500m

Indications: in the treatment of susceptible protozoal infections and in the treatment and prophylaxis of anaerobic bacterial infections.

Cautions: see under metronidazole; avoid porphyria

Drug interactions: alcohol

Side effects: see under metronidazole

Dose and Administration:

Intestinal amoebiasis, 2gm daily for 2 - 3 days; **Child:** 50 - 60 mg/kg daily for 3 days

Amoebic involvement of liver, 1.5 - 2gm daily for 3 - 6 days, **Child:** 50 - 60mg/kg daily for 5 days.

Urogenital trichomoniasis and giardiasis, single 2gm dose (repeated once if necessary); **Child:** single dose of 50 - 75 mg/kg.

5.2.3. Antigiardials

Giardiasis is caused by *Giardia intestinalis* and is acquired by oral ingestion of *Giardia* cysts. Giardiasis can be treated with tinidazole in a single dose or with another 5-nitroimidazole, such as **metronidazole**; both are highly effective and should be offered when practicable to all infected patients. Family and institutional contacts should also be treated. Larger epidemics are difficult to eradicate because of the high proportion of symptomless carriers and because excreted cysts can survive for long periods outside the human host

Metronidazole

Oral Suspension, 125mg/5ml, 200mg/5ml, 250mg/5ml

Syrup, 4% W/V, 250mg/5ml

Tablet/Capsule, 250mg

Indications: invasive giardiasis

Cautions, Drug interactions, Contraindications, Side effects under metronidazole on amoebiasis

Dose and Administration:

Oral: **Adult:** 2g once daily for 3 days,

Child: 15mg/kg daily in divided doses for 5 - 10 days.

Patient Advice: Metronidazole tablets should be swallowed whole with water, during or after a meal; metronidazole suspension should be taken one hour before a meal.

Storage: at room temperature, in a well closed, light resistant container.

Tinidazole

Tablet, 250mg, 500mg

Indications: in the treatment of susceptible protozoal infections and in the treatment and prophylaxis of anaerobic bacterial infections.

Cautions: see under metronidazole; avoid porphyria

Drug interactions: alcohol

Side effects: see under metronidazole on amoebiasis

Dose and Administration:

Single 2gm dose (repeated once if necessary); **Child:** single dose of 50 - 75 mg/kg.

5.2.4. Anthelmintics

Albendazole

Oral Suspension, 100mg/5ml

Tablet, 200mg, 400mg

Indications: for the treatment of single or mixed intestinal nematode infection such as ascariasis, enterbiasis, hookworm infection, or trichuriasis and strongyloidiasis. Also for treatment of hydatid disease caused by *Echinococcus granulosus*.

Cautions: breastfeeding. Exclude pregnancy before starting treatment.

Contraindications: pregnancy.

Side effects: GIT disturbances, headache, dizziness, changes in liver enzyme, rarely reversible alopecia (loss of hair), rash, fever, blood disorders, including leucopenia and pancytopenia.

Dose and Administration:

Adult and Child over 2 years: Oral:

Single or mixed intestinal parasites: Oral: 400 mg as a single dose (given for 3 days in heavy mixed infestations involving *Trichuris* or *Taenia* spp.). Repeated after 3 weeks if required.

Strongyloidiasis: 400mg given once or twice daily for 3 consecutive days. May be repeated after 3 weeks.

Giardiasis: 400 mg once daily for 5 days

Hydatid: <60 kg: 15mg/kg/day in 2 divided doses (maximum: 800mg/day)

: ≥ 60 kg: 400mg twice daily

(Administer dose for three 28-day cycles with a 14-day drug-free interval in between).

Storage: at room temperature.

Levamisole

Tablet, 40mg

Indications: treatment of ascariasis, hookworm and mixed ascariasis with hookworm infections; with fluorouracil for the treatment of colorectal carcinoma after complete resection of primary tumour.

Cautions: sensitive to levamisole

Drug interactions: anticoagulants (cumarine and indandione), bone marrow depressants.

Contraindications: advanced liver or kidney disease, pre-existing blood disorders.

Side effects: nausea, vomiting, abdominal pain, dizziness and headache.

Dose and Administration: Oral:

Adult: 120mg (3 tablets) as a single dose

Child: 3mg per kg of body weight as a single dose.

Mebendazole

Oral Suspension, 100mg/5ml

Tablet, 100mg, 500mg

Indications: For the treatment of whipworm (*trichuris trichuria*), pinworm (*Enterobius Vermicularis*), roundworm (*Ascaris Lumbricoids*), hookworm (*Ancylostoma duodenale*, *Nectar americanus*), and capillariasis in single or mixed infections.

Cautions: ulcerative colitis, liver diseases, hypersensitivity, treatment of intestinal worm is recommended in children over 1 year of age, there is limited data to assess the risk-benefit in those under one year. During pregnancy and in nursing women. In hookworm and whipworm infections iron supplements may be required as anemia may occur.

To prevent reinfection all other infected member of the family should be treated. Personal hygiene and sanitation should be observed and all bedding and nightclothes washed after treatment, especially in pinworm infection.

Side effects: transient abdominal pain or upset, nausea, vomiting, diarrhoea, dizziness, headache, skin rash and itching may occur occasionally in cases of massive infection and expulsion of worms.

Dose and Administration: Oral:

Adult and Child over 1 year:

Ascariasis: 500mg as a single dose or 100mg twice daily for 3 days. Hookworm infections, trichuriasis: 100mg twice daily for 3 days; if eggs persist in the faeces, second course after 3-4 weeks; alternatively 500mg as a single dose.

Adult and Child over 2 years:

Enterobiasis: 100mg as a single dose, repeated after interval of 2-3 weeks; all household members over 2 years should be treated at the same time.

Capillariasis: 200mg daily for 20-30 days; for mass treatment control programmes, 500mg as a single dose 4 times a year.

Roundworm, Whipworm, Hookworm mixed infection: 100mg twice daily, morning and evening, for 3 consecutive days. May be repeated in 2- 3 weeks if required.

Tapeworm (*Taenia spp.*): 100 mg twice daily for 6 days. There are reports of high success rates with higher doses for shorter periods (200mg twice daily for 4 days or 300mg twice daily for 3 days). Repeat after 3 weeks if necessary.

Storage: at room temperature, in well-closed containers.

Niclosamide

Tablet (chewable), 500mg

Indications: eradication of tapeworm and H.nana.

Cautions: caution in patients with hypersensitivity to niclosamide, in children under 2 years and during pregnancy.

Side effects: nausea or vomiting, stomach pain, bad taste in mouth, dizziness, drowsiness, skin rash and itching may rarely occur.

Dose and Administration: Oral: preferably after a light meal or breakfast. Tablets should be crushed or chewed thoroughly and washed down with a small amount of water.

For small children tablets should be ground as finely as possible and mixed with small amount of water.

In those with chronic constipation a mild laxative may be given before or after administering the drug.

A second course of niclosamide may be given if proglotides and /or ova persist for 7 – 14 days after treatment.

Adult: tapeworm: 2g

H.nana: 2 g on the first day, followed by 1 g for the following 6 days.

Child: 1 –5 years: 500mg; 6-12 years: 1g

Note: The dose may be given once as a single dose or half the dose first and the other half 1 hour later.

Storage: At room temperature, in a tight container, away from heat and direct light.

Piperazine

Elixir(Citrate), 500mg, 622.5mg, 706mg,

750mg, 937.5mg, 1g /5ml

Tablet (Adipate), 300mg

Indications: for the treatment of round worm (Ascaris Lumbricoids) and pinworm (Enterobius) infections.

Cautions: caution in patients with epilepsy, impaired renal or hepatic function, and hypersensitivity. Supportive therapy should

be given for anemic, dehydrated or malnourished patients prior to administration of the drug. Treat other members of the family paying attention to personal hygiene.

Drug interactions: chlorpromazine.

Side effects: nausea, vomiting, mild diarrhoea, abdominal cramps, headache, and dizziness may occur occasionally.

Dose and Administration: Oral: in constipated patients a purgative should be given to ease expulsion of the worm. A single dose is usually enough to treat roundworms. However, the dose may be repeated in 2 days if a patient has large number of roundworms.

Roundworm infection (Ascariasis):

Adult: 3- 4g (30 – 40ml) or 75mg/kg of body weight as a single dose.

Child: 75mg/kg of body weight as a single dose. Or, 1 –5 years –1g (10ml) as a single dose. 6 –12 years –2g (20ml) as a single dose.

Pinworm Infection (Enterobiasis, oxyuriasis):

Adult: 2g (20ml) or 65mg/kg of body weight every 12 hours daily for 7 days.

Child: 65 mg/kg of body weight as a single dose for 7 days. Or, 1 –5 years 750 mg (7.5ml) once daily for 7days. 6 –12 years –1½ g (15ml) once daily for 7days. Maximum – 2.5 g once daily.

Storage: at room temperature, in light containers, protected from light.

Pyrantel Pamoate

Oral Suspension, 250mg base/5ml

Tablet, 125mg base

Indications: treatment of Ascariasis, enterobiasis (pinworm infection), helminth infection (multiple), hookworm infection

Cautions: pre-existing liver dysfunction, severe malnutrition or anaemia.

Drug interactions: piperazine

Contraindications: hypersensitivity to the drug

Side effects: nausea, vomiting, tenesmus, anorexia, diarrhoea drowsiness, headache, trouble in sleeping, hypersensitivity (skin rash)

Dose and Administration:**Adult:**

Ascariasis: Oral: 11mg (base) per kg of body weight as a single dose may be repeated in 2 or 3 weeks if required.

Entrobiasis: Oral: 11mg (base) per kg of body weight as a single dose. Repeat in 2 or 3 weeks

Hookworm (infection): Oral: 11mg (base) per kg of body weight once a day for three days.

Trichostrongyliasis: Oral: 11mg (base) per kg of body weight as a single dose. Maximum - up to 1 gm (base)

Child 2 years and over same as adults

Storage: at room temperature in a tight, light resistant container.

Thiabendazole

Oral Suspension, 500mg/5ml

Tablet, 500mg

Indications: for treatment of strongyloidiasis, cutaneous and visceral larva migrans, dracontiasis, and symptoms of trichinosis. It is also used as secondary treatment for threadworm when mixed with above infestations, adjunct in hookworm, whipworm or roundworm (but not suitable for mixed infection involving round worms due to risk of migration). It is not used for prophylactic purpose

Cautions: hepatic and renal function impairment, in elderly. Discontinue if hypersensitivity reaction occur, correct anemia, dehydration or malnutrition preferably before treatment.

Drug interactions: theophylline.

Contraindications: pregnancy, breast-feeding.

Side effects: anorexia, nausea, vomiting, diarrhoea, dizziness, headache, pruritus, drowsiness, hypersensitivity reaction (fever, chills, angioedema, rashes), visual disorder.

Dose and Administration: Adult: Oral:

Cutaneous Larva migrans: 25mg per kg of body weight two times a day for two days. May be repeated two days after completion of treatment if active lesions are still present.

Visceral Larva migrans: 25mg per kg of body weight 2 times a day for 5-7 days may be repeated in 4 weeks if required

Strongyloidiasis:

- Uncomplicated infection: 25mg per kg of body weight 2 times a day for two days.

- Hyper infection syndrome: 25mg per kg of body weight 2 times a day for 5-7 days may be repeated if required.

Trichinosis: 25mg per kg of body weight two times a day for 2-4 days based on patient response. Maximum - up to 3 grams daily

Child: (children 13.6kg of body weight and above) - same as adults dose

Note: - Continue medicines for full time of treatment and take after meals.

Storage: at room temperature in a tight container.

6. MEDICINES USED IN ENDOCRINE DISORDERS AND CONTRACEPTIVES

6.1. Contraceptives

Hormonal Contraceptives

Hormonal contraceptives are only generally available for women although preparations for men are being evaluated. Oral contraceptives are divided in to 2 main types: combined (containing an oestrogen and a progestogen) and progestogen - only: They produce a contraceptive effect mainly by suppressing the hypothalamic pituitary system resulting in prevention of ovulation. In addition changes in the endometrium make it unreceptive to implantation and changes in the cervical mucus may prevent sperm penetration.

Combined Oral Contraceptives

Oral contraceptives containing an oestrogen and a progestogen are the most effective preparations for general use.

Advantage of combined oral contraceptives include:

- Reliable and reversible.
- Reduced dysmenorrhoea and menorrhagia;
- Reduced incidence of premenstrual tension.
- Less symptomatic fibroids and functional ovarian cysts;

- Less benign breast disease
- Reduced risk of ovarian and endometrial cancer
- Reduced risk pelvic inflammatory disease, which may be a risk with intra uterine devices.

An association between the amount of estrogen and progestogen in oral contraceptives and an increased risk of adverse cardiovascular effects has been observed.

The oestrogen content ranges from 20 to 50 micrograms and generally a preparation with the lowest oestrogen and progestogen content which gives good cycle control and minimal side - effects in the individual woman is chosen.

The risk of hypertension increases with increasing duration of oral contraceptive use and they should be discontinued if the woman becomes hypertensive during use. Combined oral contraceptives are associated with an increased risk of thromboembolic and thrombotic disorders and an increase in risk of cerebrovascular disorders including stroke and subarachnoid hemorrhage.

Risk factors for venous Thromboembolism or Arterial disease:

Risk factors for venous thromboembolism include family history of venous thromboembolism in first degree relative age under 45 years, obesity, long-term immobilization and varicose veins.

Risk factors for arterial disease include family history of arterial disease in first - degree relative age under 45 years, diabetes mellitus, hypertension, smoking, age over 35 years, obesity and migraine.

If two or more factors for either venous thromboembolism or arterial disease are present, combined oral contraceptives should be avoided. Combined oral contraceptives are contraindicated if there is severe or focal migraine

Reasons to stop combined oral contraceptives immediately.

Combined estrogen - containing oral contraceptives should be stopped immediately if any of the following symptoms occur.

- Sudden severe chest pain (even if not radiating to left arm):
- Sudden breathlessness (or cough with blood strained sputum):
- Severe pain in calf of one leg

- Severe stomach pain
- Serious neurological effects including unusual, severe, prolonged headache especially if first time or getting progressively worse or sudden partial or complete loss of vision or sudden disturbance of hearing or other perceptual disorders or dysphagia or bad fainting attack or collapse or first unexplained epileptic seizure or weakness, motor disturbances, very marked numbness suddenly affecting one side or one part of body:
- Hepatitis, jaundice, liver enlargement;
- Severe depression
- Blood pressure above systolic 160mmHg and diastolic 100mmHg;
- Detection of a risk factor.

Diarrhea and vomiting up to 3 hours after taking an oral contraceptive or very severe diarrhea can interfere with its absorption. Additional precautions should therefore be used during and for 7 days after recovery. If the vomiting and diarrhoea occurs during the last 7 tablets, the next pill - free intervals should be omitted (in the case of every day tablets the inactive ones should be omitted).

Interactions. The effectiveness of both combined and progestogen only oral contraceptives may be considerably reduced by interaction with drugs that induce hepatic enzyme activity (e.g carbamazepine, griseofulvin, modafinil, nelfinavir, nevirapine, oxcarbazepine, phenytoin, phenobarbital, primidone, ritonavir, topiramate, and above all, rifabutin and rifampicin) in this case additional contraceptive method should be sought.; advice on the possibility of interaction with newer antiretroviral drugs should be sought from a pharmacist: some broad - spectrum antibiotics (eg. ampicillin, doxycycline) may reduce the efficacy of combined oral contraceptives by impairing the bacterial flora responsible for recycling of ethinylestradiol from the large bowel.

Progestogen-only contraceptives

Progestogen only contraceptives, such as oral levonorgestrel may offer a suitable alternative when estrogens are contraindicated but the oral progestogen only preparations do not prevent ovulation in all cycles and have a higher failure rate than combined estrogen containing preparations. Progestogen - only contraceptives carry less risk of thromboembolic and cardiovascular disease than combined oral contraceptives and are preferable for women over 35 years, for heavy smokers, and for those with hypertension, valvular heart disease, diabetes mellitus, and migraine, they can be used as an alternative to estrogen containing combined preparations prior to major surgery. Menstrual irregularities (oligomenorrhoea, menorrhagia, amenorrhoea) are common. Injectable preparations of Medroxy progesterone acetate or norethisterone enantate may be given intramuscularly. They have prolonged action and should only be given with full counseling and manufacturer's information leaflet. **Interactions:** effectiveness of oral progestogen - only preparations is not affected by broad-spectrum antibiotics but is reduced by enzyme inducing drugs.

Starting routine. One tablet daily, on a continuous basis, starting on day 1 of cycle and taken at the same time each day (if delayed by longer than 3 hours contraceptive protection may be lost). Additional contraceptive precautions are not necessary when initiating treatment.

Changing from a combined oral contraceptive: start on the day following completion of the combined oral contraceptive course without a break (or in the case of every day tablets omitting the inactive ones).

After childbirth: start any time after 3 weeks postpartum (increased risk of breakthrough bleeding if started earlier) as lactation is not affected this preparation can be preferred.

Emergency contraception

Emergency contraception can be obtained using levonorgestrel, one tablet of 750 micrograms should be taken as soon as possible (within 72 hours) after unprotected intercourse followed 12 hours later by another one tablet. Under those circumstances it

prevents about 86% of pregnancies that would have occurred if no treatment had been given. Adverse effects include nausea, vomiting, headache, dizziness, breast discomfort, and menstrual irregularities. If vomiting occurs within 2-3 hours of taking the tablets, replacement tablets can be given orally with an antiemetic.

It should be explained to the woman that her next period may be early or late; that she needs to use a barrier contraceptive method until her next period, and that she should return promptly if she has any lower abdominal pain or if the subsequent menstrual bleed is abnormally light, heavy, brief or absent. There is no evidence of harmful effects to the fetus if pregnancy should occur.

6.1.1. Combined Oral Contraceptives

Drospirenone +Ethinyl Estradiol

Tablet, (Film Coated), 3mg+0.03mg

Levonorgestrel (D-Norgestrel) +Ethinylestradiol and with/without Iron tablets*

Tablet, 0.15mg + 0.03mg; 0.25mg + 0.05mg; 0.5mg + 0.005mg; 0.3mg + 0.03mg

0.05mg + 0.03mg (6 tablet), 0.075mg + 0.04mg (5 tablet), 0.125mg + 0.03mg (10 tablet)

Norethindrone (Norethisterone) + Ethinylestradiol

Tablet, 0.5mg + 0.035mg

Norethindrone (Norethisterone) + Mestranol and iron tablets*

Tablet, 1mg + 0.05mg

Indications: contraception, menstrual symptoms, endometriosis.

Cautions: risk factor for venous thromboembolism and arterial disease (see notes above); migraine; hyperprolactinaemia (seek specialist advice); some types of hyperlipidaemia; gallbladder disease; depression; long-term immobilization, sickle-cell disease;

* Each iron Tablet contains: Ferrous fumarate 75 mg

inflammatory bowel disease including crohn disease; see also interactions.

Drug interactions: see notes above

Contraindications: pregnancy; within twenty-one days postpartum; breastfeeding until weaning or for first 6 months postpartum; personal history of venous or arterial thrombosis, heart disease associated with pulmonary hypertension or risk of embolism; migraine; history of sub-acute bacterial endocarditis; ischaemic cerebrovascular disease; liver disease, including disorders of hepatic secretion such as Dubin - Johnson or Rotor syndromes, infections hepatitis (until liver function normal); porphyria; systemic lupus erythematosus; liver adenoma; history of cholestasis; gall stones; estrogen - dependent neoplasms; neoplasms of breast or genital tract; undiagnosed vaginal bleeding; history during pregnancy of pruritus, chorea, herpes, deteriorating otosclerosis; cholestatic jaundice; pemphigoid gestationis; diabetes mellitus (if either retinopathy, neuropathy or if more than 20 years duration); after evacuation of hydatidiform mole (until return to normal of urine and plasma gonadotrophin values)

Side effects: nausea, vomiting, headache, breast tenderness, increase in body weight, thrombosis, changes in libido, depression, skin reaction, chloasma, hypertension, impairment of liver function, 'spotting' in early cycles, absence of withdrawal bleeding, irritation of contact lenses; rarely, photosensitivity and hepatic tumours; aggravate preexisting conditions of chorea; breast cancer (small increase in risk of breast cancer during use which reduces during the 10 years after stopping; risk factor seems related to age at which contraceptive is stopped rather than total duration of use; small increase in risk of breast cancer should be weighed against the protective effect of the ovary and endometrium)

Dose and Administrations

Contraception (21 - day combined (monophasic) preparations), by mouth, Adult (female), 1 tablet ('pill') daily for 21 days; subsequent courses repeated after 7 - day pill - free interval (during which withdrawal bleeding occurs)

Administration each tablet (pill) should be taken at approximately the same time each day; if delayed by longer than 24 hours contraceptive protection may be lost. It is important to bear in mind that the critical time for loss of protection is when a pill is omitted at the beginning or end of a cycle (which lengthens the pill - free interval).

The following advice is recommended:

If you forget a pill, take it as soon as you remember, and the next one at the normal time; if the forgotten pill is not taken till the next one, take two pills and then continue as normal. If you are 12 or more hours late, the pill may not work; as soon as you remember, continue normal pill - taking, but for 7 days an additional method of contraception such as the sheath will be required. If the 7 days run beyond the end of your packet, start the next packet when you have finished the present one - do not have a gap between packets.

Storage: - at room temperature, in a well - closed container.

6.1.2. Progestogen - only contraceptives

Ethinodiol Diacetate

Tablet, 0.5mg

Lynestrenol

Tablet 0.5mg

Norethindrone (Norethisterone)

Tablet, 0.35mg

Medroxyprogesterone Acetate,

Injection (aqueous suspension), 150mg/ml in 1 ml vial

Indications: contraception

Cautions: heart disease, sex - steroid dependent functional ovarian cysts, active liver disease, recurrent cholestatic jaundice, history of jaundice in pregnancy; see also interactions

Drug interactions: see notes above under interaction and progestogen only contraceptives notes.

Contraindications: pregnancy, undiagnosed vaginal bleeding; severe arterial disease; liver adenoma, porphyria; after evacuation

of hydatidiform mole (until return to normal of urine and plasma gonadotrophin values); see notes above

Side effects: menstrual irregularities (see also notes above); nausea, vomiting, headache dizziness, breast discomfort, depression, skin disorders, disturbance of appetite, weight changes, changes in libido.

Dose and Administration:

Oral preparation: 1 tablet daily at same time each days starting on day 1 of cycle then continuously; if administration delayed for 3 hours or more it should be regarded as a 'missed pill'.

Parenteral preparation: by deep intramuscular injection, 150mg within first 5 days of cycle or within first 5 days after parturition (delay until 6 weeks after parturition if breast-feeding); for long-term contraception, repeated every 12 weeks (if interval greater than 12 weeks and 5 days, exclude pregnancy before next injection and advise patient to use additional contraceptive measures (e.g barrier) for 14 days after the injection).

Levonorgestrel (D-Norgestrel)

Tablet, 0.03 mg, 0.75mg (pack of two)

Indications: contraception (particularly when estrogens are contraindicated); emergency hormonal contraception.

Cautions: undiagnosed vaginal bleeding; cardiac disease; past ectopic pregnancy; active liver disease, recurrent cholestatic jaundice; migraine; diabetes mellitus.

Drug Interactions: see notes above.

Contraindications: contraception: severe arterial disease; liver tumours; history of breast cancer (may be used after 5 years if no evidence of current disease); thromboembolic disorders; porphyria; *emergency contraception:* porphyria.

Side effects: menstrual irregularities (including oligomenorrhoea and menorrhagia usually resolve with long-term treatment); nausea, vomiting, headache, dizziness, breast discomfort, depression, skin disorders, disturbances of appetite, weight increase, change in

libido; breast cancer (studies have shown a small increase in the risk of having breast cancer diagnosed in women using, or who have recently used, a progestogen-only contraceptive pill; this relative risk may be due to earlier diagnosis; risk appears to relate to the age at which the contraceptive is stopped rather than to the total duration of use; any increased risk disappears gradually during the 10 years after stopping and there is no excess risk after 10 years; the small increase in the risk of breast cancer should be weighed against the benefits).

Dose and Administration:

Contraception: Oral: ADULT (female), 1 tablet (0.03mg) daily, starting on day 1 of the cycle and then continuously.

Note: - Each tablet (“pill”) should be taken at approximately the same time each day. If delayed for longer than 3 hours, contraceptive protection may be lost.

Emergency (post-coital) contraception: Oral: ADULT (female), 750 micrograms (taken within 72 hours of unprotected intercourse) followed by a second dose of 750 micrograms 12 hours later

Note: - Taking emergency contraception as soon as possible after unprotected intercourse increases its efficacy.

6.1.3. Contraceptive Devices and Barriers

Condoms (*Male, Female*)

Indications: as a primary method of contraception to prevent pregnancy at times when oral contraceptives or intrauterine devices may not be effective or are contraindicated or as an adjuvant to the periodic abstinence (rhythm) method of contraception.

Also for prevention (prophylactic) of Sexually transmitted diseases (STDs)

Cautions: in medical or psychosocial conditions where a critical need exists for highly effective contraception. Patients must be sufficiently counseled regarding the need for consistent and correct use of condoms if they are to be effective in preventing pregnancy.

Contraindication: sensitivity to latex condom

Side effect: burning, stinging, warmth, itching, other irritation of the Skin, penis, rectum, or vagina, vaginal dryness or malodor, allergic vaginitis, contact dermatitis.

Note: -Condoms should be completely unrolled into the penis before any genital contact occurs and remain intact throughout intercourse

7. OBSTETRIC AND GYNAECOLOGICAL MEDICATIONS

Drugs used in obstetrics: Drugs may be used to modify uterine contractions. These include oxytocic drugs to stimulate uterine contractions both in induction of labour and to control postpartum haemorrhage.

Postpartum Haemorrhage, Ergometrine and oxytocin differ in their actions on the uterus. In moderate doses oxytocin produces slow generalized contractions with full relaxation in between; ergometrine produces faster contractions superimposed on a tonic contraction. Oxytocin is used for routine use in postpartum and post - abortion haemorrhage since it is more stable than ergometrine.

Treatment of vaginal and vulval conditions - Anti - infective drugs: Candidal vulvitis can be treated locally with cream but is almost invariably associated with vaginal infection which should also be treated. Vaginal candidiasis is treated primarily with antifungal pessaries or cream inserted high into the vagina (including during menstruation) local irritation may occur on application of vaginal antifungal products.

Trichomonal infections: Commonly involve the lower urinary tract as well as the genital system and need systemic treatment with metronidazole or tinidazole. Bacterial infections with Gram - negative organisms are particularly common in association with gynecological operations and trauma. Metronidazole is effective against certain Gram - negative organisms, especially *Bacteroides spp.* and may be used prophylactically in gynaecological surgery. Metronidazole is also indicated for bacterial vaginosis.

Clotrimazole

Tablet (vaginal), 100mg, 500mg

Cream (vaginal), 1%

Indications: in the local treatment of vulvovaginal candidiasis caused by *Candida albicans* and other species of candida in pregnant (second and third trimester only) and non-pregnant women.

Cautions: pregnancy and labour and in those patients who are allergic to clotrimazole and its family.

Note:- use hygienic measures to cure infection and prevent reinfection by wearing cotton panties instead of synthetic underclothes and wearing only freshly washed under clothes. Sex partners should be advised to use condom.

Contraindications: hypersensitivity to clotrimazole

Side effects: vaginal burning, itching, discharge, or other irritation not present before therapy, abdominal or stomach cramps or pain, burning or irritation of penis of sexual partner; headache.

Dose and Administration:

Clotrimazole cream: Intravaginal, 50mg (1 applicatorful of 1% vaginal cream), once a day, preferably at bed time, for six to fourteen consecutive day.

Clotrimazole tablets: Non-pregnant patients - Intravaginal, 500mg as a single dose, preferably at bedtime or 100mg once a day preferably at bedtime, for six or seven consecutive days.

Pregnant patients - Intravaginal (100mg once a day), preferably at bedtime, for seven consecutive days.

Storage: vaginal cream - store between 2 and 30°C in a collapsible tube or in a tight container. Vaginal tablet - at room temperature in a well-closed container

Ergometrine maleate

Tablet, 0.25mg, 0.5mg

Injection, 0.25 mg/ml, 0.5mg/ml

Indications: prevention and treatment of postpartum and postabortion hemorrhage in emergency situations and where oxytocin not available.

Cautions: cardiovascular diseases, hypertension, renal and hepatic function impairment, multiple pregnancy, sepsis, or hypersensitivity.

Drug interactions: adrenaline. Smoking tobacco should also be avoided.

Contraindications: induction of labour, first and second stages of labour, coronary artery disease, eclampsia or preeclampsia, or pregnancy.

Side effects: dizziness, mild and transient headache, ringing in the ears, and hypertension may occur rarely. Abdominal pain, nausea, vomiting and uterine cramping may also occur, especially after intravenous injection.

Dose and Administration: Adult:

Prevention and treatment of postpartum haemorrhage, when oxytocin is not available: IM injection: 200 mcg when the anterior shoulder is delivered or immediately after birth

Excessive uterine bleeding: Slow IV injection: 250-500 mcg when the anterior shoulder is delivered or immediately after birth.

Secondary postpartum haemorrhage: Oral: 0.2-0.4 mg 2-4 times daily, usually for 48 hours.

Storage: Injection: 2-8°C, or as specified by manufacturer. Protect from light and freezing.

Note: Discoloured solution or solutions containing visible particles should not be used.

Tablets – at room temperature, in tight container. Protect from light.

Metronidazole

Tablet, 250mg

Tablet (vaginal), 500mg

Indications: used for the treatment of bacterial vaginosis and trichomoniasis. It is also used in the treatment of female pelvic infections, including endometritis, endomyometritis, tube-ovarian abscess, and liver abscess, caused by bacteriodes species, including the *B. fragilis* group, clostridium species, petpococcus species, and peptostreptococcus species.

Cautions: abnormal neurologic symptoms, history of blood dyscrasias, hepatic impairment; pregnancy and breastfeeding.

Note: - Metronidazole may cause dizziness patients should be advised to avoid alcoholic beverage and to comply with full time of treatment.

Drug interactions: alcohol, anticoagulants (cumarin - or indandione - derivatives), cimetidine, disulfiram, phenobarbital, phenytoin.

Contraindications: history of hypersensitivity to the drug or other nitroimidazole derivative.

Side effects: nausea, vomiting, diarrhoea, loss of appetite, dry mouth, sharp unpleasant metallic taste, constipation, abdominal discomfort, numbness, tingling, pain, or weakness in hands or feet, seizures, leucopenia, thrombocytopenia, vaginal candidiasis (any vaginal irritation, discharge, or dryness not present before therapy).

Dose and Administration:

Adult:

Vaginosis (bacteria): Oral: 2 g as a single dose or 400 – 500 mg twice daily for 5-7 days. *Intravaginal:* 500mg placed high into the vagina every night for ten or twenty consecutive days.

Pelvic inflammatory disease: Oral: 500mg of metronidazole twice daily with ofloxacin given orally in a dosage of 400mg twice daily. Therapy should be continued for 14 days.

Trichomoniasis: Oral: 2g as a single dose or 400-500mg twice daily for 7days

Note: - Sexual partners should be treated concomitantly.

Storage: at room temperature in a well-closed, light-resistant container.

Oxytocin

Injection, 1unit/ml, 5units/ml , 10units/ml

Indications: for nonselective induction of labour for medical reasons and for stimulation or reinforcement of labour in patients with dysfunctional inertia. Parenteral oxytocin is also indicated for management of incomplete or therapeutic abortion, as well as to produce uterine contractions during the third stage of labour.

Oxytocin is also indicated to control postpartum bleeding or hemorrhage.

Cautions: particular caution needed when given for induction or enhancement of labour in presence of borderline cephalopelvic disproportion (avoid if significant), mild or moderate pregnancy-induced hypertension or cardiac disease, women over 35 years or with history of lower-uterine segment caesarean section; if fetal death in utero or meconium-stained amniotic fluid avoid tumultuous labour (may cause amniotic fluid embolism); water intoxication and hyponatraemia-avoid large infusion volumes and restrict fluid intake by mouth; effects enhanced by concomitant prostaglandins (very careful monitoring) caudal block anaesthesia (may enhance hypersensitive effects of sympathomimetic vasopressors), see also interaction.

Drug interactions: hydrocarbon inhalation anesthetic such as enflurane, halothane, isoflurane, and with vasopressors, other oxytocins.

Contraindications: significant cephalopelvic disproportion, cold presentation, total placenta previa, vasa previa, where vaginal delivery is contraindicated, fetal distress, hypertonic uterine patterns, obstetrical emergencies requiring surgical intervention, uterine inertia or severe toxemia on prolonged use.

Side effects: fast or irregular heartbeat, nausea or vomiting

Dose and Administration: Adult:

Induction or stimulation of labour: IV infusion: initially at an initial rate 0.5 to 4 milli units (0.0005 to 0.004 unit) per minute, and then increased gradually at intervals every 20-60 minutes in increments of 1 to 2 milliunits (0.001-0.002 unit) per minute until a contraction pattern similar to that of normal labour is obtained. The rate of up to 6 milli units per minute is reported to produce plasma oxytocin concentrations comparable to those in natural labour but doses of up to 20 milliunits (0.02 unit) or more per minute may be required. The rate may be reduced gradually once labour is induced.

Incomplete or therapeutic abortion: IV infusion: 10 units at a rate of 20 to 40 milliunits (0.02 to 0.04 unit) per minute.

Control of postpartum uterine bleeding: IV infusion: 10 units at a rate of 20 to 40 milliunits per minute following delivery of the infant(s) and preferably placenta(s). A rate of 20-100 milliunits per minute may be used following abortion.

Storage: store oxytocin at 2 to 8°C, protect from freezing.

8. BLOOD PRODUCTS AND DRUGS AFFECTING THE BLOOD

8.1. Hemostatic Agents

Phytomenadione (vitamin K1)

Injection, 1mg/0.5ml in 0.5ml ampoule; 10mg/ml in 1 ml ampoule.

Indications: for the treatment of hemorrhage due to Vitamin k deficiency.

Cautions: severe liver diseases.

Drug interactions: antacids (aluminium hydroxide), wide spectrum antibiotics, quinidine, quinine, high doses of salicylates, antibacterials like sulfonamides, coumarin or indandione - derivative anticoagulants (such as dicumarol), and other hemolytics.

Side effects: flushing of face, redness, pain, or swelling at place of injection, unusual taste.

Dose and Administration: *Subcutaneously or intramuscularly.* It should not be given repeatedly to patient with severe liver diseases, once the response to the initial dose is unsatisfactory.

Adult: *IM. or S.C., 2.5 – 10mg (up to 25mg), may be repeated after 6-8 hours if necessary.*

Child: *Infants - IM or SC, 1-2 mg; Child - IM or SC, 5-10mg.*

Storage: at room temperature. Protect from light and freezing.

8.2. Antianemic Agents

Iron - deficiency anaemia.

Anaemia is usually understood to mean a lowering of haemoglobin concentration, red cell count, or packed cell volume to below 'normal' values but the criteria for normality are somewhat arbitrary and difficult to establish. Before initiating treatment for anaemia it is essential to determine which type is present. Iron

salt may be harmful and result in iron over load if given alone to patients with anemias other than those due to iron deficiency.

Treatment is only justified in the presence of a demonstrable iron - deficiency state. Before starting treatment, it is important to exclude any serious underlying cause of the anaemia (e.g gastric erosion, colonic carcinoma). Prophylaxis is justifiable in pregnancy only for women who have additional risk factors for iron deficiency (e.g poor diet), menorrhagia, after subtotal or total gastrectomy, and in the management of low birth - weight infants such as premature babies, twins, and in infants delivered by caesarean section.

Ferrous salt: many iron compounds have been used for this purpose, but do not offer any real advantage over the simple ferrous fumarate, gluconate, or sulphate salts.

The usual adult dose is sufficient of these salts to supply about 100 to 200mg of elemental iron daily. The approximate elemental iron content of various ferrous salts is ferrous fumarate 200mg (65mg iron), ferrous gluconate 300mg (35mg iron), ferrous succinate 100mg (35mg iron), ferrous sulfate 300mg (60mg iron), and dried ferrous sulfate 200mg (65mg iron)

Iron intake in the evening has been reported to improve its absorption. Iron intake with meals may reduce bioavailability but improve tolerability and adherence.

If adverse effects arise with one salt, dosage can be reduced or a change made to an alternative iron salt.

The hemoglobin concentration should rise by about 100 - 200mg/100ml per day. After the haemoglobin has risen to normal, treatment should be continued for a further three months in an attempt to replenish the iron stores. Gastrointestinal irritation may occur. Nausea and epigastric pain are dose related. Oral iron may exacerbate diarrhoea in patients with inflammatory bowel disease but care is also needed in patients with intestinal strictures and diverticulae. Iron as iron dextran or iron sorbitol should be given parenterally only if the patient has severe gastrointestinal adverse effects with oral preparations, continuing

severe blood loss or malabsorption. Parenteral iron may cause more harm than benefit. Provided that the oral iron preparation is taken reliably and is absorbed then the haemoglobin response is not significantly faster with the parenteral route than the oral route.

Megaloblastic anaemias. These are due to lack of either vitamin B₁₂ (hydroxycobalamin) or folate or both. The clinical features of folate deficient megaloblastic anaemia are similar to those of vitamin B₁₂ deficiency except that the accompanying severe neuropathy does not occur; it is essential to determine which deficiency is present and the underlying cause is established in every case.

Preparations containing ferrous salt and folic acid are used for the prevention of megaloblastic anaemia in pregnancy. The low doses of folic acid in these preparations are inadequate for the treatment of megaloblastic anaemias.

Ferrous Salt[•]

Tablet (enteric coated)

Capsule

Drop

Indications: in the prevention and treatment of only iron deficiency anemia.

Cautions: hepatitis or hepatic function impairment, kidney diseases, intestinal tract inflammatory conditions (e.g. peptic ulcer, or colitis), or alcoholism. Caution patients about toxic effects of accidental overdose. Especially in children.

Drug interactions: acetohydroxamic acid, dimercaprol, etidronate (avoid using iron supplements within two hours of etidronate), fluoroquinolones (it should be taken at least two hours before or two hours after iron supplements), tetracycline, chloramphenicol, antacids, calcium (carbonate or phosphate).

Side effects: abdominal discomfort, vomiting, diarrhoea or dark stools may occur commonly, large doses may have an irritant and

[•] Any Ferrous salt containing elemental Iron of accepted therapeutic value

corrosive effects of the gastrointestinal mucosa and necrosis and perforation may occur. Iron drops may temporarily stain the teeth. **Dose and Administration:** *Orally.* Iron drops may be placed well back on the tongue followed with water. It is best given on an empty stomach but may be given with or after meals to lessen gastrointestinal irritation. Treatment may be continued for 3-6 months, and not longer except in patients with continued bleeding, or repeated pregnancies.

Prophylactic –

Adult: 300mg once daily.

Child: 5mg/kg of body weight once daily or, 150 – 300mg once daily.

Treatment:

Adult: 300mg every 12 hours, gradually increased up to 300mg every 6-8 hours daily as needed and tolerated.

Child: 10mg/kg of body weight every 8 hours daily. Or 6-12 years 300mg every 12 hours daily. 1-5 years -120mg every 8 hours daily. Under 1 year – 60mg every 8 hours daily.

Storage: At room temperature, in a tight container. Protect from light and freezing.

Ferrous salt[•] + Folic Acid

Capsule

Tablet

Indications: Prevention of iron and folic acid deficiencies in pregnancy.

Cautions: low doses of folic acid in the combination preparations above are inadequate for treatment of megaloblastic anaemia;

Side effects: see ferrous salts

Dose and Administration:

Prevention of iron and folic acid deficiencies in pregnancy: Oral:

Adult the equivalent of about 100mg elemental iron with 350 - 400 micrograms folic acid daily throughout pregnancy.

Iron Gluconate +Manganese Gluconate +Copper Gluconate

Oral solution, 5mg+1.33mg+0.77mg

[•] Any Ferrous salt containing elemental Iron of accepted therapeutic value

9. MEDICINES FOR CORRECTING WATER, ELECTROLYTE AND ACID-BASE DISTURBANCES

Electrolytes are used to correct disturbances in fluid and electrolyte homoeostasis or acid-base balance and to re-establish osmotic equilibrium of specific ions.

9.1. Oral

Oral Rehydration Salts (ORS)

Powder, each sachet for 1 litre contains:

<i>Gram/Liter</i>	<i>mmol/L</i>	
<i>75</i>	<i>Sodium chloride</i> <i>2.6</i>	<i>Sodium</i>
<i>65</i>	<i>Glucose Anhydride</i> <i>13.5</i>	<i>Chloride</i>
<i>75</i>	<i>Potassium Chloride</i> <i>1.5</i>	<i>Glucose</i>
<i>20</i>	<i>Trisodium Citrate Dehydrate</i> <i>2.9</i>	<i>Potassium</i>
<i>10</i>		<i>Citrate</i>
<i>245</i>		<i>Total osmolarity =</i>

Indications: For the prevention and treatment of mild to moderate dehydration, particularly dehydration from acute diarrhoea of any cause, in all age group.

Note: Severe dehydration should be treated with intravenous fluids (Lactated ringer's injection).

Cautions: ORS are not appropriate for patients with gastrointestinal obstruction, inability to drink, oliguric or anuric renal failure, or when parenteral rehydration therapy is indicated as in severe dehydration or intractable vomiting.

Side effects: Vomiting can occur after administration of ORS, the risk of hypernatremia or overhydration after administration of ORS is low in patients with normal renal function. Overdosage in patients with renal impairment may lead to hypernatremia and hyperkalaemia.

Dose and Administration: *Orally (by cup and spoon in young children):* Dissolve one sachet of ORS in 1 liter of water. Do not

boil the prepared solution. Discard any remaining solution after 24 hours.

Prevention of dehydration:

In diarrhoea without signs of dehydration, after each loose stool give –

Less than 2 years, 50 - 100ml (1 - 2 small coffee cups); 2 - 10 year, 100 - 200ml (2 - 4 small coffee cups).

Treatment of diarrhea:

In diarrhoea with moderate dehydration:

75ml of ORS solution per Kg of body weight in 4—6 hours. Repeat if dehydration persists.

See table below.

Note: The Table shows the approximate amount of ORS solution to be given. Use the patients age only when the weight is not known. During rehydration therapy, continue breast-feeding the infants. In Infants under 6 months of age who are not breastfeed, also give 100 – 200ml of clean water. In dehydrated children with pneumonia, without concurrent diarrhoea, give half the amounts of ORS shown in the Table below.

Oral Rehydration Salt dose by Age and weight --

Age	Less than 4 months	4 -11 Month	12- 23 month	2 - 4 year	5–14 year	15 year or older
Weight (Kg.)	<5	5-7.9	8 - 10.9	11– 15.9	16- 29.9	30+
Amount (ml.)	200-400	400-600	600-800	800-1200	1200-2200	2200-4000

Note: puffy eyelids indicate excess. It should be discontinued until it disappears.

Storage: at room temperature. In a dry place out of direct sunlight.

In high humidity, the ORS may lump or become hard and it should not be used.

9.2. Parenteral Electrolyte

Solutions of electrolytes are given intravenously, to meet normal fluid and electrolyte requirements or to replenish substantial deficits or continuing losses, when the patient is nauseated or vomiting and is unable to take adequate amounts by mouth.

Sodium, potassium, chloride, magnesium, phosphate, and water depletion can occur singly and in combination with or without disturbances of acid - base balance.

Dextrose

Injection, 5% in 500ml, 1000ml; 10% in 500ml, 1000ml; 40% in 20ml; 50% in 50ml

Indications: for the treatment of hypoglycemia due to insulin excess or other causes.

Cautions: caution in patients with diabetes mellitus or with carbohydrate intolerance for any reason.

Contraindication: anuria.

Side effects: rapid administration may cause local pain; hyperglycemia and glycosuria, which if undetected and untreated can lead to dehydration, coma, and death.

Dose and Administration: The clear solution is given slowly *by intravenous* route.

For the treatment of hypoglycemia:

Adult and child: 20 – 40ml Dextrose 40%; may be repeated in severe cases.

Storage: at room temperature.

Dextrose in Normal Saline

Injection, 5% in 500ml, 1000ml; 10% in 500ml, 1000ml

Lactated Ringer's injection (Hartmann's solution)

Injectable solution, each 1000ml contains; K⁺ 5.4meq + Na⁺130.7meq+ Ca⁺⁺3.6meq+ Cl⁻111.5meq+ Lactate 28.2meq in 500ml, 1000ml

Indications: for replacement of electrolytes and water losses in severe dehydration.

Contraindications: severe liver and renal damage.

Dose and administration: *slow intravenous.*

Adult and Older Child: 100ml/kg of body weight within 4 hours, immediately until radial pulse is easily felt.

Infant: 30ml/kg of body weight within 1 hour followed by 40ml/kg of body weight within the next 2 hours; followed by Oral Rehydration Salts (ORS) 40ml/kg of body weight within the next 3 hours.

Note: If condition worsens, the rate of administration and the amount of fluid may need to be increased. After the first 6 hours, begin breast-feeding, or for nonbreastfeed infants give 100 – 200ml clean water before continuing ORS therapy. After rehydration is complete, feeding should start immediately.

Storage: at room temperature.

Sodium chloride

Injection, 235mg/ml; 0.9% (Normal saline) in 10ml, 20ml, 500ml, 1000ml; 3% in 500ml

Indications: used for extracellular fluid replacement and in the management of metabolic alkalosis in the presence of fluid loss and mild sodium depletion. Hypertonic (3%, 5%) sodium chloride injection is used in the management of severe sodium chloride depletion when rapid electrolyte restoration is essential.

Cautions: hypertension, heart failure, peripheral or pulmonary oedema, impaired renal function or pre-eclampsia; in patients receiving corticosteroids or corticotropin, particular caution is necessary in geriatric or post operative patients.

Contraindications: in patients with conditions in which administration of sodium and chloride is detrimental. Sodium

chloride 3% and 5% injections are also contraindicated in the presence of increased, normal, or only slightly decreased serum electrolyte concentrations.

Side effects: venous thrombosis or phlebitis, extravasation, hypervolemia, hypernatremia (on excessive administration); administration of large doses may give rise to sodium accumulation and oedema, nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivation and lachrymation, sweating, fever, tachycardia, hypertension, renal failure.

Dose and Administration:

Adult: *IV infusion* - 1 liter of 0.9% sodium chloride injection daily or 1-2 L of 0.45% sodium chloride injection daily.

The usual initial IV dose of 3 or 5% sodium chloride injection is 100ml given over a 1-hour period, before additional amounts are administered. It should not exceed 100ml/hour.

Storage: at room temperature, protect from freezing.

9.3. Enteral Nutrition

Enteral nutrition includes feeding by mouth, by nasogastric or nasoenteric tube, or directly into a gastrostomy or other enterostomy. It may be supplemental, if normal food intake is possible but inadequate, or total. Individual patients vary in their requirements according to age, size, and metabolic state, but a diet supplying 2000 to 3000 kcal of energy and 10-15g of nitrogen (as 60 to 90 g of protein) in 2 to 3 litres of fluid is fairly typical; because absorption from the gastrointestinal tract is incomplete requirements are higher than by parenteral route. Preparations containing whole protein (often derived from milk or soya) are generally preferred. Although preferred to parenteral nutrition, enteral feeding is not without complications. Patients may be at risk of oesophagitis, aspiration, and regurgitation as a result of the tube insertion; other potential problems include diarrhea, nausea and vomiting, gastric retention, hyperglycaemia, fluid and electrolyte disturbances, and microbial contamination of the feed regimen.

Calcium Caseinate

Soya-based non-milk preparations

10. VITAMINS

Vitamins are used for the prevention and treatment of specific deficiency states or when the diet is known to be inadequate. Large doses of vitamins (megavitamin therapy) have been proposed for a variety of disorders, but adequate evidence of their value is lacking. Excessive intakes of most water - soluble vitamins have little effects due to their rapid excretion in urine, but excessive intakes of fat - soluble vitamins accumulate in the body and are potentially dangerous.

Vitamin A (Retinol) is a fat - soluble substance stored in body organs, principally the liver.

Deficiency of Vitamin A (Retinol) is associated with ocular defects (particularly xerophthalmia) and an increased susceptibility to infections particularly measles and diarrhoea. Despite initial epidemiological evidence suggesting that vitamin A or carotene may have a protective effect against some epithelial cancers, the claims have not been substantiated.

Massive overdose can cause rough skin, dry hair, an enlarged liver, and a raised erythrocyte sedimentation rate and raised serum calcium and serum alkaline phosphatase concentrations.

In view of evidence suggesting that high levels of vitamin A may cause birth defects. Women who are (or may become) pregnant are advised not to take vitamin A supplements (including tablets and fish liver oil drops), except on the advice of a doctor or an antenatal clinic; nor should they eat liver or products such as liver pate or liver sausage.

Vitamin B is composed of widely differing substances which are, for convenience, classed as 'vitamin B complex'. Thiamine (Vitamin B1) is used orally for deficiency due to inadequate dietary intake, severe deficiency may result in 'beri-beri'. Thiamine is given by intravenous injection in doses of up to 300mg daily (parenteral preparations may contain several B group

vitamins) as initial treatment in severe deficiency states. Potentially severe allergic reactions may occur after parenteral administration; facilities for resuscitation should be immediately available. Pyridoxine (Vitamin B₆) deficiency is rare as the vitamin is widely distributed in foods, but deficiency may occur during isoniazid therapy and is characterized by peripheral neuritis. High doses are given in some metabolic disorders, such as hyperoxaluria.

Nicotinic acid inhibits the synthesis of cholesterol and triglyceride and is used in some hyperlipidaemias.

Nicotinic acid and nicotinamide are used to prevent and treat nicotinic acid deficiency (pellagra). Nicotinamide is generally preferred as it does not cause vasodilation.

Folic acid is essential for the synthesis of DNA and certain proteins. Deficiency of folic acid or vitamin B₁₂ is associated with megaloblastic anaemia. Folic acid should not be used in undiagnosed megaloblastic anaemia unless Vitamin B₁₂ is administered concurrently, otherwise neuropathy may be precipitated.

Supplementation with folic acid 400 micrograms daily is recommended for women of child-bearing potential in order to reduce the risk of serious neural tube defects in their offspring.

Ascorbic acid (Vitamin c) is used for the prevention and treatment of scurvy. Claims that ascorbic acid is of value in the treatment of common colds are unsubstantiated.

The term Vitamin D covers a range of compounds including ergocalciferol (Vitamin D₂) and colecalciferol (Vitamin D₃). These two compounds are equipotent and either can be used to prevent and treat rickets.

Simple deficiency of Vitamin D occurs in those who have an inadequate dietary intake or who fail to produce enough colecalciferol (Vitamin D₃) in their skin from the precursor 7-dehydrocholesterol in response to ultraviolet light.

Children with dark skin must continue vitamin D prophylaxis for up to 24 months because of their inability to produce enough vitamin D₃ in their skin. Dark skin with high melanin content must be exposed to daylight longer than light skin in order to obtain the same synthesis of vitamin D₃. Vitamin D is also used in deficiency states caused by intestinal malabsorption or chronic liver disease and for the hypocalcaemia of hypoparathyroidism.

Vitamin K is necessary for the production of blood clotting factors.

10.1. Vitamins, Single

Ascorbic Acid (Vitamin C)

Tablet, 100mg, 500mg, 1gm

Drops, 200mg/ml

Injection, 50mg/ml in 2ml ampoule, 100mg/ml in 5ml ampoule, 200mg/ml

Indications: for prophylaxis and treatment of vitamin C (ascorbic acid) deficiency states which lead to scurvy.

Cautions: caution should be necessary not to take large amount during pregnancy. Importance of not taking more than the recommended dietary allowance (RDA) should also be considered. Caution is required in those with sensitivity to ascorbic acid.

Drug interactions: cellulose sodium phosphate, deferoxamine, disulfiram and vitamin B12 (with large doses of vitamin C).

Side effect: dizziness or faintness, kidney stones (oxalate)

Dose and Administration:

Adult:

Dietary supplement: Oral: 50 to 100mg a day

Treatment of deficiency: Oral, IV or IM: 100 to 250mg one or three times a day.

Child:

Dietary supplement: Infants and Children up to 4 years of age:

Oral: 20 to 50mg a day.

Treatment of deficiency: Oral, IV or IM: 100 to 300mg a day in divided doses.

Storage: at room temperature in a tight, light resistant container.

Phytomenadione (Vitamin K₁)

Injection, 1mg/ml in 0.5ml ampoule, 10mg/ml in 1ml ampoule

Indications: prothrombogenic nutritional supplement, it is also used for treatment and prevention of various coagulation disorders including hypoprothrombinemia, or as an antidote to drug induced hypoprothrombinemia; for the treatment of hemorrhage due to Vitamin k deficiency.

Cautions: severe liver diseases.

Drug interactions: antacids (aluminium hydroxide), wide spectrum antibiotics, quinidine, quinine, high doses of salicylates, antibacterials like sulfonamides, coumarin or indandione - derivative anticoagulants (such as dicumarol), and other hemolytics.

Side effects: flushing of face, redness, pain, or swelling at place of injection, unusual taste.

Dose and Administration: *SC or IM*, it should not be given repeatedly to patients with severe liver disease, once the response to the initial dose is unsatisfactory.

Adult: *Nutritional supplement (Vitamins), prothrombogenic or Antidote (to drug-induced hypoprothrombinemia):* 2.5 to 10mg (up to 25mg), may be repeated after 6-8 hours if necessary.

Child: *Nutritional supplement (vitamin), prothrombogenic or Antidote (to drug - induced hypoprothrombinemia), Treatment of hypoprothrombinemia:*

Infants: *IM or Sc:* 1-2 mg.

Child: *IM or Sc:* 5-10mg.

Storage: at room temperature, protect from light and freezing.

Vitamin A

Tablet, 50,000 IU, 100,000 IU 200,000 IU

Capsule, 25,000 IU, 50,000 IU, 100,000 IU

Oral solution, 150,000 IU/ml (concentrated), 50,000 IU/ml

Injection, under 200,000 IU/ml

Indications: for prevention or treatment of vitamin A deficiency states, causing keratomalacia, xerophthalmia and nyctalopia

(night blindness). This may occur as a result of inadequate nutrition or intestinal malabsorption.

Note: Vitamin A is not useful for treatment of dry or wrinkled skin, eye problems, or prevention or treatment of infections not related to vitamin A deficiency.

Cautions: high doses exceeding 6000 units are not recommended during pregnancy, caution is recommended in young children taking high doses of vitamin A; long-term vitamin A use in the elderly may increase the risk of vitamin A overload; in patients with chronic renal failure, chronic alcoholism, cirrhosis, hepatic disease and viral hepatitis.

Drug interactions: calcium supplements, isotretinoin, tetracycline, vitamin E, cholestyramine, colestipol, mineral oil, oral neomycin.

Contraindications: hypervitaminosis A

Side effects: symptoms of acute overdose - bleeding from gums or sore mouth; bulging soft spot on head-in babies, confusion or unusual excitement; diarrhoea, dizziness, or drowsiness, double vision, severe headache, severe irritability, peeling of skin, especially on lips and palms; severe vomiting

Dose and Administration:

Adult:

Deficiency: Oral: 30,000 RE (100,000units) a day for 3 days followed by 7500 to 15,000 RE (25,000 to 50,000 unit) a day for 14 days.

With xerophthalmia: Oral: 7500 to15, 000 RE (25,000 to 50,000 units) a day.

Note: -RE=Retinol Equivalent; one RE = one mcg of Retinol = 3.33 units of vitamin A.

- *IM, Intravenous infusion*, as a part of total parenteral nutrition solution, the specific amount determined by individual patient need.

- *IM* 15,000 to 30,000 RE (50,000-100,000 units) a day for three days, followed by 15,000 RE (50,000 units) a day for two weeks.

Child:

Deficiency

Infants less than 1year: *Oral:* 3000 RE (10,000 units) per kg per day for 5 days followed by 2250 -4500 RE (7500 to 15,000 units)

per day for 10 days; *IM*, 1500 - 3000 RE (500-10,000 units) a day for ten days; in severe deficiency - *IM*, 2250 to 4500 RE (7500 to 15,000 units) a day for ten days.

Children 1-8 years of age: *Oral*: 3000 RE (10,000 units) per kg per day for 5 days followed by 5100 to 10,500 RE (17,000 to 35,000 units) a day for 10 days.

With xerophthalmia: *Oral*: 1500 RE (5000 units) per kg of body weight for five days, then in combination with intramuscular Vitamin A (7500 RE or 25,000 units per kg of body weight a day) until recovery occurs.

IM: 1500-4500 RE (5000-15,000 units) a day for ten days; in severe deficiency – *IM*: 5250 to 10,500 RE (17,500-35,000 units) a day for ten days.

Storage: at room temperature in a tight, light-resistant container. Protect from light and freezing.

10.2. Vitamins, Combinations

Vitamin A + D

Capsule, 4,000 IU + 400IU; see notes above

10.3. Vitamin B complex preparations[†]

The most important B group vitamins appear to be thiamine (vitamin B1), riboflavin (vitamin B2), pyridoxine (vitamin B6), Pantothenic acid (vitamin B5), nicotinic acid/nicotinamide (niacin, vitamin B3, niacinamide), cyanocobalamin (vitamin B12) and folic acid/foilate.

Indications: supplement for use in the wasting syndrome in chronic renal failure, uremia, impaired metabolic functions of the kidney, dialysis; labeled for OTC use as a dietary supplement.

Dose and Administration: *Oral*:

Adult:

Dietary supplement: One tablet daily

Renal patients: One tablet or capsules daily between meals; take after treatment if on dialysis.

[†] Any combination proven to be therapeutically effective can be used

10.4. Multivitamin preparations✦

10.5. Multivitamin with minerals and/or extracts✦

11. ANTIHISTAMINES AND ANTIALLERGICS

11.1. Antihistamines

Antihistamines diminish or abolish the main actions of histamine in the body by competitive, reversible blockade of histamine receptor sites on tissues; they do not inactivate histamine or prevent its synthesis or release.

Antihistamines are used for the symptomatic relief of hypersensitivity reactions including urticaria and angioedema, rhinitis, and conjunctivitis. Antihistamines are generally considered to be ineffective in asthma, but they may be used as adjunct therapy to improve symptoms.

Antihistamines are widely used, often with a decongestant, in compound preparations for the symptomatic treatment of coughs and the common cold.

Antihistamines are also used to control the pruritus associated with skin disorders such as atopic eczema. Some antihistamines, including promethazine, are used for their sedative effects.

Side effects: The most common side effects of the older antihistamines is sedation, varying from slight drowsiness to deep sleep, and including lassitude, dizziness, and incoordination, sedative effects, when they occur, may diminish after a few days of treatment.

Paradoxical CNS stimulation may occur especially in children, with insomnia, nervousness, euphoria, irritability, tremors and rarely nightmares, hallucinations, and convulsions. In high doses CNS stimulation may be attributed to antimuscarinic activity. Older antihistamines possess antimuscarinic properties and may

* Any combination proven to be therapeutically effective can be used

produce similar adverse effects to atropine. In addition headache, psychomotor impairment, gastro intestinal disturbances such as nausea, vomiting, diarrhoea, or epigastric pain have occurred with antihistamines.

Other side effects of antihistamines include palpitations and arrhythmias, hypotension, hypersensitivity reactions (including bronchospasm, angioedema, and anaphylaxis, rashes and photosensitivity reactions), extrapyramidal effects, dizziness, confusion, depression, sleep disturbances, tremor, convulsions, blood disorders, and liver dysfunction.

Caution and Contraindications: Antihistamines should not be given to premature infants or neonates: this group of patients has an increased susceptibility to antimuscarinic effects. Phenothiazine antihistamines should be avoided in young children because of the potential risk of central and obstructive apnoea and reduced arousal. Recommendations range from avoidance in children under one year of age to children under two years. Elderly patients are also more susceptible to many adverse effects of antihistamines, including antimuscarinic effects, sedation, and hypotension.

Many antihistamines may cause drowsiness; so patients should not drive or operate machinery. Because of their antimuscarinic properties antihistamines should be used with care in conditions such as closed angle glaucoma, urinary retention prostatic hyperplasia, or pyloroduodenal obstruction. Other adverse effects of antihistamines suggest caution in patients with epilepsy, severe cardiovascular disorders, or, for phenothiazines, in those with liver disorders.

Drug interactions: Antihistamines may enhance the sedative effects of central nervous system depressants including alcohol, barbiturates, hypnotics, opioid analgesias, anxiolytic sedatives, and neuroleptics. MAOIs may enhance the antimuscarinic effects of antihistamines, and antihistamines have an additive antimuscarinic action with other antimuscarinic drugs, such as atropine and tricyclic antidepressants. Antihistamines could mask the warning signs of damage caused by ototoxic drugs such as aminoglycoside antibiotics.

Cetirizine

Tablet, 5mg, 10mg

Oral solution, 1mg/ml

Indications: symptomatic relief of hypersensitivity reactions including rhinitis and chronic urticaria.

Cautions and Drug interactions: see notes above; also pregnancy and breast-feeding.

Contraindications: see notes above

Side effects: see notes above, incidence of sedation and antimuscarinic effect is low

Dose and Administration: *Oral:*

Adult and Child over 6 years: 10mg daily or 5mg twice daily,

Child 2 - 6 years: *hay fever*, 5mg daily or 2.5mg twice daily.

Storage: store in a well - closed container at room temperature.

Chlorpheniramine Maleate

Tablet, 2mg, 4mg, 6mg

Syrup, 2mg/5ml

Indications: symptomatic relief of allergy such as hay fever, urticaria, emergency treatment of anaphylactic reactions.

Cautions: see notes above; also pregnancy and breast-feeding.

Drug interactions, Contraindications: see notes above.

Side effects: see notes above; also exfoliative dermatitis and tinnitus reported;

Dose and Administration: *Oral:*

Adult: 4 mg every 4-6 hours, max. 24 mg daily;

Child: under 1 year not recommended. 1-2 years 1mg twice daily; 2-5 years 1mg every 4-6 hours, max. 6 mg daily; 6-12 years 2 mg every 4-6 hours, max. 12 mg daily.

Storage: at room temperature in a tight, light-resistant container.

Dexchlorpheniramine Maleate

Tablet, 2mg, 4mg, 6mg

Syrup, 2mg/5ml

Indications: perennial and seasonal allergic rhinitis and other allergic symptoms including urticaria.

Cautions and Drug interactions: see notes above; also pregnancy and breast-feeding

Contraindications: see notes above

Side effects: see notes above,

Dose and Administration: *Oral:*

Adult and Child over 12 years: 2mg, generally given every 4 to 6 hours.

Child 2 - 5 years: *0.5 mg* every 4-6 hours.

Child 6 – 11 years: *1 mg* every 4-6 hours

Storage: at room temperature in a tight, light-resistant container

Loratadine

Tablet, 10mg

Syrup, 5mg/5ml

Indications: symptomatic relief of allergy such as hay fever, urticaria.

Cautions, Drug interactions: see notes above; also pregnancy and breast-feeding.

Contraindications: see notes above,

Side effects: see notes above; incidence of sedation and antimuscarinic effect is low.

Dose and Administrations:

Oral: **Adult and Child over 6 years:** 10mg daily;

Child 2 - 5 years: 5mg daily.

Storage: store in airtight containers, protect from light.

Pheniramine Aminosalicylate

Tablet, 50mg, 75mg

Indications: symptomatic relief of hypersensitivity reactions including urticaria and angioedema, rhinitis and conjunctivitis, and in pruritic skin disorders; prevention and control of motion sickness.

Cautions, Drug interactions, Contraindications and Side effects: see notes above.

Dose and Administration:

Oral: 25 to 50 mg two or three times a day

Storage: Protect from light.

Promethazine Hydrochloride

Tablet, 10 mg, 25 mg

Suppository, 25 mg, 50 mg

Elixir, 5 mg/5ml

Injection, 25 mg/ml in 1 ml and 2 ml ampoules

Indications: symptomatic relief of allergy such as hay fever, urticaria, premedication; emergency treatment of anaphylactic reactions; sedation; motion sickness

Cautions: see notes above; also pregnancy and breast-feeding.

Contraindications, Drug interactions; see notes above

Side effects: see notes above; intramuscular injection may be painful.

Dose and Administration:

Adult:

Oral: 5-12.5 mg three times a day before meals and at bed time or 25 mg at bed time as needed.

IM or IV: 25mg; may be repeated within two hour if necessary

Rectal: 25mg; may be repeated in two hours if necessary.

Child (Children 2 years of age and over):

Oral: 125mcg per kg of body weight every four to six hours, or 500 mcg (0.5mg) at bed time as needed, or 5 to 12.5mg three times a day or 25mg at bed time as needed.

IM: 125mcg (0.125mg) per kg of body weight every four to six hours or 500 mcg (0.5mg) per kg of body weight at bed time as needed, or 6.25-12.5mg three times a day or 25mg at bed time as needed.

Storage: Tablet and Injectables - store at room temperature in a tight and light resistant container. Suppository - store between 2°C and 8°C in a tight, light resistant container.

11.2. Medicines Used in Allergic Emergencies

Anaphylactic shock and conditions such as angioedema are medical emergencies that can result in cardiovascular collapse and/or death. They require prompt treatment of possible laryngeal edema, bronchospasm or hypertension. Atopic individuals are particularly susceptible. Insect bites and certain foods including

eggs, fish, peanuts and nuts are also a risk for sensitized persons. Therapeutic substances particularly associated with anaphylaxis include blood products, vaccines, hyposensitizing (allergen) preparations, antibiotics (especially penicillins), iron injections, heparin, and neuromuscular blocking drugs. Acetyl salicylic acid and other non-steroidal anti-inflammatory drugs (NSAIDs) may cause bronchoconstriction in leukotriene-sensitive patients. In the case of drug allergy, anaphylaxis is more likely to occur after parenteral administration. Resuscitation facilities should always be available when injecting a drug associated with a risk of anaphylactic reactions.

First line treatment of a severe allergic reaction includes administering epinephrine (adrenaline), keeping the airway open (with assisted respiration if necessary) and restoring blood pressure. Epinephrine (adrenaline) should immediately be given by intramuscular injection to produce vasoconstriction and bronchodilation and injections should be repeated every 10 minutes until blood pressure and pulse have stabilized. If there is cardiovascular shock with inadequate circulation, epinephrine (adrenaline) must be given cautiously by slow intravenous injection of a dilute solution.

Adrenaline (Epinephrine)

Injection, 0.1 % in 1 ml ampoule

Indications: emergency treatment of acute anaphylaxis; angioedema; cardiopulmonary resuscitation; see also section 2.5 and 3.2 for other uses of Adrenaline

Cautions: hyperthyroidism, diabetes mellitus, heart disease, hypertension, arrhythmias, cerebro-vascular disease, angle-closure glaucoma, second stage of labor, elderly patients.

Side effects: anxiety, tremor, tachycardia, arrhythmias, headache, cold extremities; also hypertension (risk of cerebral hemorrhage) and pulmonary edema (on excessive dosage or extreme sensitivity) nausea, vomiting, sweating, weakness, dizziness, and hyperglycemia also reported

Dose and Administrations:

Caution: Different dilutions of epinephrine injection are used for different routes of administration

IM or SC injection use 1:1000 epinephrine injection.

Slow IV injection use 1:10,000 epinephrine injection.

This route should be reserved for severely ill patients when there is doubt about the adequacy of circulation and absorption from the intramuscular site.

Promethazine Hydrochloride

Injection, 25 mg/ml in 1 ml and 2 ml ampoules

Indications: symptomatic relief of allergy such as hay fever, urticaria, premedication; emergency treatment of anaphylactic reactions; sedation; motion sickness

Cautions: see notes above; also pregnancy and breast-feeding.

Contraindications, Drug interactions; see notes above

Side effects: see notes above; intramuscular injection may be painful.

Dose and Administration:

Adult:

IM or IV: 25mg; may be repeated within two hour if necessary

Child (Children 2 years of age and over):

IM: 125mcg (0.125mg) per kg of body weight every four to six hours or 500 mcg (0.5mg) per kg of body weight at bed time as needed, or 6.25-12.5mg three times a day or 25mg at bed time as needed.

Storage: store at room temperature in a tight and light resistant container.

12. OPHTHALMIC AGENTS

12.1. Anti-infective, Ophthalmic

12.1.1. Antibacterials

Acute bacterial infection of the external eye, including acute bacterial conjunctivitis, corneal ulceration, blepharitis, dacryocystitis, and discharging sockets are caused by the pathogens *Staphylococcus aureus*, *Streptococcus pneumoniae*, and

Haemophilus

influenza.

Most cases of acute bacterial conjunctivitis are self-limiting; where treatment is appropriate, antibacterial eye drops or an eye ointment are used. A poor response might indicate viral or allergic conjunctivitis. *Gonococcal conjunctivitis* is treated with systemic and topical antibacterials.

Bacterial infections are generally treated topically with eye drops and eye ointments. Systemic administration is sometimes appropriate in blepharitis.

Intra-ocular infection, a variety of routes (intra corneal, intra vitreal and systemic) may be used. Chloramphenicol has a broad spectrum of activity and is the drug of choice for superficial eye infections. Topical Chloramphenicol is well tolerated and the risk of development of aplastic anaemia from topical use is minimal.

Tetracycline is a broad spectrum antibiotic with activity against many Gram-positive and Gram-negative bacteria including *N. gonorrhoea*. Ophthalmic tetracycline is used in blepharitis, conjunctivitis, and keratitis produced by susceptible bacteria.

Chloramphenicol

Eye ointment, 1 %,

Solution (eye drop), 0.4 %, 0.5 %, 1 %,

Indications: topical treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by susceptible organisms.

Contraindications: previous allergy or toxic reaction to chloramphenicol.

Side effects: hypersensitivity (burning, itching, redness, skin rash, swelling or other signs of irritation not present before therapy)

Dose and Administration:

Adult and Child: *Ointment topical:* to the conjunctiva, a thin strip (approximately 1cm) of ointment every three hours or more frequently;

Solution (eye drops), topical: to the conjunctiva, 1 drop every one to four hours.

Storage: at room temperature in a tight container, protect from freezing.

Tetracycline

Eye ointment, 1 %

Solution (eye drop), 1 %

Indications: for the treatment of superficial bacterial infections of the eye (*Purulent conjunctivitis*), trachoma, and for the prophylaxis of gonococcal and nongonococcal ophthalmia neonatorum.

Contraindications: hypersensitivity to tetracycline group of antibiotics.

Cautions: prolonged use may lead to overgrowth of non-susceptible organisms.

Side effects: hypersensitivity (burning, itching, redness, skin rash, swelling or other signs of irritation not present before therapy)

Dose and Administration: *Topical*, to the conjunctiva.

Purulent Conjunctivitis: Adult and Child: Apply a thin strip (approximately 1cm) of ointment onto the infected eye every 6 hours daily for 5 days.

Trachoma: Adult and Child: Apply a thin strip of ointment onto each eye twice daily for a minimum of 6 weeks.

Prophylaxis of gonococcal and nongonococcal ophthalmia neonatorum: Apply a thin strip of ointment onto each of neonates shortly (no later than 1 hour) after delivery.

Storage: Store at room temperature.

12.2. Miscellaneous Agents

Artificial tear (Carboxymethyl cellulose +Hydroxypropyl methyl cellulose)

Ointment, drops

Indications:-It is used to relieve dry, irritated eyes.

Cautions:-Pregnancy, use caution if driving or performing duties requires clear vision.

Contraindications: hypersensitivity to any ingredient in artificial tear.

Side effects:-Blurred vision, short term discomfort after use.

Storage: Store at room temperature.

13. EAR, NOSE AND THROAT PREPARATIONS

13.1. Nasal and Oropharyngeal Preparations

The nasal mucosa is sensitive to changes in atmospheric temperature and humidity and these alone may cause slight nasal congestion. The nose and nasal sinuses produce a litre of mucus in 24 hours and much of this finds its way silently into the stomach via the nasopharynx. Slight changes in the nasal airway, accompanied by an awareness of mucus passing along the nasopharynx causes some patients to be inaccurately diagnosed as suffering from chronic sinusitis. These symptoms are particularly noticeable in the later stages of the common cold. Sodium chloride 0.9% (saline solution) given as nasal drops or spray may relieve nasal congestion by helping to liquefy mucous secretions.

Inhalation of warm moist air is useful in the treatment of symptoms of acute infective conditions. The addition of volatile substances such as menthol and eucalyptus may encourage the use of warm moist air.

Symptoms of nasal congestion associated with vasomotor rhinitis and the common cold can be relieved by the short-term use (usually not longer than 7 days) of decongestant nasal drops and sprays. These all contain sympathomimetic drugs which exert their effect by vasoconstriction of the mucosal blood vessels which in turn reduces oedema of the nasal mucosa. They are of limited value because they can give rise to rebound congestion (rhinitis medicamentosa) on withdrawal, due to a secondary vasodilatation with a subsequent temporary increase in nasal congestion. Ephedrine nasal drop is the safest sympathomimetic preparation and can give relief for several hours. All of these preparations may cause a hypertensive crisis if used during treatment with a monoamine oxidase inhibitor.

Mouthwashes have a mechanical cleansing action and freshen the mouth. Providone - Iodine mouthwash is useful for mucosal infections but does not inhibit plaque accumulation. It should not be used for periods longer than 14 days because a significant amount of iodine is absorbed.

There is no convincing evidence that antiseptic lozenges and sprays have a beneficial action and they sometimes irritate and cause sore tongue and sore lips. Some of these preparations also contain local anesthetics which relieve pain but may cause sensitization. The throat lozenges are Amyl-metacresol + Dichlorobenzyl Alcohol and Dequalinium Chloride.

Amyl Meta-cresol + Dichlorobenzyl Alcohol

Lozenges, 0.6 mg + 1.2 mg

Indications: symptomatic relief of sore throats, coughs and colds.

Cautions: patients with problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.

Contraindications: known hypersensitivity to amyl meta-cresol, dichlorobenzyl alcohol or other product ingredients.

Dose and Administration: Adult and Child over 12 years: one lozenge to be sucked slowly every hour until relief is obtained. Do not take more than 24 lozenges in 24 hours.

Child 6 to 12 years: one lozenge to be sucked slowly every two hours until relief is obtained. Do not take more than 12 lozenges in 24 hours.

Do not give to children under 6 unless on medical advice.

Storage: do not store above 25°C.

Chlorhexidine Gluconate

Oral Solution, 0.12%

Indications: treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing. It is an effective antiseptic which has the advantage of inhibiting plaque formation on the teeth. It does not, however, completely control plaque deposition and is not a substitute for effective tooth brushing.

Drug interactions: chlorhexidine gluconate may be incompatible with some ingredients in toothpaste; leave an interval of at least 30 minutes between using mouthwash and toothpaste.

Contraindications: hypersensitivity to chlorhexidine gluconate or any component of the formulation.

Side effects: mucosal irritation (if desquamation occurs, discontinue treatment or dilute mouthwash with an equal volume of water); taste disturbance; reversible brown staining of teeth, and of silicate or composite restorations; tongue discoloration; parotid gland swelling

Dose and Administration: Recommended use is twice daily oral rinsing for 30 seconds, morning and evening after tooth brushing. Patients should be instructed to not rinse with water, or other mouthwashes, brush teeth, or eat immediately after using chlorhexidine gluconate oral rinse. Chlorhexidine gluconate oral rinse is not intended for ingestion and should be expectorated after rinsing.

Storage: store at room temperature.

Dequalinium chloride

Lozenge, 0.25mg

Indications: symptomatic and supportive treatment in the case of both the inflammations and infections limited by the oral cavity and throat such as vincent's angina, pharyngitis, sore throats, tonsillitis, stomatitis, aphthous ulcers, thrush, glossitis.

Cautions: pregnancy, breast-feeding and for children under 10 years old.

Contraindications: hypersensitivity to dequalinium chloride or any component of the formulation.

Side effects: occasional hypersensitivity reactions and soreness of the tongue are possible.

Dose and Administration: *Oral:* **Adult** and **Child** over 10 years:

One lozenge to be sucked every 2 to 3 hours, up to a maximum of eight in one day.

Storage: store at room temperature.

Gentian Violet

Solution, 1 %

Indications: candidal infections of the mouth and throat (thrush).

Cautions: avoid swallowing of the solution. Infants should be turned face downward after application to minimize the amount of drug ingested.

Side effects: irritation or sensitivity reactions or ulceration of mucosal membranes may occur. Esophagitis, laryngitis, or trachitis may result from swallowing the solution.

Dose and Administration: *Topical*, to the oral mucous membranes.

It should be painted only on individual lesions with cotton.

Adult and Child: every 8 – 12 hours daily for 3 years.

Storage: at room temperature, in tight containers.

Hexetidine[☞]

Solution, 0.1 %

Indications: used as a 0.1% mouthwash for local infection and/or hygiene.

Side effects: allergic contact dermatitis and alterations in taste and smell.

Dose and Administration: Rinse with 15-30ml, undiluted, for 30 seconds twice daily.

Hexidine

Oral solution, 0.1gm/100ml, 0.2%

Indications: -Prevention of plaque in absence of brushing, prevention and treatment of gingivitis, treatment of oral thrush and oral ulcers, aid in treatment of mouth and throat infections.

Hydrogen peroxide

Solution, 1.5%, 3 %

Indications: hydrogen peroxide 1.5% solution is used as an antiseptic and deodorant mouthwash. By its effervescence, it may liberate debris from inaccessible cavities and aid in proper cleansing of the buccal cavity.

Side effects: hypertrophy of papillae of tongue on prolonged use.

[☞] Any mouth wash and antiseptic preparations are also acceptable

Dose and Administration: dilute to 1.5% before use as a mouthwash.

Menthol + Eucalyptus oil + Light Magnesium carbonate

Inhalation, 2 % + 10 % + 7 %

Indications: for relief of nasal obstruction in acute rhinitis or sinusitis and to promote warm moist air inspiration in bronchitis.

Cautions: boiling water should not be used for the preparation.

Dose and Administration: add one teaspoonful to a pint of hot, not boiling, water and inhale the vapour.

Pseudoephedrine Hydrochloride

Syrup, 30 mg/ml

Indications: symptomatic relief or nasal congestion.

Cautions: avoid excessive or prolonged use, caution in infants under 3 months (no good evidence of value - if irritation occurs might narrow nasal passage)

Drug interactions: anesthetics, antibacterial, antidepressants, antihypertensives, Beta-blockers, dopaminergics.

Side effects: local irritation, nausea, headache; after excessive use tolerance with diminished effect; rebound congestion; cardiovascular effects also reported.

Dose and Administrations:

Oral: **Adult:** 60mg, 3 - 4 times daily, child, 2 to 5 years, 15 mg 3 times daily; 6 to 12 years, 30 mg 3 times daily.

Povidone - Iodine

Solution, 1 %

Indications: for oral hygiene.

Cautions: caution should be taken during pregnancy and breast feeding.

Contraindications: avoid regular use in patients with thyroid disorders and receiving lithium therapy; hypersensitivity to iodine or any component of the formulation.

Side effects: edema, idiosyncratic mucosal irritation and hypersensitivity reactions may interfere with thyroid function tests and with tests for occult blood.

Dose and Administration: *Mouth washes or gargles.*

Adult and Child over 6 years, up to 10ml undiluted or diluted with an equal quantity of warm water for 30 seconds up to 4 times daily for 14 days.

Saline solution

Indications: irrigation, including first-aid removal of harmful substances, oral hygiene, used as an effective adjunctive therapy for the symptom of chronic rhinosinusitis and for mild to moderate rhinitis.

Contraindications: incompletely healed facial trauma.

Drug interactions: lithium serum concentrations may be decreased.

Side effects: congestive conditions, over hydration, extravasation.

13.2. Otic Agent

Otitis externa. Otitis externa or inflammation of the skin of the external auditory canal may be due to infections with bacteria, viruses, or fungi or secondary to skin disorders such as eczema, although more than one factor is often responsible for chronic otitis externa. The treatment includes thorough cleansing and the use of appropriate antibiotic eardrops, often containing a corticosteroid as well, even though some have doubted the value of topical antibiotics. Eardrops containing aminoglycosides, such as gentamicin, neomycin, or polymixins should not be used when the eardrum is perforated because of the risk of ototoxicity.

Otitis media. Otitis media or inflammation of the middle ear can be acute or chronic, serous (with effusion; secretary) or supportive local treatment of acute otitis media is ineffective and there is no place for drops containing a local anaesthetic. Many attacks are viral in origin and need only treatment with a simple analgesic such as paracetamol for pain. Severe bacterial infection should be treated with systemic antibiotics. The organisms recovered from patients with chronic otitis media are often opportunists living in the debris, keratin, and necrotic bone present in the middle ear and mastoid. Thorough cleansing with an aural suction tube may completely resolve infection of many years duration.

Acute exacerbations of chronic infection may require systemic antibiotics.

Hydrogen peroxide

Solution, 3 %

Hydrogen peroxide has antimicrobial properties, which are reduced in the presence of organic matter. Their frothing action makes them useful to loosen and aid removal of debris in the ear canal.

Storage: at room temperature in airtight container. Solutions should not be stored for long periods. Those not containing a stabilizer should be stored at a temperature not exceeding 15 °C. Protect from light.

14. DERMATOLOGIC AGENTS

14.1. Anti-infective, Topical

14.1.1. Antifungals

Most localized fungal infections are treated with topical preparations. To prevent relapse, local antifungal treatment should be continued for 1–2 weeks after the disappearance of all signs of infection. Systemic therapy is necessary for nail or scalp infection or if the skin infection is widespread, disseminated, or intractable. Skin scrapings should be examined if systemic therapy is being considered or where there is doubt about the diagnosis.

Dermatophytoses. Ringworm infection can affect the scalp (*tinea capitis*), body (*tinea corporis*), groin (*tinea cruris*), hand (*tinea manuum*), foot (*tinea pedis*, athlete's foot), or nail (*tinea unguium*). Scalp infection requires systemic treatment additional application of a topical antifungal, during the early stages of treatment, may reduce the risk of transmission. A topical antifungal can also be used to treat asymptomatic carriers of scalp ringworm. Most other local ringworm infections can be treated adequately with topical antifungal preparations (including shampoos). The imidazole antifungals clotrimazole, ketoconazole, and miconazole are all effective. Other topical antifungal includes the undecenoates. Compound benzoic acid ointment (Whitfield's ointment) has been used for ringworm infections but it is cosmetically less acceptable than proprietary preparations.

Candidiasis. Candidal skin infections can be treated with a topical imidazole antifungal, such as clotrimazole, ketoconazole, miconazole. Refractory candidiasis requires systemic treatment.

Pityriasis versicolor. Pityriasis (*tinea*) versicolor is caused by commensal yeast. It may be treated topically with tolnaftate or selenium sulphide. Topical imidazole antifungals are alternatives but large quantities may be required. If topical therapy fails or if

the infection is widespread, pityriasis versicolor is treated systemically with a triazole antifungal. Relapse is common, especially in immunocompromised

Choice of Antifungal formulation.

Lotions or sprays are suitable for application to large and hairy areas.

Ointments are generally used on dry areas; they are best avoided on moist skin. Creams are cosmetically more acceptable than ointments and they are best suitable for moist areas.

Paints and solutions for application to the nail are occasionally effective for early dystrophy in onychomycosis.

Dusting powders are of little therapeutic value in the treatment of fungal skin infections and may cause skin irritation; they may have some role in preventing re-infection.

Cautions. Contact with eyes and mucous membranes should be avoided.

Side effects. Occasional local irritation and hypersensitivity reactions include mild burning sensation, erythema, and itching. Treatment should be discontinued if these are severe.

Benzoic Acid + Salicylic Acid (Whitfield's Ointment)

Ointment, 6% + 3%, 12% + 6%

Indications: mild dermatophyte infections, particularly tinea pedis and tinea corporis.

Cautions: it should not be applied to broken or inflamed skin.

Side effects: skin irritation and dryness may occur.

Dose and Administration: Adult and Child: *Topical, apply* directly to the affected area twice daily until the infected skin is shed (usually at least 4 weeks). Prolonged use should be avoided since irritation of the skin may occur.

Storage: at room temperature, in a tight container.

Clotrimazole

Cream 1%

Solution 1%

Topical powder, 1%

Ointment, 1%

Indications: treatment of cutaneous candidiasis (moniliasis) caused by *Candida albicans*, *tinea corporis* (ring worm of the body), *tinea cruris* (ringworm of the groin, jock itch), *tinea pedis* (ringworm of the foot; athlete's foot), *tinea versicolor* (*pityriasis versicolor*, 'sun fungus'), and in the treatment of paronychia, *tinea barbae*, and *tinea capitis*.

Cautions: sensitive to clotrimazole and also see notes above.

Side effects: hypersensitivity (skin rash, hives, blistering, burning, itching peeling, redness, stinging, swelling and other sign of skin irritation not present before therapy).

Dose and Administration: Adult and Child: *topical*, to the skin and surrounding area, two times a day, morning and evening.

Storage: at room temperature in a tight container, protect from freezing.

Gentian Violet

Solution, 0.5 %, 1 %

Indications: for the treatment of skin infections caused by candida and bacteria, and genital candidiasis.

Cautions: It should not be applied on ulcerative lesions of the face.

Side effects: skin or genital irritation may occur. It also stains skin and clothing.

Dose and Administration: *Topical*, to the skin. Do not cover the affected area with dressings after application.

Apply every 8 – 12 hours daily for about 3 days.

Storage: at room temperature, in tight containers.

Ketoconazole

Cream, 2 %

Ointment, 2%

Shampoo, 2 %

Lotion, 2%

Indications: fungal skin infections.

Cautions: see notes above; do not use within 2 weeks of a topical corticosteroid for seborrhoeic dermatitis—risk of skin sensitization

Side effects: itching, stinging, or irritation not present before therapy for cream and shampoo; contact dermatitis for cream.

Note – Ketoconazole 2 % cream is intended for topical application to the skin only and should not be applied to the eye nor administered intravaginally.

Dose and Administration:

Ketoconazole cream

Adult: *Topical* to the affected skin and surrounding area.

Tinea corporis or Tinea cruris, Tinea pedis or Pityriasis versicolor: once a day.

Candidiasis, cutaneous: once a day. More resistant cases may require twice a day treatment.

Seborrheic dermatitis: two times a day.

Paronychia or Tinea barbae or Tinea capitis: two or three times a day.

Safety and efficacy have not been established for pediatric use.

Ketoconazole shampoo

Adult:

Dermatitis, seborrheic: *Topical*, twice a week for 2 to 4 weeks. Leave in place for 3 to 5 minutes before rinsing. Prophylaxis: once a week every 1 or 2 weeks

Pityriasis versicolor: *Topical*, to the affected skin and surrounding area(s), as a single application. Leave in place for 5 minutes before rinsing.

Child: safety and efficacy have not been established.

Storage: at room temperature. Protect from freezing.

Ketoconazole + Zinc Pyrithione

Shampoo, 2% + 1% w/w

Indications: seborrheic dermatitis and dandruff.

Cautions: allergic to ketoconazole and pyrithione zinc.

Dose and Administration: Wash hair and scalp daily or at least 2 times per week.

Miconazole Nitrate

Cream, 2 %

Lotion, 2 %

Tincture, 2 %

Indications: superficial fungal infections due to dermatophytes and yeasts, and secondary infections caused by Gram-positive cocci, including ringworm, intertrigo, candida napkin rash, paronychia, and pityriasis versicolor.

Cautions: see notes above

Side effects: occasional local irritation and burning, also contact dermatitis; discontinue if sensitization occurs

Dose and Administration:

Adult and Child: Skin infections, *apply* directly to clean dry lesions twice daily, continuing for at least 10 days after the condition has cleared.

Nail infections; *apply* directly to the affected area 1–2 times daily.

Storage: at room temperature in a tight container

Salicylic Acid

Ointment, 2 %, 5 %, 10 %

Indications: fungal nail infections, particularly tinea.

Cautions: avoid contact with eyes, mouth, and mucous membranes; avoid application to large areas.

Contraindications: broken or inflamed skin; pregnancy; children under 2 years.

Side effects: stinging, local irritation, and salicylism may occur when large areas are treated particularly in children.

Dose and Administration:

Adult and Child over 5 years: apply twice daily and after washing.

Selenium Sulphide

Suspension, 2.5 %

Selenium sulfide is a complementary drug for use in rare disorders or in exceptional circumstances.

Indications: seborrhoeic dermatitis (detergent-based suspension)

Cautions: do not apply to damaged skin (risk of systemic toxicity); avoid contact with eyes; do not use within 48 hours of applying preparations for hair colouring, straightening, or permanent waving.

Contraindications: children under 5 years.

Side effects: local irritation, hair discoloration or loss; absorption may result in systemic toxicity including tremors, weakness, lethargy, pain in lower abdomen, occasional vomiting (symptoms usually resolve within 10 days).

Dose and Administration:

Adult and Child 5 years and above: Seborrhoeic dermatitis, *massage* 5–10 ml

of shampoo into wet hair and leave for 2–3 minutes before rinsing thoroughly; repeat twice weekly for 2 weeks, then once weekly for 2 weeks, thereafter only when needed.

NOTE. To minimize absorption, rinse hair thoroughly after use and remove all traces from skin (including nails).

Storage: at room temperature. Freezing should be avoided.

Tolnaftate

Solution, 1%

Indications: tolnaftate is an antifungal agent used topically in the treatment or prophylaxis of various forms of tinea and of pityriasis versicolor.

Note –Tolnaftate is not considered suitable for deep infections in nail beds or hair follicles but it may be used concomitantly with a systemic agent

Cautions: if irritation or hypersensitivity occurs, or if the patient's skin disease does not improve within 10 days or becomes worse during self medication with tolnaftate, treatment should be discontinued and the patient should consult a physician or paediatrician. Tolnaftate preparations should not come in contact with the eyes.

Side effects: irritation, contact dermatitis.

Dose and Administration: Tolnaftate is applied twice daily for 2 to 6 weeks. Repeat treatment may be required.

Storage: It should be stored in tight container at room temperature. Freezing of the solution should be avoided.

Zinc undecenoate + Undecenoic Acid

Ointment, 20 % + 5 %

Powder, 20 % + 2 %

Powder (aerosol), 20 %+ 2 %

Indications: for the treatment and prevention of athlete's foot (tinea pedis), jock itch (tinea cruris), and other skin infections caused by dermatophytic fungi (ring worm)

Dose and Administration:

Treatment of athlete's foot, apply twice daily continuing for 7 days after lesions have healed

Prevention of athlete's foot, apply once daily

Jock itch: topically, twice daily after cleansing the affected area, for two weeks.

Note: - The ointment or cream should be used at night and the powder may be used during the day.

14.1.2. Antibacterial preparations

Staphylococcal infections of the skin (such as impetigo, folliculitis, and furunculi) and streptococcal infections (such as cellulitis and erysipelas) are very common where the climate is hot and humid, where standards of hygiene are compromised, and in immunodeficient patients.

In all skin infections, an important part of treatment is cleansing and thorough drying. Washing with soap and water will often help to prevent infection. Light localized infections can often be treated effectively with an antiseptic solution such as chlorhexidine (section 14.6).

Topical use of preparations containing antimicrobials which are widely used to treat skin infections systemically should be avoided. These include the penicillins, the sulfonamides, streptomycin and gentamicin, which should be reserved for the

systemic treatment of infections because of the possibility of inducing sensitivity and favouring the emergence of resistant organisms.

Metronidazole

Cream, 0.75%, 1%

Gel, 1%

Lotion, 1%

Indications: treatment of inflammatory lesions and erythema of rosacea.

Cautions and Contraindications: hypersensitivity reactions to any of the components. Use with caution in those with blood dyscrasias. Avoid contact with the eyes. Avoid exposure to strong sunlight or UV light

Side effects: tearing of the eyes, transient erythema, dryness, burning and skin irritation.

Dose and Administration: Adult: *Acne rosacea: Topical:*

0.75%: Apply and rub thin film twice daily, morning and evening, to entire affected areas after washing. Significant therapeutic results should be noticed within 3 weeks.

1%: Apply thin film to affected area once daily.

Nitrofurazone Gauze Dressing

Indications: as an adjunctive therapy for second and third degree burns when resistance to other agents is a real or potential problem.

Cautions: if over growth of nonsusceptible organisms occur, or if irritation, sensitization, or superinfection develops, treatment should be discontinued. Caution should be taken in patient with renal function impairment.

Side effects: contact dermatitis

Dose and Administration:

Adult:

Burns or Skin infections: Topical directly to lesion or place on gauze depending on the usual dressing technique

Child: safety and efficacy have not been established

Storage: at room temperature in a well-closed container. Protect from freezing.

Tetracycline

Ointment, 3 %

Indications: bacterial skin infections

Cautions: sensitivity (photosensitivity) to tetracyclines; overgrowth with non-susceptible organisms; stains clothing

Side effects: rarely local hypersensitivity reaction

Dose and Administration:

Adult: *Antibacterial (topical): Topical*, to the skin, one or two times a day.

Child: see adult dose.

Storage: store at room temperature in a well-closed container. Protect from freezing.

14.1.3. Scabies and Pediculicides

Scabies

Scabies is caused by a mite, *Sarcoptes scabiei* that burrows into the skin. It is readily transmitted from person to person, and therefore the entire household must be treated at the same time to prevent reinfection. Although it is not necessary to take a bath before treatment with an acaricide, all clothing and bedding should be washed to prevent reinfection.

Benzyl benzoate is an inexpensive scabicide. It must be applied to all skin surfaces, from the scalp to the soles of the feet, avoiding contact with the eyes; it is, however, too irritant for use on children. **Permethrin** is less irritant and, usually, more effective than benzyl benzoate; it is also more expensive, but it may be used on children. Young infants can be treated with a cream containing precipitated sulfur, 6–10%, applied once daily for one week.

Pediculosis

Pediculosis of the head and body is caused by *Pediculus humanus capitis* and *Pediculus humanus corporis* respectively; pubic lice (crab lice) infestations are caused by *Phthirus pubis*, which may also affect the eye lashes and brows. All are transmitted by person to person contact, and may also contaminate clothing and bedding. All members of the affected household (and sexual contacts) must be treated at the same time, and clothing and bedding should be washed or exposed to the air; in head lice infestations, hair brushes and combs should also be disinfected.

Head and body lice are readily treated with **permethrin**. **Malathion** is effective against public lice. **Benzyl benzoate** may be used for all lice infections.

Benzyl Benzoate

Lotion, 25 %

Indications: **scabies; head, body and pubic lice.**

Cautions: avoid contact with face, eyes, mucous membranes and urethral meatus. Do not apply to inflamed skin or weeping surfaces; not recommended for children; breastfeeding (suspend feeding until product has been washed off).

Side effects: slight local irritation, transient burning sensation, occasionally rashes. Frequent use causes contact dermatitis.

Dose and Administration:

Scabies: Adult and Child: *apply* over whole body; repeat application without bathing on the following day and wash off 24 hours later; a third application may be needed in some cases.

Pediculosis: Adult and Child: *apply* to the affected area and wash off 24 hours later; further applications possibly needed after 7 and 14 days.

Note: Not recommended for children—dilution to reduce irritant effect also reduces efficacy. Some manufacturers recommend application to the body but to exclude the head and neck. However, application should be extended to the scalp, neck, face, and ears

Storage: At room temperature, in airtight, light resistant containers. Protect from heat.

Gamabenzene Hexachloride (Lindane)

Cream, 1 %

Indications: treatment of pediculosis (lice) infestation caused by *Pediculus humanus var. capitis* (head louse) and *phthirus pubis* (pubic or crab louse) and their ova.

It is also indicated for the treatment of scabies infestation caused by *Sarcoptes scabies*.

Cautions: caution is required in children and infants. It is not recommended for use in premature neonates. Caution should be taken in patients with convulsive disorders, in those who are sensitive to lindane and in patients with skin rash or raw or broken skin.

Contraindication: pregnancy and lactation.

Side effects: skin irritation not present before therapy (if it is applied in correctly and repeatedly), itching of skin, CNS toxicity (if absorbed systemically) - convulsions, dizziness, clumsiness, or unsteadiness, fast heartbeat, muscle cramp, nervousness, restlessness, or irritability, vomiting.

Dose and Administration: pediculicide, scabicide - *Topical*, to the skin, as a 1% cream for one application.

Storage: at room temperature in a tight container.

Malathion

Shampoo, 1%

Indications: scabies, head lice and crab lice

Cautions: avoid contact with eyes; do not use on broken or secondarily infected skin; children under 6 months, medical supervision required

Contraindications: use in neonates and/or infants; hypersensitivity to malathion.

Side effects: skin irritation and hypersensitivity reactions; chemical burns also reported

Dose and Administration:

Head lice: rub 0.5% preparation into dry hair and scalp, allow to dry naturally, remove by washing after 12 hours repeat application after 7 days

Crab lice: apply 0.5% aqueous preparation over whole body, allow to dry naturally, wash off after 12 hours or overnight; repeat application after 7 days

Scabies: apply 0.5% preparation over whole body, and wash off after 24 hours; if hands are washed with soap within 24 hours, they should be retreated; repeat application after 7 days

Note: For scabies, manufacturer recommends application to the body but not necessarily to the head and neck. However, application should be extended to the scalp, neck, face, and ears

Permethrine

Cream, 5 %

Lotion, 1%, 5%

Indication: scabies, head and body lice

Cautions: do not use on inflamed or broken skin; avoid contact with eyes; breast feeding (with hold during treatment)

Side effects: local irritation; rarely rashes and oedema

Dose and Administration:

Adult and Child:

Scabies and body lice *apply* cream over whole body and wash off after 8–12 hours; if hands area washed with soap within 8 hours of application, treat the hands again; repeat application after 7 days.

Head lice, *apply* lotion to clean, damp hair and rinse off after 10 minutes.

Storage: store between 15 and 25°C. Protect from freezing

Note: for external use only.

Sulphur

Ointment, 5 %, 10 %

Indications: for the treatment of seborrheic dermatitis, scabies especially infants under 2 months of age and in pregnant and nursing women. It is also indicated as an aid in the treatment of acne vulgaris.

Cautions: sensitivity to sulfur.

Drug interactions: medicated soaps, acne preparations or preparations containing a peeling agent, such as benzoyl peroxide,

resorcinol, salicylic acid, tretinoin, after shave lotions, astringents, perfumed toiletries, shaving creams or lotions, cosmetics, isotretinoin, medicated cosmetics or “cover-ups”, topical mercury compounds.

Side effect: skin irritation not present before therapy, redness and peeling of skin.

Dose and Administration:

Adult and Child (>2 years)

Antiacne agent: *topical*, to the skin, as a 0.5% ointment as needed.

Antiseborrheic or keratolytic: *topical*, to the skin, as to 10% ointment once or two times a day.

Scabicides: *Topical*, to the entire body from the neck down, as 6% sulfur in petrolatum at bedtime for 3 nights, patients may bath before each application and should bath after 24 hours following the last application to remove the drug.

Storage: at room temperature, protect from freezing

14.2. Anti-Inflammatory, Topical

Contact dermatitis can result from an allergic or irritant skin reaction. Removal of the substance provoking the reaction is the first step in treating this condition. Mild cases of contact dermatitis can be treated with **hydrocortisone** (is a representative mild topical corticosteroid) which suppresses inflammation.

Atopic dermatitis (or eczema) is a common skin disorder, which mainly occurs in infants and children; it is associated with intense itching, with areas of red skin. Topical **hydrocortisone** should be applied in short courses of 1–2 weeks to treat even mild areas of involvement.

Hydrocortisone Acetate

Cream 1%

Ointment 1%

Indications: contact dermatitis, atopic dermatitis (eczema), lichen planus; pityriasis rosea; intractable pruritus and phototoxic reactions, including polymorphic light eruptions and actinic prurigo; short-term treatment of psoriasis of the face and flexures

Cautions: children (avoid prolonged use); concomitant use with occlusive dressings (may increase penetration into keratinized lesions); secondary infection requires treatment with an appropriate antimicrobial.

Contraindications: untreated skin infections, broken skin, rosacea, acne, perioral dermatitis.

Side effect: exacerbation of local infection; atrophic changes less likely with mild corticosteroids, but infants and children particularly susceptible; contact dermatitis; perioral dermatitis; hypertrichosis.

Dose and Administration:

Adult and Child: Inflammatory skin conditions, *apply* sparingly to the affected area, 1–2 times daily until improvement occurs, then less frequently.

Storage: at room temperature in a well closed container, protect from freezing.

14.3. Keratolytics/Caustics and Antiacne Agents

Salicylic acid may be used in all hyperkeratotic and scaling conditions to enhance the rate of loss of surface scale. Some preparations contain combination of **salicylic acid**, **lactic acid** and **polidocanol**. They are suitable for the removal of warts on hands and feet.

Camphor

Cream, Lotion, Solution

Indication: for acne

Salicylic Acid

Ointment, 2 %, 5 %, 10 %

Indications: treatment of acne vulgaris, seborrheic dermatitis, psoriasis, and common wart (excluding on the face).

Cautions, Contraindications and Side effects: see section under 14.1

Dose and Administration: *Topical to the skin:*

Apply to affected area every 12-24 hours daily starting with the 2% progressively increasing the concentration up to 5% for *acne*

vulgaris and up to 10% for *seborrheic dermatitis, psoriasis and common wart*. Apply until it gets better.

Storage: at room temperature, in tight containers.

Salicylic Acid + Lactic Acid + Polidocanol

Tincture, 2 g + 0.5 g + 0.2g in each 10 g

See notes above.

14.4. Medicines for Psoriasis and Eczema

Zinc oxide is mildly astringent and is used topically as a soothing and protective application in eczema and slight excoriations and for hemorrhoids. It is usually mixed with purified talc, which is used in massage to allay irritation and prevent chafing. Zinc oxide reflects UV radiation and is used as sunscreens. **Ichthammol** is usually used in chronic lichenified forms of eczema or to control pruritus.

Ichthammol

Ointment, 10 %, 20%

Indications: for treatment of chronic lichenified eczema.

Side effect: skin irritation.

Dose and Administration: topically, apply to the skin 1-3 times daily.

Zinc Oxide

Ointment, 15 %

Lotion, 15 %

Indications: protective coating for mild skin irritations and abrasions, soothing and protective ointment to promote healing of chapped skin, diaper rash

Dose and Administration: Infants, Children and Adults: Topical: Apply as required for affected areas several times daily.

Zinc oxide + Talc

Paste, 15 % + 25 %

See notes above

14.5. Antipruritics

Pruritus (itching) is a common symptom of many skin disorders as well as of several systemic diseases and may be extremely distressing. However, contact with certain substances, conditions that dry the skin, stress, and extremes of temperature may also be a cause. Thus, an important part of treatment is to eliminate or minimize the reason for the irritation.

Preparations containing crotamiton are used as an antipruritic agent. One application may be effective for 6 to 10 hour.

Preparations containing calamine are often ineffective.

Calamine

Lotion (oily), 5 %

Calamine is a representative topical antipruritic. Various medicines can serve as alternatives.

Uses: mild pruritus.

Administration:

Adult and Child: Mild pruritus, *apply* liberally to the entire affected area 3–4 times daily

Calamine + Zinc Oxide

Cream, 4 % + 3 %

Lotion, 15 % + 5 %

Indications: mild pruritus

Dose and Administrations: *Topically:* Apply liberally 3 – 4 times daily

Crotamiton

Cream, 10%

Lotion, 10 %

Indications: treatment of scabies and symptomatic treatment of pruritus.

Cautions: crotamiton should not be applied to acutely inflamed skin or raw, weeping surfaces. If primary irritation or hypersensitivity occurs, treatment should be discontinued and the drug should be removed with soap and water. Crotamiton should

be used during pregnancy only when clearly needed. Contact with the face, eyes, mucous membranes and urethral meatus should be avoided, use on physician's advice for children under 3 years.

Contraindications: a history of sensitivity or allergy to the drug and in those who exhibit a primary irritation response to topically applied medications. Acute exudative dermatoses

Side effects: slight local irritation, allergic skin sensitivity may occur with prolonged use

Dose and Administration:

Adult and Child:

Scabicide: Wash thoroughly and scrub away loose scales, then towel dry; apply a thin layer and massage drug onto skin of the entire body from the neck to the toes (with special attention to skin folds, creases, and interdigital spaces). Repeat application in 24 hours. Take a cleansing bath 48 hours after the final application. Treatment may be repeated after 7-10 days if live mites are still present.

Pruritus: Massage into affected areas until medication is completely absorbed; repeat as necessary.

14.6. Skin Disinfecting Agents

The choice of disinfectant is an important factor in treating skin conditions. For example, scaling disorders are best treated with emulsifying ointment or other disinfectants that do not irritate the skin. Some of the useful disinfectants for skin cleansing available include Chlorhexidine; Potassium permanganate and Povidone - iodine. Povidone- iodine is preferred to chlorinated solutions (such as dilute sodium hypochlorite solution; not described here) which are too irritant and are no longer recommended. Astringent preparations, such as potassium permanganate solution are useful for oozing eczematous reactions.

Chlorhexidine Gluconate + Cetrimide

Solution, 1.5 % + 15 %, 0.3% + 3%w/v

Indications: for skin disinfection and wound cleansing, and also for the cleansing and disinfection of equipments.

Side effects: skin sensitivity may occur rarely. Strong solutions may cause irritation of the conjunctiva and other sensitive tissues.

Dose and Administration: *Topically*

For skin disinfection and wound cleansing:

Apply to the affected area the diluted solution (1 in 100 (1%) with water).

For disinfection of equipment (e.g bowls, tables), spraying wards:

Use 1 in 2000 dilution with water.

Storage: at room temperature protected from light.

Ethyl Alcohol

Solution, 70 %

Indications: for disinfection of the skin in preparation for injections.

Cautions: it should not be applied to fresh wounds.

Dose and Administration: Topical, to the skin.

Storage: in airtight containers, in a cool place.

Hydrogen peroxide

3 %, 6 %

Indications: skin disinfectant, particularly cleansing and deodorizing wounds and ulcers.

Cautions: in large and deep wounds, avoid use in normal skin.

Dose and Administration: topically, apply to the wound to cleanse.

Iodine

Solution, 2 %

Indications: for the disinfection of minor superficial skin wounds.

Cautions: do not apply to sensitive area such as the axillary, perianal, or genitalia.

Side effects: skin sensitivity, irritation, sloughing of soft tissues and staining of the skin may occur.

Dose and Administration: Topical to the affected areas as necessary. Do not cover with a tight bandage.

Storage: at room temperature. In yellowish brown coloured glass bottles, preferably glass stoppered.

Potassium permanganate

Tablet (for solution), 50 mg, 120 mg, 200 mg, 250 mg, 300 mg

Indications: as skin disinfectant for cleansing and deodorizing suppurating eczematous reactions and wounds.

Cautions: irritant to mucous membrane and it stains skin and clothing

Side effect: irritation to tissues, corrosive burns.

Dose and Administration: one tablet dissolved in suitable amount of water to provide a 0.01% solution. It is applied as wet dressings or baths, approximately of 0.01% solution.

Povidone - Iodine

Solution (aqueous), 4 %, 7.5 %, 10 %

Indications: as skin disinfectant and antiseptic mainly for the treatment of contaminated wounds and pre-operative preparation of the skin and mucous membranes.

Cautions: during pregnancy and breast-feeding, in patients with broken skin and renal impairment. The application of povidone - iodine to large wounds or severe burns may produce systemic adverse effects such as metabolic acidosis, hypernatremia and impairment of renal function.

Contraindications: avoid regular use in patients with thyroid disorders, those receiving lithium therapy, and very low birth weight infants.

Side effects: rarely sensitivity may interfere with thyroid function tests; see also caution.

Dose and Administration:

Alcoholic solution, povidone - iodine 10%:

Adult: to be applied undiluted in pre- and post-operative skin disinfection.

Child: not recommended for regular use in neonates (and contraindicated in very low birth weight infants)

Antiseptic solution, povidone - iodine, 10% in aqueous solution:

Adult: to be applied undiluted in pre-and postoperative skin disinfection

Child: not recommended for regular use in neonates (and contraindicated in very low birth weight infants)

Scalp and skin cleanser solution, povidone - iodine, 7.5%, in a surfactant basis:

Adult: use of seborrhoeic condition of scalp and acne vulgaris of face and neck 1-2 times daily child dose. **Child** under 2 years not recommended.

Skin cleanser solution, povidone - iodine, 4% in a surfactant basis:

Adult: for infective condition of the skin. Retain on skin for 3-5 minutes before rinsing, repeat twice daily. **Child** under 2 years not recommended

14.7. Dermatologicals, Others

Methylsalicylate[∞]

Methyl salicylate is irritant to the skin and is used topically in rubefacient preparations in musculoskeletal, joint and soft-tissue disorders and for minor peripheral vascular disorders such as chilblains. It is absorbed through intact skin and can produce effects typical of systemic salicylates.

Paraffin Gauze Dressing

Paraffin Gauze Dressing - is Fabric of Leno weave, weft and warp threads of cotton and/or viscose yarn, impregnated with white or yellow soft paraffin.

Indications: treatment of abrasions, burns, and other injuries of skin, and ulcerative conditions; post-operatively as a penile and vaginal dressing and for sinus packing; heavier loading for skin graft transfer.

Talc Dusting powder

Indications: used in folds where a friction may occur between opposing skin surfaces.

Cautions: they should not be applied in areas that are very moist as they tend to take and abrade the skin.

[∞] Any other rubefacient proven to be therapeutically effective can be used

Urea

Cream, 10%, 15%, 20%, 40%

Indications: hydrating agent and keratolytic for dry, scaling and itching skin conditions, including mild psoriasis.

Cautions: avoid application to face or broken skin; avoid contact with eyes.

Side effects: transient stinging and local irritation.

Dose and Administration:

Adult and Child: Dry, scaling skin disorders, *apply* directly to the affected area twice daily, preferably to damp skin.

15. Antidotes and Other Substances Used In Poisoning

In the treatment of acute poisoning most patients require only supportive and symptomatic therapy. The active removal of poisons from the stomach by gastric lavage or emesis induction may be considered, as should the administration of substances like activated charcoal by mouth to reduce their absorption. However, the use of emetics and gastric lavage has been questioned and these measures, including the administration of charcoal are for instance inappropriate in corrosive poisoning, and aspiration should only be carried out with great care. Some poisons, in particular pesticides, may be absorbed through the skin and clothing should be removed and the skin thoroughly washed to avoid continued absorption.

Ipecac syrup was administered to patients prior to referral to the emergency department in attempts to start the gastric emptying process as early as possible.

Techniques such as forced diuresis, haemodialysis, or haemoperfusion are only of value for a limited number of poisons in a few severely poisoned patients.

Activated Charcoal

Tablet, 125mg, 250mg

Powder for reconstitution, 15gm/120ml, 25gm

Gel, 300ml

Indications: treatment of acute poisoning.

Cautions: intestinal obstructions, drowsy or unconscious patients (risk of aspiration; intubate before administration via nasogastric or gastric tube); not effective for poisoning with alcohols, clofenotane (dicophane, DDT), cyanides, malathion, and metal salts including those of iron and lithium.

Drug interactions: charcoal decreases the effect of Ipecac syrup.

Contraindications: poisoning by hydrocarbons with high potential for harm if aspirated; poisoning by corrosive substances (may prevent visualization of lesions caused by the poison).

Side effect: black stools; vomiting, constipation or diarrhoea; bowel obstruction pneumonitis (due to aspiration).

Dose and Administration:

Poisoning (reduction of absorption), *Oral:* as soon as possible after ingestion of poison, **Adult**, 50–100 g as a single dose; **Infant**, 1 g/kg as a, single dose; **Child** 1–12 years, 25 g as a single dose (50 g in severe Poisoning).

Poisoning (active elimination), *Oral:* **Adult**, 50 g every 4 hours (in case of intolerance 25 g every 2 hours); **Infant**, 1 g/kg every 4–6 hours; **Child** Over 1 year, 25–50 g every 4–6 hours.

Ipecac

Syrup, 7% powdered Ipecac

Indications: an emetic for emergency use in the treatment of drug overdose and in some cases of poisoning

Cautions: children under one year of age; heart disease active or impending seizures and in conditions of strychnine poisoning or ingestion of petroleum distillates, such as kerosene, gasoline, coal oil, fuel oil, paint thinner, or cleansing fluid.

Drug interactions: activated charcoal, milk or milk products, carbonated beverages, antiemetics.

Contraindications: impending coma, severe inebriation, corrosive poisoning with alkali and strong acids, depressed gag reflex, impending shock states.

Side effect: diarrhoea, fast or irregular heartbeat, nausea or vomiting, stomach cramps or pain, troubled breathing, unusual tiredness or weakness, aching, and stiffness of muscles, especially those of the neck, arms, and legs.

Dose and Administration: Oral:-

Adult: Emetic: 15 to 30ml followed immediately by one glass (240ml) of water. Dose may be repeated in twenty minutes if emesis does not occur. The dosage should be reversed by gastric lavage if emesis does not occur after the second dose.

Child: Emetic:

Children up to 1 year of age: 5 to 10ml

Children 1-12 years of age: 15 ml preceded or followed by ½-1 full glass (120-240ml) of water.

Storage: at a temperature below 25°C.

Universal Antidote (charcoal + tannic acid + magnesium oxide)

Powder, 2 parts + 1 part + 1 part

Indications: treatment of selected cases of acute poisoning to adsorb the toxic substance and thereby reduces its systemic absorption.

Note: The "Universal antidote" is inferior to activated charcoal alone. In addition, the tannic acid component is potentially hepatotoxic. Thus, there is no justification for the use of the "Universal antidote".

16. Immunological Preparations

Immunoglobulins

Immunoglobulins are preparations containing antibodies against infectious micro-organisms and are prepared usually from human plasma or serum. They are used for passive immunization, thus conferring immediate protection against some infectious diseases. They are preferred to antisera of animal origin as the incidence of adverse reactions is less.

Side effects: Local reactions with pain and tenderness at the site of intramuscular injection; hypersensitivity reactions, including rarely anaphylactic reactions, have also been reported; systemic reactions with fever, chills, facial flushing, headache, and nausea may occur following intravenous administration, particularly at high rates of infusion.

Cautions: If immunoglobulins are given after administration of a live vaccine at interval of at least 3 weeks should be allowed to elapse. An interval of 3 months should be allowed between the use of live vaccines and the prior administration of immunoglobulins.

Antisera

Antisera (immunosera) are sterile preparations containing immunoglobulins obtained from the serum of immunised animals by purification. Antisera have the specific power of neutralising venoms or bacterial toxins, or combining with the bacterium, virus, or other antigen used for their preparation.

Side effects and cautions

Anaphylactic reaction may occur, with hypotension; dyspnoea, urticaria, and shock; serum sickness frequently 7 to 10 days after the injection of serum of animal origin.

Before injecting serum, information should be obtained whenever possible as to whether previous injections of serum have been received and whether the patient is subject to hypersensitivity disorders. Sensitivity testing should be performed before the administration of antisera.

Vaccines

Vaccines are preparations of antigenic materials which are administered with the object of inducing in the recipient active immunity to specific bacteria or viruses. They may contain living or killed microorganisms, bacterial toxoids, or antigenic material from particular parts of the bacterium, rickettsia or virus.

The term vaccination and immunization are often used synonymously and interchangeably. Vaccination is strictly only the administration of a vaccine whereas immunization results in the demonstrable presence of protective levels of antibodies confirmed usually by serological testing.

Side effects: Administration of a vaccine by injection may be followed by a local reaction, possibly with inflammation and lymphangitis. At the site of injected vaccine an induration or sterile abscess may develop. The administration of a vaccine may

be followed by fever, headache, and malaise starting a few hours after injection and lasting for 1 or 2 days.

Cautions: Vaccination should be postponed in patients suffering from any acute illness although minor infections without fever or systemic upset are not regarded as contra-indications. Immunization should not be carried out in individuals who have previously had a severe local or generalized reaction to the vaccine. Asthma, eczema, hay fever, or a history of allergy, should not be regarded as contraindications to vaccination. Before injection of a vaccine any alcohol or disinfectant used for cleansing the skin should be allowed to evaporate otherwise inactivation of live vaccines may occur.

Live vaccines should not be given to patients receiving high-dose systemic corticosteroid therapy; to patients receiving immunosuppressive therapy including general irradiation; to patients suffering from certain malignant conditions such as lymphoma, leukemia, Hodgkin's disease, or other tumors of the reticuloendothelial systems; or to patients with other types of impaired immunological responses, such as hypogammaglobulinaemia. Vaccination should also be postponed for at least 6 months after the cessation of antineoplastic chemotherapy and for at least 3 months after high-dose systemic corticosteroid therapy.

Because of a theoretical risk to the fetus, live vaccines should not be administered during pregnancy unless it is considered there is a significant risk of exposure to infection.

As with other causes of immunosuppression, the efficacy of vaccines may be reduced in HIV positive individuals.

Any agent which is active against the bacterial or viral strain present in the vaccine may interfere with development of a protective immune response but treatment with antibiotics should not be considered to be a contraindication to immunization.

Scorpion Venom Antisera (Scorpion Antivenom)

Injection, 0.5ml

Indications: to neutralize the venom of one or more species of scorpion

Cautions: allergic to the antivenin, sensitivity testing should be preformed.

Side effect: as for antisera in general; urticaria, nephritis, myocarditis, polyarthritis, neuritis, ureitis.

Dose and Administration: The use of a scorpion antiserum suitable for the species of scorpion can prevent symptoms provided it is done with the least possible delay, other general supportive measures may also be needed. The volume stated on the label as the dose, should preferably be made directly into the site of the sting but if this cannot be done, as much as possible should be injected into the site and the remainder *intramuscularly* into a convenient proximal position.

Snake Venom Antiserum Polyvalent

Injection, 10ml

Indications: antivenin (crotalidae) polyvalent neutralizes absorbed venom of crotalid snakes (pit vipers), including the rattlesnake, copperhead, water moccasin and tropical and asiatic crotalids, and is used to prevent or minimize the effects of poisoning by these snakes.

Cautions: history of asthma, hay fever, urticaria or other allergic manifestation. Intradermally sensitivity testing should be performed before administration.

Side effect: as for antisera in general; itching, edema of the face, tongue and throat, cough, vomiting, cardiovascular collapse.

Dose and Administration: For *IV infusion*, a 1:1 to 1:10 dilution of reconstituted antivenin in 0.9% sodium chloride or 5% dextrose injection is prepared.

Usual dose - *IV infusion*, 5-10ml of diluted antivenin, infused over 3-5 minutes with careful observation of the patient.

Tetanus Antitoxin, Equine

Injection, 1500 units, 3000Units, 20,000 units

Indications: tetanus antitoxin, equine is indicated for temporary passive immunization against tetanus and also to prevent tetanus infection that arise from the toxins produced by *Clostridium tetani*.

Cautions: allergic to the antitoxin. For this sensitivity testing should be performed.

Side effects: anaphylaxis (with hypotension, dyspnoea, urticaria, shock), serum sickness (fever, vomiting, diarrhoea, bronchospasm, urticaria).

Dose and Administration:

Adult: *prophylaxis after injury of non-immune or partially immune persons:* SC, or IM: 3000 - 5000 units of tetanus antitoxin.

Treatment of established tetanus: 50,000 - 100,000 units part of which is administered by IV injection with the remainder being given intramuscularly.

17. Miscellaneous

Aluminum sulphate+Calcium hypochlorite+sodium carbonate

Water treatment powder in the ratio of 23:1:1 by weight

Indications: used as a disinfectant in water.

Calcium hypochlorite+Iron sulphate+Bentonite+Potassium permanganet polyacrylamide+sodium carbonate

Water treatment powder

Indications: used as a disinfectant in water.

Formaldehyde Solution

Solution, 3%, 8% (v/v)

Indications: a disinfectant active against bacteria, fungi, and many viruses, with a slow action against bacterial spores. It is used for the disinfection of the blankets, bedding, and membranes in dialysis equipment.

Cautions and Side effects: ingestion of formaldehyde solution causes intense pain, with inflammation, ulceration, and necrosis of mucous membranes. There may be vomiting, haematemesis, blood-stained diarrhoea, haematuria, and anuria; metabolic acidosis, vertigo, convulsions, loss of consciousness, and circulatory failure may occur. Death has occurred after the ingestion of the equivalent of about 30ml of formaldehyde solution. If the patient survives 48 hours, recovery is probable.

Formaldehyde vapour is irritant to the eyes, nose, and upper respiratory tract, and may cause coughing, dysphagia, spasm and oedema of larynx, bronchitis, pneumonia, and rarely, pulmonary oedema. Asthma has been reported after repeated exposure.

Storage: at temperature between 15 and 25°C in airtight containers. Avoid contact with plastics.

Halazone

Tablet, 4mg

Indications: a disinfectant with the general properties of chlorine in aqueous solution and is used for the disinfection of drinking water. One tablet containing 4mg of Halazone, stabilized with sodium carbonate and sodium chloride, is sufficient to treat about a litre of water in about 30 minutes to 1 hour, more being required for heavily contaminated water. The taste of residual chlorine may be moved by adding sodium thiosulphate.

Storage: in airtight containers. Protect from light.

KY Jelly (Hydroxyethyl cellulose)

Indications: It is present in lubricant preparations, some of which are used as artificial tears in ocular disorder or dry eye.

Iodized Salt

Indications: prevention and treatment of iodine deficiency.

Contraindications: breastfeeding

Cautions: those over 45 years old or with nodular goiter (especially susceptible to hyperthyroidism when given iodine supplements); pregnancy, breast-feeding.

Side effects: hypersensitivity reactions; goiter and hypothyroidism; hyperthyroidism

Saccharin

Tablet

Indications: Saccharin and its salts (sodium, calcium, potassium) are intense sweeteners being several hundred times sweeter than sucrose and are used as food additives and artificial sweetener for

diabetes. The salts are more often used as they are considered to be the most palatable.

Side effects: allergic and photosensitivity reaction.

Dose and Administration: 5mg per kg of saccharine salt taken daily.

Sodium Chloride Free Salt

Indications: treatment of extracellular volume depletion and sodium depletion

Cautions: Sodium chloride should be used with extreme caution, if at all, in patients with hypertension, congestive heart failure, or other edematous or sodium-retaining conditions, in patients with liver cirrhosis and in patients receiving corticosteroids or corticotropin. Particular caution is necessary in geriatric and post-operative patients.

Contraindications: sodium chloride is contraindicated in patients with conditions in which administration of sodium and chloride is detrimental.

Side effects: nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduce salivation and lachrymation, sweating, fever, tachycardia, hypertension, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache.

Dose and Administration: *Oral:* 1-2 gm 3 times daily depending on individual needs either with food or as a solution; doses of up to 12g daily may be necessary in severe cases.

Sodium Dichloroisocyanurate

Tablet, 67mg, 75mg

Indications: used as a disinfectant in water. It dissociates in water to form a number of chemical species, notably free chlorine and cyanuric acid.

Cautions:

- Harmful if swallowed; also harmful in contact with the skin or eyes, or if inhaled.
- Do not expose the product to flames
- Do not mix with detergents

Storage: Store in a dry, well-ventilated area.

Sorbitol

Indications: Sorbitol is used in limited quantities either as a sweetening agent or as a source of carbohydrate in diabetic food products. It is also used as a sweetening agent instead of sucrose in many sugar-free oral liquid preparations and in sugar free-preparation of dental caries.

Cautions: impaired kidney function or severe liver damage.

Side effects: flatulence, abdominal pain, diarrhoea, and lactic acidosis hyperuricemia.

Storage: store in airtight container.

Water for injections

In 2ml, 5ml, 10ml

Indications: water for injection is distilled water free from pyrogens used to produce solutions for injections.

Cautions: water for injection is a hypotonic solution intended for the preparation of parenteral solutions. It must not be injected alone.

Dose and Administration: depend on the solutes to be dissolved in the water for injection.

APPENDIXES

APPENDIX I. VITAL SIGNS

Normal Body Temperature

Thermometer held in Armpit (Axillary) = 36.5°C

Thermometer held under Tongue (Oral) = 37°C

Thermometer held in Anus (rectal) = 37.5°C

Normal Pulse Rate

In Babies = 100-140/minute

In Children = 80-100/minute

In Adults = 60-80/ minute

Normal Respiratory Rate

Infants (Birth-2 years) = About 50/minute

Babies (2-5 years) = About 40/minute

Adult = About 12-16/minute.

Normal Blood Pressure (measured after rest)

Adult = Systolic: 120 -140mmHg

Diastolic: 80 -90mmHg

APPENDIX II. ROUTES OF ADMINISTRATION

Oral = By Mouth

I.M. = Intramuscular

I.V. = Intravenously

S.C = Subcutaneously

I.D. = Intradermally

APPENDIX III. AGE/BODY WEIGHT CHART

Age	Ideal Body Weight (Kg)
Newborn	3.4
1 Month	4.2
3 Months	5.6
6 Months	7.7
1 year	10.0
3 years	14.0
5 years	18.0
7 years	23.0
12 years	37.0
Adult	
Male	68.0
Female	56.0

Note: This is not a local data. It is intended as a guide only.

APPENDIX IV. APPROXIMATE MEASURES

- 1 teaspoonful = 5ml
- 1 dessertspoonful = 10ml
- 1 tablespoonful = 15ml

APPENDIX V. PREPARATION OF PROCAINE PENICILLIN 4 MU (DRY POWDER) FOR PARENTERAL USE

Add 8ml of water for injection to the Procaine Penicillin 4 MU vial to make it a 10ml solution. Each 1ml contains now 400,000IU (250mg) Procaine Penicillin. See Table below.

P.PEN ML	P.PEN IU	P.PEN Milligram
----------	----------	--------------------

0.2	80,000	50
0.3	120,000	75
0.5	200,000	125
1.0	400,000	250
2.0	800,000	500
3.0	1,200,000	750
4.0	1,600,000	1000 (1gm)
5.0	2,000,000	1250 (1.25gm)
10.0	4,000,000	2500 (2.5gm)

APPENDIX VI. STORAGE CONDITION

- ".. in a dry place" - relative humidity less than 5%
- "..protect from heat" - not more than 30°C
- ".. at room temperature" - 15 to 25 °C
- "..in a cool/cold place" - 8 to 15°C
- "..in a refrigerator" - 0 to 8°C
- "..in a deep freezer" - -15 to 0°C

APPENDIX VII. Pregnancy

During pregnancy the mother and the fetus form a non-separable functional unit. Maternal well-being is an absolute prerequisite for the optimal functioning and development of both parts of this unit. Consequently, it is important to treat the mother whenever needed while protecting the unborn to the greatest possible extent.

Drugs can have harmful effects on the fetus at any time during pregnancy. It is important to remember this when prescribing for a woman of childbearing age. However, irrational fear of using drugs during pregnancy can also result in harm. This includes untreated illness, impaired maternal compliance, suboptimal treatment and treatment failures.

Such approaches may impose risk to maternal well-being, and may also affect the unborn child. It is important to know the 'background risk' in the context of the prevalence of drug-induced adverse pregnancy outcomes. Major

congenital malformations occur in 2–4% of all live births. Up to 15% of all diagnosed pregnancies will result in fetal loss. The cause of these adverse pregnancy outcomes is understood in only a minority of the incidents.

During the *first trimester* drugs may produce congenital malformations (teratogenesis), and the greater risk is from third to the eleventh week of pregnancy. During the *second* and *third trimester* drugs may affect the growth and functional development of the fetus or have toxic effects on fetal tissues. Drugs given shortly before term or during labour may have adverse effects on labour or on the neonate after delivery. Few drugs have been shown conclusively to be teratogenic in man but no drug is safe beyond all doubt in early pregnancy. Screening procedures are available where there is a known risk of certain defects.

Prescribing in pregnancy

If possible counselling of women before a planned pregnancy should be carried out including discussion of risks associated with specific therapeutic agents, traditional medicines and abuse of substances such as smoking and alcohol. Folic acid supplements should be given during pregnancy planning because periconceptual use of folic acid reduces neural tube defects.

Drugs should be prescribed in pregnancy only if the expected benefits to the mother are thought to be greater than the risk to the fetus. All drugs should be avoided if possible during the first trimester. Drugs which have been used extensively in pregnancy and appear to be usually safe should be prescribed in preference to new or untried drugs and the smallest effective dose should be used. Well known single component drugs should usually be preferred to multi-component drugs.

The following list includes medicines which may have harmful effects in pregnancy and indicates the trimester of risk. It is based on human data but information on *animal* studies has been included for some newer drugs when its omission might be misleading.

Absence of a drug from the list does not imply safety

Table of drugs to be avoided or used with caution in pregnancy

Drug	Comment
Acetylsalicylic acid	Third trimester: Impaired platelet function and risk of haemorrhage; delayed onset and increased duration of labour with increased blood loss; avoid analgesic doses if

	possible in last few weeks (low doses probably not harmful); with high doses, closure of fetal ductus arteriosus <i>in utero</i> and possibly persistent pulmonary hypertension of newborn; kernicterus in jaundiced neonates
Albendazole	Contraindicated in cestode infections; First trimester: avoid in nematode infections;
Alcohol	First, second trimesters: Regular daily drinking is teratogenic (fetal alcohol syndrome) and may cause growth retardation; occasional single drinks are probably safe Third trimester: Withdrawal may occur in babies of alcoholic mothers
Aminophylline	Third trimester: Neonatal irritability and apnoea have been reported
Amoxicillin	Not known to be harmful
Ampicillin	Not known to be harmful
Artemether + Lumefantrine	Avoid. Toxicity in <i>animal</i> studies with artemether
Benzathine benzylpenicillin	Not known to be harmful
Chloramphenicol	Third trimester: Neonatal 'grey' syndrome
Chloroquine	First, third trimesters: Benefit of prophylaxis and treatment in malaria outweighs risk; important: <i>see also</i> section 7.4.1
Chlorphenamine	No evidence of teratogenicity
Cloxacillin	Not known to be harmful
Contraceptives, oral	Epidemiological evidence suggests no harmful effects on fetus
Ephedrine	Increased fetal heart rate reported with parenteral ephedrine
Ergotamine	All trimesters: Oxytocic effects on the pregnant uterus
Ethinylestradiol	Epidemiological evidence suggests no harmful effects on fetus
Ibuprofen	Avoid unless potential benefit outweighs risk Third trimester: With regular use closure of fetal ductus arteriosus <i>in utero</i> and possibly persistent pulmonary hypertension of the newborn. Delayed onset and increased duration of labour
Levamisole	Third trimester: Avoid
Levonorgestrel	In oral contraceptives, epidemiological evidence suggests

	no harmful effects on fetus
Magnesium sulfate	Third trimester: not known to be harmful for short-term intravenous administration in eclampsia but excessive doses may cause neonatal respiratory depression
Mebendazole	Toxicity in <i>animal</i> studies. Contraindicated in cestode infections; <i>see</i> section 7.5.3 First trimester: Avoid in nematode infections; <i>see</i> section 7.5.3
Metoclopramide	Not known to be harmful
Metronidazole	Avoid high-dose regimens
Niclosamide	<i>T. solium</i> infections in pregnancy should be treated immediately; <i>see</i> section 7.5.3
Paracetamol	Not known to be harmful
Polyvidone–iodine	Second, third trimesters: Sufficient iodine may be absorbed to affect the fetal thyroid
Potassium iodide	Second, third trimesters: Neonatal goitre and hypothyroidism
Praziquantel	<i>T. solium</i> infections in pregnancy should be treated immediately; <i>see</i> section 7.5.2 Benefit of treatment in schistosomiasis outweighs risk If immediate treatment not considered essential for fluke infections, treatment should be delayed until after delivery
Promethazine	No evidence of teratogenicity
Salbutamol	For use in asthma <i>see</i> section 2.2 [text] Third trimester: For use in premature labour <i>see</i> section 9
Tetracycline	First trimester: Effects on skeletal development in <i>animal</i> studies Second, third trimesters: Dental discoloration; maternal hepatotoxicity with large doses
Theophylline	Third trimester: Neonatal irritability and apnoea have been reported

APPENDIX VIII. BREASTFEEDING

Administration of some drugs (for example, ergotamine) to nursing mothers may harm the infant, whereas administration of others (for example, digoxin) has little effect. Some drugs inhibit lactation (for example, estrogens).

Toxicity to the infant can occur if the drug enters the milk in pharmacologically significant quantities. The concentration in milk of some drugs (for example, iodides) may exceed that in the maternal plasma so that therapeutic doses in the mother may cause toxicity to the infant. Some drugs

inhibit the infant's sucking reflex (for example, phenobarbital). Drugs in breast milk may, at least theoretically, cause hypersensitivity in the infant even when the concentration is too low for a pharmacological effect.

The following table lists drugs:

which should be used with caution or which are contraindicated in breastfeeding for the reasons given above; which, on present evidence, may be given to the mother during breastfeeding, because they appear in milk in amounts which are too small to be harmful to the infant; which are not known to be harmful to the infant although they are present in milk in significant amounts.

For many drugs insufficient evidence is available to provide guidance and it is advisable to administer only drugs essential to a mother during breastfeeding. Because of the inadequacy of information on drugs in breast milk the following table should be used only as a guide; absence from the table does not imply safety.

Table of drugs present in breast milk

Drug	Comment
Acetylsalicylic acid	Short course safe in usual dosage; monitor infant; regular use of high doses could impair platelet function and produce hypoprothrombinaemia in infant if neonatal vitamin K stores low; possible risk of Reye syndrome
Alcohol	Large amounts may affect infant and reduce milk consumption
Aminophylline	Present in milk—irritability in infant reported
Amoxicillin	Trace amounts in milk; safe in usual dosage; monitor infant
Ampicillin	Trace amounts in milk; safe in usual dosage; monitor infant
Analgesics	See Aspirin, NSAIDs, Opioid Analgesics and Paracetamol
Artemether + Lumefantrine	Discontinue breastfeeding during and for 1 week after stopping treatment; present in milk in <i>animal</i> studies
Atropine	Small amount present in milk; monitor infant
Benzathine	Trace amounts in milk; safe in usual

benzylpenicillin	dosage; monitor infant
Chloramphenicol	Continue breastfeeding; use alternative drug if possible; may cause bone-marrow toxicity in infant; concentration in milk usually insufficient to cause 'grey syndrome'
Chloroquine	For malaria prophylaxis, amount probably too small to be harmful; inadequate for reliable protection against malaria, avoid breastfeeding when used for rheumatic disease
Chlorphenamine	Safe in usual dosage; monitor infant for drowsiness
Cloxacillin	Trace amounts in milk; safe in usual dosage; monitor infant
Contraceptives, oral	Combined oral contraceptives may inhibit lactation—use alternative method of contraception until weaning or for 6 months after birth; progestogen-only contraceptives do not affect lactation (start 3 weeks after birth or later)
Diclofenac	Amount too small to be harmful
Diphenhydramine	See Antihistamines
Ephedrine	Irritability and disturbed sleep reported
Ergotamine	Use alternative drug; ergotism may occur in infant; repeated doses may inhibit lactation
Ethinylestradiol	Use alternative method of contraception; may inhibit lactation; <i>see also</i> Contraceptives, Oral
Hydrocortisone	Systemic effects in infant unlikely with maternal dose of <i>less than equivalent</i> of prednisolone 40 mg daily; monitor infant's adrenal function with higher doses
Hyoscine	Amount too small to be harmful
Ibuprofen	Amount too small to be harmful; short courses safe in usual doses
Iodine	Stop breastfeeding; danger of

	neonatal hypothyroidism or goitre; appears to be concentrated in milk
Ketoconazole	Manufacturer advises avoid
Levamisole	Breastfeeding contraindicated
Levonorgestrel	Combined oral contraceptives may inhibit lactation—use alternative method of contraception until weaning or for 6 months after birth; progestogen-only contraceptives do not affect lactation (preferably start 6 weeks after birth or later)
Loratadine	See Antihistamines
Mebendazole	No information available
Medroxyprogesterone	Present in milk—no adverse effects reported (preferably start injectable contraceptive 6 weeks after birth or later)
Metoclopramide	Present in milk; adverse effects possible; monitor infant for adverse effects
Metronidazole	Significant amount in milk; continue breastfeeding; avoid large doses; use alternative drug if possible
Miconazole	Manufacturer advises caution – no information available
Oestrogens	Avoid; adverse effects on lactation; see also contraceptives, oral
Paracetamol	Small amount present in milk: short courses safe in usual dosage; monitor infant
Penicillins	Trace amounts in milk
Piperazine	Present in milk – manufacturer advises avoid breastfeeding for 8 hours after dose (express and discard milk during this time)
Polyvidone–iodine	Avoid; iodine absorbed from vaginal preparations is concentrated in milk
Praziquantel	Avoid breastfeeding during and for 72 hours after treatment; considered safe to continue breastfeeding in treatment of schistosomiasis
Promethazine	Safe in usual dosage; monitor infant

	for drowsiness
Salbutamol	Safe in usual dosage; monitor infant
Senna	Avoid; large doses may cause increased gastric motility and diarrhoea
Sulfamethoxazole + Trimethoprim	Continue breastfeeding; monitor infant for jaundice—small risk of kernicterus in jaundiced infants and of haemolysis in G6PD-deficient infants (due to sulfamethoxazole)
Tetracycline	Continue breastfeeding; use alternative drug if possible (absorption and therefore discoloration of teeth in infant probably usually prevented by chelation with calcium in milk)
Theophylline	Present in milk—irritability in infant reported; modified-release preparations preferable
Tinidazole	Present in milk – manufacturer advises avoid breastfeeding during and for 3 days after stopping treatment

APPENDIX IX. RENAL IMPAIRMENT

Reduced renal function may cause problems with drug therapy for the following reasons:

The failure to excrete a drug or its metabolites may produce toxicity.

The sensitivity to some drugs is increased even if the renal elimination is unimpaired.

The tolerance to adverse effects may be impaired.

The efficacy of some drugs may diminish.

The dosage of many drugs must be adjusted in patients with renal impairment to avoid adverse reactions and to ensure efficacy. The level of renal function below which the dose of a drug must be reduced depends on how toxic it is and whether it is eliminated entirely by renal excretion or is partly metabolized to inactive metabolites.

In general, all patients with renal impairment are given a *loading dose* which is the same as the usual dose for a patient with normal renal function. *Maintenance doses* are adjusted to the clinical situation. The maintenance dose of a drug can be reduced either by reducing the individual dose leaving the normal interval between doses unchanged or by increasing the interval

between doses without changing the dose. The interval extension method may provide the benefits of convenience and decreased cost, while the dose reduction method provides more constant plasma concentration.

In the following table drugs are listed in alphabetical order. The table includes only drugs for which specific information is available. Many drugs should be used with caution in renal impairment but no specific advice on dose adjustment is available; it is therefore important to also refer to the individual drug entries. The recommendations are given for various levels of renal function as estimated by the glomerular filtration rate (GFR), usually measured by the creatinine clearance. The serum-creatinine concentration can be used instead as a measure of renal function but it is only a rough guide unless corrected for age, sex and weight by special nomograms.

Renal impairment is usually divided into three grades:

Mild —GFR 20–50 ml/minute *or* approximate serum creatinine 150–300 micromol/litre

Moderate —GFR 10–20 ml/minute *or* serum creatinine 300–700 micromol/litre

Severe —GFR < 10 ml/minute *or* serum creatinine >700 micromol/litre

When using the dosage guidelines the following must be considered:

Drug prescribing should be kept to a minimum.

Nephrotoxic drugs should, if possible, be avoided in all patients with renal disease because the nephrotoxicity is more likely to be serious.

It is advisable to determine renal function not only before but also during the period of treatment and adjust the maintenance dose as necessary.

Renal function (GFR, creatinine clearance) declines with age so that by the age of 80 it is half that in healthy young subjects. When prescribing for the elderly, assume at least a mild degree of renal impairment.

Uraemic patients should be observed carefully for unexpected drug toxicity. In these patients the complexity of clinical status as well as other variables for example altered absorption, protein binding or metabolism, or liver function, and other drug therapy precludes use of fixed drug dosage and an individualized approach is required.

Table of drugs to be avoided or used with caution in renal impairment

Drug	Degree of Impairment	Comment
Acetylsalicylic acid	Severe	Avoid; sodium and water retention; deterioration in renal function; increased risk of gastrointestinal bleeding
Aluminium hydroxide	Severe	Aluminium is absorbed and may accumulate NOTE. Absorption of aluminium from aluminium salts is increased by citrates

		which are contained in many effervescent preparations (such as effervescent analgesics)
Amoxicillin	Severe	Reduce dose; rashes more common
Ampicillin	Severe	Reduce dose; rashes more common
Artemether + Lumefantrine	Severe	Caution; monitor ECG and plasma potassium
Benzathine benzylpenicillin	Severe	Neurotoxicity—high doses may cause convulsions
Cetirizine	Moderate	Use half normal dose
Chloramphenicol	Severe	Avoid unless no alternative; dose-related depression of haematopoiesis
Chloroquine	Mild to moderate	Reduce dose in rheumatic disease
Chlorphenamine	Severe	Dose reduction may be required
Cloxacillin	Severe	Reduce dose
Diclofenac		See NSAIDs
Ephedrine	Severe	Avoid; increased CNS toxicity
Ergometrine	Severe	Manufacturer advises avoid
Ibuprofen	Mild	Use lowest effective dose and monitor renal function; sodium and water retention; deterioration in renal function possibly leading to renal failure
Magnesium hydroxide	Moderate	Avoid or reduce dose; increased risk of toxicity
Magnesium sulfate	Moderate	Avoid or reduce dose; increased risk of toxicity
NSAIDs	Mild Moderate to Severe	Use lowest effective dose and monitor renal function; sodium and water retention; deterioration in renal function possibly leading to renal failure; deterioration also reported after topical use Avoid if possible
Opioid Analgesics	Moderate to Severe	Reduce dose or avoid; increased and prolonged effects; increased cerebral sensitivities
Polyvidone–iodine	Severe	Avoid regular application to inflamed or broken mucosa
Procaine benzylpenicillin	Severe	Neurotoxicity—high doses may cause convulsions
	Severe	Use half normal dose

Sodium chloride	Severe	Avoid
Sulfamethoxazole + Trimethoprim	Mild	Use half normal dose if creatinine clearance 15–30 ml/minute; avoid if creatinine clearance less than 15 ml/minute and if plasma-sulfamethoxazole concentration cannot be monitored
Tetracyclines	Mild	Avoid tetracyclines except doxycycline or minocycline which may be used cautiously (avoid excessive doses)

APPENDIX X. HEPATIC IMPAIRMENT

Liver disease may alter the response to drugs. However, the hepatic reserve appears to be large and liver disease has to be severe before important changes in drug metabolism take place. The ability to eliminate a specific drug may or may not correlate with liver's synthetic capacity for substances such as albumin or clotting factors, which tends to decrease as hepatic function declines. Unlike renal disease, where estimates of renal function based on creatinine clearance correlate with parameters of drug elimination such as clearance and half-life, routine liver function tests do not reflect actual liver function but are rather markers of liver cellular damage.

The altered response to drugs in liver disease can include all or some of the following changes:

Impaired intrinsic hepatic eliminating (metabolizing) capacity due to lack of or impaired function of hepatocytes.

Impaired biliary elimination due to biliary obstruction or transport abnormalities (for example rifampicin is excreted in the bile unchanged and may accumulate in patients with intrahepatic or extrahepatic obstructive jaundice).

Impaired hepatic blood flow due to surgical shunting, collateral circulation or poor perfusion with cirrhosis and portal hypertension.

Altered volume of distribution of drugs due to increased extracellular fluid (ascites, oedema) and decreased muscle mass.

Decreased protein binding and increased toxicity of drugs highly bound to proteins (for example phenytoin) due to impaired albumin production.

Increased bioavailability through decreased first-pass metabolism.

Decreased bioavailability due to malabsorption of fats in cholestatic liver disease.

In severe liver disease increased sensitivity to the effects of some drugs can further impair cerebral function and may precipitate *hepatic encephalopathy* (for example morphine). *Oedema* and *ascites* in chronic liver disease may be

exacerbated by drugs that cause fluid retention (for example acetylsalicylic acid, ibuprofen, prednisolone, dexamethasone).

Usually drugs are metabolized without injury to the liver. A few drugs cause dose-related hepatotoxicity. However, most hepatotoxic reactions to drugs occur only in rare persons and are unpredictable. In patients with impaired liver function the dose-related hepatotoxic reaction may occur at lower doses whereas unpredictable reactions seem to occur more frequently. Both should be avoided.

Information to help prescribing in hepatic impairment is included in the following table. The table contains only those drugs that need dose adjustment. However, absence from the table does not automatically imply safety as for many drugs data about safety are absent; it is therefore important to also refer to the individual drug entries.

Table of drugs to be avoided or used with caution in liver disease

Drug	Comment
Acetylsalicylic acid	Avoid—increased risk of gastrointestinal bleeding
Aluminium hydroxide	In patients with fluid retention, avoid antacids containing large amounts of sodium; also avoid those causing constipation (can precipitate coma)
Aminophylline	Reduce dose
Antacids	In patients with fluid retention, avoid those containing large amounts of sodium, e.g. magnesium trisilicate mixture, Avoid those causing constipation- can precipitate coma.
Artemether + Lumefantrine	Caution in severe impairment; monitor ECG and plasma potassium
Chloramphenicol	Avoid if possible—increased risk of bone-marrow depression; reduce dose and monitor plasma-chloramphenicol concentration
Chlorphenamine	Sedation inappropriate in severe liver disease—avoid
Contraceptives, oral	Avoid in active liver disease and if history of pruritus or cholestasis during pregnancy
Diclofenac	See NSAIDs
Diphenhydramine	Caution in mild to moderate liver disease; avoid in severe disease if

	sedation is inappropriate
Ergometrine	Avoid in severe liver disease
Estradiol	See Oestrogens
Estriol	See Oestrogens
Ethinylestradiol	Avoid; <i>see also</i> Contraceptives, oral
Ibuprofen	Increased risk of gastrointestinal bleeding and can cause fluid retention; avoid in severe liver disease
Ketoconazole	Avoid
Levonorgestrel	Avoid in active liver disease and if history of pruritus or cholestasis during pregnancy
Magnesium hydroxide	Avoid in hepatic coma if risk of renal failure
Magnesium sulfate	Avoid in hepatic coma if risk of renal failure
Metronidazole	In severe liver disease, reduce total daily dose to one-third and give once daily
Miconazole	Avoid
NSAIDs	Increased risk of gastro-intestinal bleeding and can cause fluid retention; avoid in severe liver disease.
Oestrogens	Avoid; See also contraceptives, oral
Paracetamol	Dose-related toxicity—avoid large doses
Piperazine	Manufacturer advises avoid
Promethazine	Avoid—may precipitate coma in severe liver disease; hepatotoxic
Sulfamethoxazole + Trimethoprim	Manufacturer advises avoid in severe liver disease
Tetracyclines	Avoid (or use with caution); tetracycline and demeclocycline max. 1g daily in divided doses
Theophylline	Reduce dose

APPENDIX XI. Adverse Drug Event reporting form

Patient Name(abbreviation)	Card No	Age, Date of birth -----	Sex -----	Weight -----	Height -----	
Ethnic group.....		Substance of abuse....				
Information on suspected drug/vaccine used drugs S=suspected drug C=concomitantly used drugs						
Drug name(write all information including brand name batch no and manufacturer)	S/ C	Dose/dosage form, route, frequency	Date drug taking was started (D/M/Y)	Date drug reaction started (D/M/Y)	Date drug taking was stopped (D/M/Y)	Indication (Reason for drug use)
Adverse drug event description(include all available laboratory test results)						

Reaction necessitated Discontinuation of drug/s <input type="checkbox"/> YES <input type="checkbox"/> No			Reaction subside after D/C of suspected drug <input type="checkbox"/> YES <input type="checkbox"/> No <input type="checkbox"/> Information not available			
Hospitalization prolonged <input type="checkbox"/> YES <input type="checkbox"/> No			Reaction reappear after restart of suspected drug <input type="checkbox"/> YES <input type="checkbox"/> No <input type="checkbox"/> Information not available			
Treatment of reaction -----						
Outcome: <input type="checkbox"/> Died due to the adverse event <input type="checkbox"/> Died, drug may be contributory <input type="checkbox"/> Not yet recovered <input type="checkbox"/> Recovered without sequeale <input type="checkbox"/> Recovered with sequeale <input type="checkbox"/> Unknown Sequelae						
Relevant medical conditions such as allergies, renal disease, liver disease, other chronic diseases, pregnancy etc						
Reported by: Name -----	Profession: -----	Email address: -----			Telephone -----	
Name of health institution					Date	

Product quality problem: Color change, separating of components, powdering, crumbling, caking, molding, change of odor, incomplete pack, suspected contamination, poor packaging/poor labeling, etc (Write if anything different than given above)				
Drug trade name	Batch No	Registration no	Dosage form and strength	Size /type of package
For office use only				
Received on:			Registration no:	
Key: D/M/Y ; Date /Month/Year		D/C; Discontinue treatment		Y;YES N;NO

□□□□□ □□□ □□ □□□

what to report

- All suspected reactions to drugs
- Unknown or unexpected reactions
- Serious adverse drug reactions
- Unexpected therapeutic effects
- All suspected drug interactions
- Product quality problems
- Treatment failures
- Medication errors

This ADE reporting form was prepared by FMHACA in collaboration with MSH/SPS and the financial support from USAID

NB. Drugs includes

- Conventional drugs, Herbal drugs,
- Traditional medicines, Biologicals
- Medical supplies, Medicated cosmetics

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**Regulatory Information Development and
Dissemination Team
P.O.Box 5681-Tel.0115-523142
Addis Ababa, Ethiopia**

APPENDIX X. Standard prescription paper

Annex III: Standard Prescription

PRESCRIPTION PAPER Code _____
 Institution Name: _____ Tel. No... ..
 Patient's full Name: _____
 Sex: ___ Age: ___ Weight: _____ Card No. _____
 Region: _____ Town _____ Woreda _____ Kebele _____
 House No. _____ Tel. No: _____ Inpatient Outpatient
 Diagnosis, if not ICD _____

Drug Name, Strength, Dosage Form, Dose, Frequency, Duration, Quantity, How to use & other information	Price (dispensers use only)
R_x	
Total Price	

Prescriber's Full name _____ Qualification _____ Registration # _____ Signature _____ Date: _____	Dispenser's _____ _____ _____ _____ _____
--	--

See overleaf

Please Note the Following Information

1. Prescriptions:

- are valid only if it has the seal of the health institution
- filled and blank are legal documents, treat them as fixed assets
- written and verbal information to the client complement one another

2. The prescriber:

- drug treatment is only one of the treatment options
- write the prescription correctly and legibly
- diagnosis and other parts of the prescription have to be complete
- abbreviations are NOT recommended
- please accept prescription verification call from the dispenser

3. The Dispenser:

- check legality of the prescription
- check completeness and accuracies before dispensing
- check for whom the medicine is being dispensed: actual client or care taker
- if in doubt about the contents of the prescription; verify with the prescriber
- containers used for packaging must be appropriate for the product
- labels of drugs should be clear, legible and indelible
- drugs should be dispensed with appropriate information and counseling
- keep filled prescriptions at least for 2 years

4. **Minimum drug label information** should include the following:

- Patient name
- Generic name, strength and dosage form of the medicine
- Dose, Frequency and Duration of use of the medicines
- Quantity of the medicine dispensed
- How to take or administer the medicine?
- Storage condition

GLOSSARY

Analgesics - **medicines which relieve pain.**

Antiflatulants - **medicines which expel gases from the stomach or intestine.**

Antipyretics- **medicines which reduce elevated body temperature.**

Central Nervous System (CNS) depressants - **agents which reduce the activity of the brain (e.g. alcohol, phenobarbitone).**

Contraindications - **A sign or symptom suggesting that a certain line of treatment (usually used for that disease) should be discontinued or avoided.**

Drug interactions- **a condition of two or more drug interacting with one another when taken together to produce an undesirable effect such as nullifying the action of the drug or increasing the toxicity.**

Expectorants - **medicines used to assist in the removal of mucus from the trachea, bronchi, or lungs.**

Generic Name or Non-proprietary Name - **the name by which a drug is scientifically and internationally recognized (often by reference to a pharmacological monograph).**

Hemostatic- **an agent that arrests the escape of blood**

Laxative- **a medicines that produces a soft formed stool over a prolonged period.**

Side effects - **any physiological change or undesirable drug reaction other than the desired one, which occurs when a drug is given or administered in therapeutic doses.**

Cautions/Warnings- **refers to careful attention to be taken when giving or administering drugs in the presence of conditions such as some other medical problems, pregnancy, breast-feeding or age of patient e.t.c.**

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