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The following is a list of resourceful Professionals involved in the evaluation of the draft formulary:

Dr. Tilahun Teka, Department of Paediatrics, Faculty of Medicine, Addis Ababa University

Dr. Ephrame Engidawork, Department of Pharmacology, School of Pharmacy, Addis Ababa University.

Dr. Ameha G/Medihen, Department of Internal Medicine, Faculty of Medicine, Addis Ababa University

Dr. Zufan Lakew, Department of Gynecology and Obstetrics, Faculty of Medicine, Addis Ababa University.

Prof. Eyasu Mekonnen, Department of Pharmacology, Faculty of Medicine, Addis Ababa University.

Dr. Dagnachew Shebeshe, Department of Pharmacology, Faculty of Medicine, Addis Ababa University

Mr. Eyob Debebe, Department of Pharmacology, Medical faculty, Addis Ababa University.

Dr. Negussu Mekonnen, Department of Pharmacology, School of Pharmacy, Addis Ababa University.

Dr. Kebrebeal Melaku, Department of Internal Medicine, Faculty of Medicine, Addis Ababa University

Mr. Tenaw Andualem

Dr. Abebe Melaku, Department of paediatrics, Black Lion Hospital

Dr. Zenebe Melaku, Department of paediatrics, Black Lion Hospital

Mr. Teshome Nedi, Department of Pharmacology, School of Pharmacy, Addis Ababa University.



Drugs Formulary for Health Centers

Dr. Minilik Desta ,Medical Director ,Amanuel Hospital, Addis Ababa

Dr. Ayalew Tegegne, Department of Surgery, Faculty of Medicine, Addis Ababa University.

**Editors**

Mr. Abraham G/iyorgis; Pharmacist; Head, Planning, Drug Information establishment and Distribution Department, DACA.

Mr. Wondie Alemu; Pharmacist; Head, Drug Information establishment and Distribution Division, DACA.

Mr.Mengistu Tadesse; Pharmacist; Expert, Drug Information establishment and Distribution Division, DACA.



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## INTRODUCTION

The Drug Administration and Control Authority of Ethiopia recognizing the urgent need for information, appropriate to the different categories of health personnel, particularly to those working in the periphery, has developed this formulary for Health center.

The draft of this formulary was first prepared by the planning, Drug information establishment and distribution department of the Authority. The draft was then sent to different departments of the Authority for comments, and some modifications were made based on the comments and suggestions received. It was then finalized through an organized workshop in October 2003, that participated distinguished professionals in the field of pharmacy and medicine.

The Formulary aims to provide doctors, pharmacists and other healthcare professionals working at Health center level with sound up to date information about the use of medicines. And hence the central goals of the formulary are to help prescribers in the appropriate choice of treatment and to make prescribers follow uniform choice of treatment.

The drug formulary is an extended version of drug list, which offers information on the drugs. This formulary is prepared based on the lists of drugs developed by Drug Administration and Control Authority for Health centers.

Drugs that are generally prescribed at Health center level are included and hence the formulary provides ready access to key information on the selection, prescribing, dispensing and administration of medicines available at Health center level.

The Drugs formulary is designed on Pharmacologic–Therapeutic Classification of Drugs so as to help in relating the pharmacological action of specific drugs. The formulary contains general notes for each pharmacologic class of drugs and specific information for each drug including indication, caution, drug interaction, side effect, contraindication, dose and administration and information on storage condition. The formulary also contains general notes in prescribing practices, and supplementary information under appendixes. About 253 drugs with their 390 dosage forms are included in this formulary.

The formulary 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 substitute manuals for treatment guideline.

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 will also contribute to attaining the betterment of the quality of the health service. It is also hoped that this 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.

**Despite all efforts it is unavoidable that this first edition of the Drugs Formulary for Health center (DFHC) may contain some omissions or errors. All readers are encouraged to send their comments, corrections and suggestions to the Editor of the DFHC; Department of planning, Drug information establishment and distribution; Drug Administration and control Authority; Addis Ababa, Ethiopia, fax 251 - 1 - 521395, P.O.Box 5681, E-mail-daca@telecon.net.et**



## GENERAL ADVICE TO PRESCRIBERS

### RATIONAL APPROACH TO THERAPEUTICS

Drugs should only be prescribed when they are necessary, and in all cases the benefit of administering the medicine should be considered in relation to the risks involved. Bad prescribing habits lead to ineffective and unsafe treatment, exacerbation or prolongation of illness, distress and harm to the patient, and higher cost.

The following steps will help to remind prescribers of the rational approach to therapeutics.

1. **Define the patient's problem**
2. **Specify the therapeutic objective**
3. **Selecting therapeutic strategies**
  - (a) *Non-pharmacological treatment*
  - (b) *Pharmacological treatment*
    - . *Selecting the correct group of drugs*
    - . *Selecting the drug from the chosen group*
    - . *Verifying the suitability of the chosen pharmaceutical treatment for each patient*
    - . *Prescription writing*
    - . *Giving information, instructions and warnings*
    - . *Monitoring treatment*

### VARIATION IN DOSE RESPONSE

Success in drug treatment depends not only on the correct choice of drug but on the correct dose regimen. Unfortunately drug treatment frequently fails because the dose is too small or produces adverse effects because it is too large. This is because most texts, teachers and other drug information sources continue to recommend standard doses.

The concept of a standard or 'average' adult dose for every medicine is firmly rooted in the mind of most prescribers. After the initial 'dose ranging' studies on new drugs, manufacturers recommend a dosage that appears to produce the desired response in the majority of subjects. These studies are usually done on healthy, young male Caucasian volunteers, rather than on older men and women with illnesses and of different ethnic and environmental backgrounds. The use of standard doses in the marketing literature suggest that standard responses are the rule, but in reality there is considerable variation in drug response. As a result many prescribed doses are far too low or too high, leading to treatment failure or toxicity. There are many reasons for this variation which include adherence (see below), drug formulation, body weight and age, composition, variation in absorption, distribution, metabolism and



excretion, variation in pharmacodynamics, disease variables, genetic and environmental variables.

### **Drug formulation**

Poorly formulated drugs may fail to disintegrate or to dissolve. Enteric-coated drugs are particularly problematic, and have been known to pass through the gastrointestinal tract intact. Some drugs like digoxin or phenytoin have a track record of formulation problems, and dissolution profiles can vary not only from manufacturer to manufacturer but from batch to batch of the same company. The problem is worse if there is a narrow therapeutic to toxic ratio, as changes in absorption can produce sudden changes in drug concentration. For such drugs quality control surveillance should be carried out.

### **Body weight and age**

Although the concept of varying the dose with the body weight or age of children has a long tradition, adult doses have been assumed to be the same irrespective of size or shape. Yet adult weights vary two to threefold, while a large fat mass can store large excesses of highly lipid soluble drugs compared to lean patients of the same weight.

Age changes can also be important. Adolescents may oxidize some drugs relatively more rapidly than adults, while the elderly may have reduced renal function and eliminate some drugs more slowly.

### **Physiological and pharmacokinetic variables**

Drug absorption rates may vary widely between individuals and within the same individual at different times and in different physiological states. Drugs taken after a meal are delivered to the small intestine much more slowly than in the fasting state, leading to much lower drug concentrations. In the case of drugs like paracetamol with a high rate of metabolism on 'first pass' through the liver, this may render a standard dose completely ineffective. In pregnancy gastric emptying is also delayed, while some drugs may increase or decrease gastric emptying and affect absorption of other drugs.

### **Drug distribution**

Drug distribution varies widely: fat soluble drugs are stored in adipose tissue, water soluble drugs are distributed chiefly in the extracellular space, acidic drugs bind strongly to plasma albumin and basic drugs to muscle cells. Hence variation in plasma albumin levels, fat content or muscle mass may all contribute to dose variation. With very highly albumin bound drugs like warfarin, a small change of albumin



concentration can produce a big change in free drug and a dramatic change in drug effect.

### **Drug metabolism and excretion**

Drug metabolic rates are determined both by genetic and environmental factors. Drug acetylation shows genetic polymorphism, whereby individuals fall clearly into either fast or slow acetylators types. Drug oxidation, however, is polygenic, and although a small proportion of the population can be classified as very slow oxidizers of some drugs, for most drugs and most subjects there is a normal distribution of drug metabolizing capacity, and much of the variation is under environmental control. Many drugs are eliminated by the kidneys without being metabolized. Renal disease or toxicity of other drugs on the kidney can therefore slow excretion of some drugs.

### **Pharmacodynamic variables**

There is significant variation in receptor response to some drugs, especially central nervous system responses, for example pain and sedation. Some of this is genetic, some due to tolerance, some due to interaction with other drugs and some due to addiction, for example, morphine and alcohol.

### **Disease variables**

Both liver disease and kidney disease can have major effects on drug response, chiefly by the effect on metabolism and elimination respectively (increasing toxicity), but also by their effect on plasma albumin (increased free drug also increasing toxicity). Heart failure can also affect metabolism of drugs with rapid hepatic clearance (for example lidocaine, propranolol). Respiratory disease and hypothyroidism can both impair drug oxidation.

### **Environmental variables**

Many drugs and environmental toxins can induce the hepatic microsomal enzyme oxidizing system (MEOS) or cytochrome P450 oxygenases, leading to more rapid metabolism and elimination and ineffective treatment. Environmental pollutants, anaesthetic drugs and other compounds such as pesticides can also induce metabolism. Diet and nutritional status also impact on pharmacokinetics. For example in infantile malnutrition and in malnourished elderly populations drug oxidation rates are decreased, while high protein diets, charcoal cooked foods and certain other foods act as metabolizing enzyme inducers. Chronic alcohol use induces oxidation of other drugs, but in the presence of high circulating alcohol concentrations drug metabolism may be inhibited.



## ADHERENCE (COMPLIANCE) WITH DRUG TREATMENT

It is often assumed that once the appropriate drug is chosen, the prescription correctly written and the medication correctly dispensed, that it will be taken correctly and treatment will be successful. Unfortunately this is very often not the case, and physicians overlook one of the most important reasons for treatment failure—poor adherence (compliance) with the treatment plan.

There are sometimes valid reasons for poor adherence—the drug may be poorly tolerated, may cause obvious adverse effects or may be prescribed in a toxic dose. Failure to adhere with such a prescription has been described as ‘intelligent noncompliance’.

Bad prescribing or a dispensing error may also create a problem, which patients may have neither the insight nor the courage to question. Even with rational prescribing, failure to adhere to treatment is common. Factors may be related to the patient, the disease, the doctor, the prescription, the pharmacist or the health system and can often be avoided.

The Following points are recommended to increase patient compliance

- ✓ Review the prescription to be sure it is correct.
- ✓ Spend time explaining the problem and the reason for the drug.
- ✓ Establish a good relationship with the patient, rather than a hurried or brusque manner with little eye contact.
- ✓ Explore problems, for example reading the label, getting the prescription filled.
- ✓ Insist that patients bring their medication to the clinic ‘for checking’, so that tablet counts can be made unobtrusively.
- ✓ Insist that patients learn the names of their tablets, and review their regimen with them. Write notes for them.
- ✓ Keep treatment regimens simple.
- ✓ Communicate with the pharmacist, to develop teamwork and collaboration in helping and advising the patient.
- ✓ Involve the partner or another family member,
- ✓ Listen to the patient.



## ADVERSE EFFECTS AND INTERACTIONS

### Adverse drug reactions

An adverse drug reaction (ADR) may be defined as ‘any response to a drug which is noxious, unintended and occurs at doses normally used for prophylaxis, diagnosis, or therapy. . .’

ADRs are therefore unwanted or unintended effects of a medicine, including idiosyncratic effects, which occur during its proper use. They differ from accidental or deliberate excessive dosage or drug maladministration.

Any drug may produce unwanted or unexpected adverse reactions. Detection and recording of these is of vital importance. Doctors and pharmacists are urged to help by reporting adverse reactions to:

**Drug Administration and Control Authority of Ethiopia**

**Planning, Drug information establishment and distribution department**

**P.o.Box 5681**

**Fax. 251-1-524122**

**E-mail: [daca@telecom.net.et](mailto:daca@telecom.net.et)**

### Major factors predisposing to adverse effects

It is well known that different patients often respond differently to a given treatment regimen. For example, in a sample of 2422 patients who had been taking combinations of drugs known to interact, only 7 (0.3%) showed any clinical evidence of interactions. In addition to the pharmaceutical properties of the drug therefore, there are characteristics of the patient which predispose to ADRs.

**EXTREMES OF AGE.** The very old and the very young are more susceptible to ADRs. Drugs which commonly cause problems in the elderly include hypnotics, diuretics, non-steroidal antiinflammatory drugs, antihypertensives, psychotropics and digoxin.

All children, and particularly neonates, differ from adults in the way they respond to drugs. Some drugs are likely to cause problems in neonates (for example **morphine**), but are generally tolerated in children. Other drugs (for example **valproic acid**) are associated with increased risk of ADRs in children of all ages. Other drugs associated with problems in children include **chloramphenicol** (grey baby syndrome), **antiarrhythmics** (worsening of arrhythmias), **aspirin** (Reye syndrome).

**INTERCURRENT ILLNESS.** If besides the condition being treated the patient also suffers from another disease, such as kidney, liver or heart disease, special precautions are necessary to prevent ADRs. Remember also that, as well as the above factors, the genetic make-up of the individual patient may predispose to ADRs.



**DRUG INTERACTIONS.** Interactions may occur between drugs which compete for the same receptor or act on the same physiological system. They may also occur indirectly when a drug-induced disease or a change in fluid or electrolyte balance alters the response to another drug. Interactions may occur when one drug alters the absorption, distribution or elimination of another drug, such that the amount which reaches the site of action is increased or decreased. Drug-drug interactions are some of the commonest causes of adverse effects. When two drugs are administered to a patient, they may either act independently of each other, or interact with each other. Interaction may increase or decrease the effects of the drugs concerned and may cause unexpected toxicity. As newer and more potent drugs become available, the number of serious drug interactions is likely to increase. Remember that interactions which modify the effects of a drug may involve non-prescription drugs, non-medicinal chemical agents, and social drugs such as **alcohol, marijuana, and traditional remedies**, as well as certain types of food. The physiological changes in individual patients, caused by such factors as age and gender, also influence the predisposition to ADRs resulting from drug interactions.

#### **Incompatibilities between drugs and IV fluids**

Drugs should not be added to blood, amino acid solutions or fat emulsions. Certain drugs, when added to IV fluids, may be inactivated by pH changes, by precipitation or by chemical reaction. **Benzympenicillin** and **ampicillin** lose potency after 6– 8 hours if added to dextrose solutions, due to the acidity of these solutions. Some drugs bind to plastic containers and tubing, for example **diazepam** and **insulin**. **Aminoglycosides** are incompatible with **penicillins** and **heparin**. **Hydrocortisone** is incompatible with **heparin, tetracycline,** and **chloramphenicol**.

#### **Adverse effects caused by traditional medicines**

Patients who have been or are taking traditional herbal remedies may develop ADRs. It is not always easy to identify the responsible plant or plant constituent. Refer to the drug and toxicology information service if available and/or to suitable literature.

#### **The effect of food on drug absorption**

Food delays gastric emptying and reduces the rate of absorption of many drugs; the total amount of drug absorbed may or may not be reduced. However, some drugs are preferably taken with food, either to increase absorption or to decrease the irritant effect on the stomach.



## PRESCRIPTION WRITING

A prescription is an instruction from a prescriber to a dispenser. The prescriber is not always a doctor but can also be a paramedical worker, such as a medical assistant, a midwife or a nurse. The dispenser is not always a pharmacist, but can be a pharmacy technician, an assistant or a nurse.

The following guidelines will help to ensure that prescriptions are correctly interpreted and leave no doubt about the intention of the prescriber. The guidelines are relevant for primary care prescribing; they may, however, be adapted for use in hospitals or other specialist units.

### Prescription form

The most important requirement is that the prescription be clear. It should be legible and indicate precisely what should be given. The local language is preferred.

The following details should be shown on the form:

- ⌘ The prescriber's name, address and telephone number. This will allow either the patient or the dispenser to contact the prescriber for any clarification or potential problem with the prescription.
- ⌘ Date of the prescription.
- ⌘ Name, form and strength of the drug. The International Nonproprietary Name of the drug should always be used. If there is a specific reason to prescribe a special brand, the trade name can be added. The pharmaceutical form (for example 'tablet', 'oral solution', 'eye ointment') should also be stated.
- ⌘ The strength of the drug should be stated in standard units using abbreviations that are consistent with the *Système Internationale* (SI). 'Microgram' and 'nanogram' should not, however, be abbreviated. Also, 'units' should not be abbreviated. Avoid decimals whenever possible. If unavoidable, a zero should be written in front of the decimal point.
- ⌘ Specific areas for filling in details about the patient including name, address and age.

### Directions

Directions specifying the route, dose and frequency should be clear and explicit; use of phrases such as 'take as directed' or 'take as before' should be **avoided**. For preparations which are to be taken on an 'as required' basis, the minimum dose interval should be stated together with, where relevant, the maximum daily dose. It is good practice to qualify such prescriptions with the purpose of the medication (for example 'every 6 hours as required for pain', 'at night as required to sleep').



It is good practice to explain the directions to the patient; these directions will then be reinforced by the label on the medicinal product and possibly by appropriate counseling by the dispenser. It may be worthwhile giving a written note for complicated regimens although it must be borne in mind that the patient may lose the separate note.

#### **Quantity to be dispensed**

The quantity of the medicinal product to be supplied should be stated such that it is not confused with either the strength of the product or the dosage directions.

Alternatively, the length of the treatment course may be stated (for example 'for 5 days').

Wherever possible, the quantity should be adjusted to match the pack sizes available.

For liquid preparations, the quantity should be stated in millilitres (abbreviated as 'ml') or litres (preferably not abbreviated since the letter 'l' could be confused with the figure '1').

#### **Narcotics and controlled substances**

The prescribing of a medicinal product that is liable to abuse requires special attention and may be subject to specific statutory requirements. Practitioners may need to be authorized to prescribe controlled substances; in such cases it might be necessary to indicate details of the authority on the prescription. In particular, the strength, directions and the quantity of the controlled substance to be dispensed should be stated clearly,

with all quantities written in words as well as in figures to prevent alteration. Other details such as patient particulars and date should also be filled in carefully to avoid alteration.





## 1.DRUGS ACTING ON THE GASTROINTESTINAL SYSTEM

### 1.1.Antacids

Antacids are basic compounds which neutralize hydrochloric acid in the gastric secretions.

They are used to prevent and relieve pain in the symptomatic management of gastro-intestinal disorders associated with gastric hyperacidity such as dyspepsia, gastro-oesophageal reflux disease, and peptic ulcer.

#### **Aluminium - and/or Magnesium containing antacids**

Several basic compounds are employed as antacids, notably aluminium salts and magnesium salts, calcium carbonate, and sodium bicarbonate. They are normally given between meals and at bedtime when symptoms will usually occur, the presence of food in the stomach can prolong the neutralizing activity.

Aluminium salts tend to produce constipation and to delay gastric emptying because of its astringent property, while magnesium salts have the reverse effect; a combination of the two 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.

Antacids interfere with the gastro-intestinal absorption of a number of other 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 re-absorption (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.



**Aluminium Hydroxide***Mixture or Gel, 320 mg/ml.**Suspension, 360 mg/5 ml.***Indications:** ulcer and non ulcer dyspepsia; gastro-oesophageal reflux**Cautions:** see notes above, hepatic impairment, gastrointestinal disorders associated with decreased bowel motility or obstruction.**Drug interactions:** - see notes above**Side effects:** - see notes above, hypophosphataemia with increased bone resorption, hypercalciuria and risk of osteomalacia (patients on low phosphate diet or prolonged therapy)**Contraindications:** - hypophosphataemia, undiagnosed gastrointestinal or rectal bleeding; appendicitis; porphyria.**Dose and Administration:** - *oral*, shake the bottle well before use. 10 ml (2 teaspoonfuls) every 6 hours usually after meals and at bedtime, or as required.**Storage:** - at room temperature, avoid freezing.**Aluminium Hydroxide and Magnesium Hydroxide\****Suspension - Each 5 ml contains**Aluminium Hydroxide .....220 mg**Magnesium Hydroxide .....200 mg*

Indications, Cautions, Drug Interaction, Side effect, and Contraindications, Storage; see note above

**Dose and Administrations:** - *Oral*, shake the bottle well before use. 10 ml (2 teaspoonfuls) every 6 hours usually after meals and at bedtime, or as required.**Aluminium Hydroxide and Magnesium Trisilicate\****Tablets - Aluminium Hydroxide .....120 mg**-Magnesium Trisilicate .....250 mg**Suspension - Each 5 ml contains**Aluminium Hydroxide .....220 mg**Magnesium Trisilicate .....620 mg*

Indications, Side effect, Drug interaction, Cautions, and Contraindications, Storage; see note above

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

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



**Magnesium Hydroxide***Tablet (chewable), 300 mg - 311 mg**Mixture, 375 mg/5ml, 7.75 %***Indications:** - ulcer and non-ulcer dyspepsia; gastro-oesophageal reflux.**Cautions** - see notes above, hepatic impairment**Contraindications, Drug interactions, Storage;** see notes above**Side effects:** - diarrhoea**Dose and administration:** - *Oral*,

Tablet, Adult, *Chew* 2 - 4 tablets repeated according to patients needs with maximum daily dose of 16 tablets. Children (7-14 years) one tablet with maximum of 4 tablets per day.

Mixture, Adult 5 -15 ml repeated according to patient's needs with maximum daily dose of 60 ml.

**Magnesium Trisilicate***Tablet (Chewable) - 500 mg***Indications, Contraindications, Cautions, Drug interactions, Storage;** see notes under magnesium hydroxide**Side effects:** - see notes above; silica renal stones; diarrhoea**Dose and Administration** - *Oral*, Chew 2 tablets as required before swallowing.

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**1.2. Antispasmodics/spasmolytic Analgesics**

The Smooth muscle relaxant properties of anti-muscarinic (formerly termed 'anticholinergics') and other antispasmodic drugs (e.g Camylofin Hydrochloride) 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 **Atropine sulphate** and **Hyoscine (Scopolamine) Hydrobromide** and the quaternary ammonium compounds **Hyoscine (Scopolamine) Butylbormide**. Antimuscarinics are commercially available in combination with Phenothiazines, or benzodiazepines or other anxiolytics (e.g. **chlordiazepoxide + clidinium Bromide**) for the benefit of its supportive role in patients with irritable bowel Syndrome who respond to sedatives or in some patients with peptic ulcer disease.

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 & down syndrome, and also in patients with hyperthyroidism, hepatic or renal disease, or hypertension, tachyarrhythmias, congestive heart failure, or coronary artery disease; autonomic neuropathy, gastroesophageal reflux, known or suspected GI infections, diarrhea & 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 or toxic megacolon complicating ulcerative colitis, obstructive disease of the GI tract, cardiospasm, paralytic ileus, or intestinal atony, known hypersensitivity to the drugs, angle-closure glaucoma, obstructive uropathy (caution for patients with partial obstructive uropathy) & myasthenia gravis (unless the antimuscarinic is used to reduce adverse muscarinic effects of an anticholinesterase agent).

Antimuscarinics may interact with antacids or antidiarrheals (adsorbent) (-reduce absorption of anticholinergics), anticholinergics or other medications with anticholinergic activity, cyclopropane (-result in ventricular arrhythmias), Ketoconazole (reduction in ketoconazole absorption) & potassium chloride (increase severity of potassium chloride induced - gastrointestinal lesions).

### **Atropine Sulphate**

*Injection, 1 mg/ml in 1 ml ampoule*

**Indications:** - dyspepsia, irritable bowel syndrome, diverticular disease; premedication; mydriasis and cycloplegia; poisoning (section 17); see also notes above

**Cautions:** - see notes above

**Drug interactions, Contraindications, Side effects;** see notes above

#### **Dose and Administration**

Adults - *IM, S.C., I.V.* - 0.4 - 0.6 mg. every four to six hours.

Children - *SC* - 0.01 mg/kg of body weight, not to exceed 0.4 mg, every for to six hours.

**Storage:** - at room temperature, protect from freezing.

### **Chlordiazepoxide + Clidinium Bromide**

*Tablet, 5 mg + 2.5 mg*

**Indications:** - used in the treatment of functional disturbances of GI motility such as irritable bowel syndrome, see also notes above.

**Cautions, Contraindications, Side effect, Drug interactions** - see notes above. The precautions and contraindications associated with chlordiazepoxide must be considered.



**Dose and Administration:** -The usual adult dose - one or two tablets 3 or 4 times daily (i.e. 2.5 or 5 mg of Clidinium bromide 3 or 4 times a day)

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

### **Hyoscine (scopolamine) Hydrobromide**

*Tablet, 0.6 mg*

*Injection, 0.4 mg/ml, 0.6 mg/ml in 1 ml 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; see also notes above. Not indicated for peptic ulcer.

Note: - Hyoscine Butylbromide is preferable to Hyoscine hydrobromide in the relief of visceral spasms of the gastro-intestinal tract and pain associated with other smooth muscle spasm. (See below)

**Cautions, Contraindications, Side effects;** see notes above

**Drug interactions:** - CNS depressants; see notes above

### **Dose and Administration**

*IM, IV, or SC,* Adults: 0.3 to 0.6 mg; if necessary, the dose may be repeated 3 or 4 times daily. Children: 0.006 mg/kg or 0.2 mg/m<sup>2</sup>.

*Oral,* Adult: 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. Children - aged 4 to 10 years 75 to 150 mg and those over 10 years, 150 to 300 mg.

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

### **Hyoscine (Scopolamine) Butylbromide**

*Tablet, 10 mg*

*Drops, 5mg/5ml*

*Injection, 20 mg/ml*

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

**Cautions, Contraindications, Side effect, Storage;** see notes above

**Drug interactions:** - CNS depressants, see also notes above.

### **Dose and Administrations**

*Oral,* 20mg four times daily; child 6-12 years, 10mg 3 times daily.

*IM or IV,* 20 mg repeated after 30 minutes if necessary. Child not recommended.

### **Camylofin Hydrochloride**

*Tablet, 50 mg*

*Oral solution, 100 mg/ml*

**Indications:** -used as antispasmodic in doses of 30 to 100 mg 2 - 3 times daily. It is usually given in combination with other agents.



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### 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.

Antiemetics described here include: the dopamine antagonists metoclopramide and chlorpromazine hydrochloride; antihistamines such as dimenhydrinate, meclizine hydrochloride & promethazine hydrochloride; and the phenothiazine thiethylperazine maleate.

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 HT<sub>3</sub> antagonist and ondansetron.

The antihistamines may be slightly less effective than hyoscine against motion sickness but are often tolerated.

There is no evidence that any one antihistamine is superior to another but their duration of action and incidence of adverse effects (drowsiness, and antimuscarinic effects) differ. For example dimenhydrinate causes drowsiness more frequently; meclizine has a longer duration of action than scopolamine and most other antihistamines.

If a sedative effect is desired promethazine is useful.

A popular choice of antiemetic is metoclopramide which is effective against nausea and vomiting following surgery and chemotherapy and is also effective against radiation - induced nausea and vomiting. Combining metoclopramide with corticosteroids (such as Dexamethasone) can improve its antiemetic effect in chemotherapy - induced nausea and vomiting. 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 unnecessarily and some times harmful when the cause can be treated, e.g. as in diabetic ketoacidosis, or in excessive digoxin or antiepileptic dosage.



**Meclizine Hydrochloride**

*Tablet, 12.5 mg, 25 mg*

**Indications:** -for the prevention and treatment of nausea, vomiting and/or vertigo associated with motion sickness; see also notes above.

**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. See also Interactions.

**Drug interactions:** - alcohol, CNS depressants including barbiturates, tranquilizers.

**Side effects:** - drowsiness, fatigue and rarely blurred vision, dryness of mouth, nose and throat.

**Contraindications:** - in patients who are hypersensitive to it.

**Dose and Administration**

Adults & Children (>12 years of age): -

Motion sickness (prophylaxis & treatment) - *Oral*, 25 to 50 mg one hours before travel. Dose may be repeated every twenty-four ours as needed.

Vertigo (prophylaxis and treatment)- *Oral*, 25 to 100 mg a day as needed; in divided doses.

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

**Dimenhydrinate**

*Tablet, 50 mg*

**Indications:** - see under Meclizine Hydrochloride

**Cautions:** - patients should be cautioned against performing hazardous activities requiring mental alertness or physical condition; prolonged therapy may produce blood dyscrasia; in patients in whom anticholinergics may aggravate other clinical conditions (e.g angle-closure glaucoma, enlargement of the prostate gland); risk-benefit should be considered for the use of the drug to pregnant and nursing mothers; see also interactions.

**Drug interactions:** -alcohol, CNS depressants such as barbiturates, drugs with anticholinergic effects including tricyclic antidepressants, ototoxic drugs such as aminoglycoside antibiotics (Dimenhydrinate may mask the early symptoms of ototoxicity).

**Side effects:** - drowsiness (if it is excessive, dosage should be reduced), paradoxical excitement in children and occasionally in adults, headache lassitude, tinnitus, blurred vision, dryness of mouth and respiratory passage ways, palpitation, dizziness and hypotention.

**Dose and Administration**

Adults, *Oral*, 50 to 100 mg every four to six hours. Children (6-12 Years of age) - oral, 25 to 50 mg every six to eight hours as needed, not to exceed 150 mg per day. Children (2-6 years of age), *Oral*, 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 motion

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

### **Promethazine Hydrochloride**

*Tablets, 10 mg, 25 mg*

*Elixir, 5mg/5 ml.*

*Suppository, 25 mg, 50 mg*

*Injection, 25 mg/ml in 1 ml and 2 ml ampoules*

**Indications:** - control of nausea, vomiting, and vertigo of various cause, as a sedative and hypnotic, and as a common ingredient of cough and cold preparations; also see notes above.

**Cautions:** - see under Meclizine Hydrochloride, intravenous injection of promethazine hydrochloride must be given slowly and extreme care must be taken; should not be given by subcutaneous injection, avoid in porphyria.

**Drug interactions:** - see under Meclizine hydrochloride; epinephrine, extrapyramidal reaction causing medications, levodopa, metrizamide and monoamine oxidase (MAO) inhibitors including furazolidone, procarbazine, and selegiline.

**Side effects:** see under Meclizine Hydrochloride, and blood dyscrasias, sedative effect is more pronounced.

**Contraindications:** - patients who have exhibited hypersensitivity to the drug; also in those who have received large doses of CNS depressants and/or in those who are comatose, in epileptic seizures.

### **Dose and Administration**

*Antiemetic,*

**Oral,** Adult, 25 mg initially, then 10 to 25 mg every 4 - 6 hours as needed.

Note: For motion sickness, the initial 25 mg dose should be taken one half to one hour before travel, and the dose repeated 8 - 12 hours later, if necessary.

Children (>2 years of age); 0.25 to 0.5 mg per kg of body weight every 4 to 6 hours or 10 to 25 mg every four to six hours as needed.

**IM or IV,** Adults, 12.5 to 25 mg every 4 hours as needed. Children (> 2 years of age); 0.25 to 0.5 mg per kg of body weight every 4 to 6 hours as needed.

**Rectal,** Adult, 25mg initially, then 12.5 to 25mg every 4 to 6 hours as needed. Children (> 2 years of age); 0.25 to 0.5mg per kg of body weight, or 12.5 to 25mg every 4 to 6 hours as needed.

*Antivertigo agent,*

**Oral,** Adult, 25mg 2 times a day as needed. Children (> 2 years of age), 0.5mg to 1mg per kg of body weight or 10 to 25mg 2 times a day as needed.

**Rectal,** Adult, 25mg 2 times a day as needed. Children (> 2 years of age), 0.5mg per kg of body weight, or 12.5 to 25mg 2 times a day as needed.



**Storage:** - Suppositories: store between 2 and 8°C, in a tight, light-resistant container. Tablet & Injection - at room temperature protect from light & from freezing

### **Metoclopramide Hydrochloride**

*Tablet: 10 mg, 25 mg*

*Suppository, 25 mg, 50 mg*

*Drop, 5 mg/ml*

*Injection, 25 mg/ml in 1 ml and 2 ml ampoule*

**Indications:** -nausea and vomiting in gastrointestinal disorders and treatment with cytotoxics or radiotherapy; gastro-oesophageal reflux, gastroparesis; pre-medication and postoperatively, aid to gastrointestinal intubation, nausea and vomiting in migraine; see also notes above

Note: In children (and in some countries, patients under 20 years); use is restricted to severe intractable vomiting of known cause, vomiting of radiotherapy and chemotherapy, aid to gastrointestinal intubations; pre-medication.

**Cautions:** -elderly, children and young adults; hepatic & 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; see also interactions.

**Drug interactions:** - alcohol, CNS depressants

**Side effects:** -extrapyramidal symptoms, tardive dyskinesia on prolonged use; hyperprolactinaemia; drowsiness, restlessness, dizziness, headache, diarrhoea, depression, hypotension and hypertension reported; rarely neuroleptic malignant syndrome; cardiac conduction abnormalities following IV administration.

**Contraindications:** - epilepsy; gastrointestinal hemorrhage, mechanical obstruction or perforation; pheochromocytoma.

### **Dose and administration**

Nausea and vomiting, gastro-oesophageal reflux, gastroparesis: -

Adult; *Orally, or IM, or slow IV injection*; Adult 10 mg 3 times daily; young adult 15 - 19 years (under 60 kg) 5 mg 3 times daily; child 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)

Pre-medication, *by slow I.V.*, Adults 10 mg as a single dose.

Aid to gastrointestinal intubation, *Orally, or IM or by Slow intravenous injection*, 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.



**Chlorpromazine Hydrochloride**

*Tablet, 25 mg, 50mg, 100 mg*

*Syrup, 25 mg/5 ml*

*Drop, 25 mg/ml*

*Injection, 25 mg/ml in 1 and 2 ml ampoules*

**Indications:** - for the prevention and control of severe nausea and vomiting, other indications (see section 4.2)

Note: It should not be used for motion sickness

**Cautions:** - liver diseases, alcoholics, hypersensitivity, or in children, elderly or weak patients, during pregnancy and breast-feeding. It has a sedative effect. Advise patients to avoid driving and operating machines.

**Drug interactions:** - alcohol, adrenaline, piperazine, antacids, phenobarbitone or other CNS depressants.

**Side effects:** - drowsiness, postural hypotension, dry mouth, nasal congestion, may occur commonly.

**Contraindications:** - severe central nervous system depression, or severe cardiovascular diseases and hypotension.

**Dose and Administration:** -

**Adults:** *Oral*, 12.5 –25mg every 4 – 6 hours, as necessary.

*Slow, deep I.M.*, 25 mg as a single dose, the dosage being increased to 25 – 50mg every 3 – 4 hours until vomiting stops; it is then given orally if necessary.

**Children (6 month and over):** *Oral or slow, deep I.M.*, 0.55mg/kg every 6 – 8 hour as necessary.

Note: Patients should remain lying down for at least 30 minutes after injection.

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

Do not use if solution is markedly discolored or if a precipitate is present.

**Thiethylperazine Maleate**

*Tablet, 6.5 mg*

*Suppository, 6.5 mg*

*Injection, 6.5 mg 1 ml in 1 ml ampoule*

**Indications:** -for the control of nausea and vomiting of various etiologies.

**Cautions:** -caution should be taken in patients with extrapyramidal effects; children, pregnancy, elderly and breast-feeding. Advise patients not to drive vehicles and operate machineries.

**Drug interactions:** - alcohol, antacids, adrenaline, levodopa, quinidine, extrapyramidal reaction causing medications, Anticholinergics, barbiturates or other CNS depressants.

**Contraindications:** -severe cardiovascular disease, severe CNS depression, in comatose state and in those patients who have exhibited hypersensitivity reaction (example Dyscarsia, jaundice) to phenothiazine.



**Side effects:** - drowsiness or dizziness, dryness of the mouth, nose and throat, CNS depression, postural hypotension, seizures, headache, fever, blurred vision, tinnitus, peripheral edema of the arm, hands and the face.

**Dose and Administration:** -

Adults: *Orally, Rectally, IM* - 10mg 1-3 times a day.

Children - safety and efficacy has not been established

Elderly - see adult dose.

**Storage:** -Thiethylperazine Maleate should be protected from light. It should be stored in tight, light-resistant container at room temperature

#### 1.4.Cathartics and Laxative

Cathartic, laxative and purgative are terms describing drugs that promote evacuation of the intestine; the difference between the terms is largely one of degree. Cathartic and purgative are interchangeable terms describing drugs that promote rapid evaluation of the intestine and noticeable alteration of stool consistency. The evacuant action of a laxative is less pronounced, but large doses of a laxative may produce catharsis or purgation. Cathartic, laxative and purgative drugs will be referred to as laxatives.

Laxatives available at health center level are usually subdivided into several categories including the bulk forming laxatives such as cellulose derivatives, psyllium preparations; stimulant laxatives (contact laxatives) include anthraquinone-containing agents such as **senna & cascara**, diphenylmethane derivatives such as **bisacodyl** and also other miscellaneous agent such as **castor oil**, osmotic laxatives such as **Glycerin**, and the lubricant laxative liquid paraffin.

Bulk forming laxatives which relieve constipation by increasing faecal mass and stimulating 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. 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. Powerful stimulants such as cascara and castor oil are obsolete.



Faecal softeners such as liquid paraffin, which is the classical lubricant, lubricate and soften impacted faeces.

Osmotic laxatives act by retaining fluid in the bowel by osmosis or by changing the pattern of water distribution in the faeces.

### **Bisacodyl**

*Tablet, 5 mg*

*Suppository 5 mg, 10 mg*

**Indications:** - constipation and for bowel evacuation.

**Cautions:** -care should be taken in patients with 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.

**Side effects:** - see notes above; and abdominal discomfort (such as colic or cramp); gripping (tablets); local irritation (suppositories).

**Contraindications:** -appendicitis, rectal bleeding, congestive heart failure, hypertension, diabetes mellitus, intestinal obstruction or undiagnosed abdominal symptoms; see also notes above

#### **Dose and Administration:**

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

**Rectal:** Adults and children (>12 years) - 10mg daily as a single dose. Children 2-11 years, 5-10mg daily given as a single dose. Children (< 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.

-Swallow the enteric-coated bisacodyl whole and not crushed to avoid gastric irritation.

-Take each dose with a full glass of water or other liquid.

-Rectal bisacodyl suppositories and enemas may be administered at the time a bowel movement is desired.

**Storage:** -store 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; see also notes above.

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

**Contraindications:** - see notes under bisacodyl

**Dose and Administrations:** - *Orally*



Adults and children (10 years and over) - 0.3 - 1g, usually at bedtime. A laxative effect usually occur 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.

### **Senna**

*Tablet (total sennosides), 7.5 mg*

**Indication:** -constipation and bowel evacuation,

**Cautions, Contraindications** - see under cascara sagrada

#### **Dose and Administrations**

Adult, *orally*, 15 - 30 mg, as a single dose at bedtime. Children (over 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

### **Castor oil**

**Indications:** to facilitate defecation in geriatric patients with diminished colonic motor response; constipation occurring secondary to idiopathic slowing of transit time, to constipating drugs or to irritable bowel or spastic colon syndrome; neurologic constipation and to empty the bowel prior to surgery or radiologic proctoscopic or sigmoidoscopic procedure.

**Cautions:** – avoid prolonged use, and use in children up to six years of age; elderly patient.

**Drug interactions:** potassium sparing diuretics, potassium supplements.

**Side effects:** - abdominal discomfort, nausea, mild cramp, gripping or faintness, excessive irritation of the colon, violent purgation.

**Contraindications:** - pregnancy, acute abdominal pain, nausea, vomiting or other symptoms of appendicitis or undiagnosed abdominal pain, intestinal obstruction.

**Dose and administration:** - *Orally*,

Constipation, Adult, 15 ml daily; Child (< 2 years) - 1-5 ml daily, (> 2 years)- 5 - 15 ml daily.

**For total colonic evacuation prior to surgery or radiologic sigmoidoscopic or proctopic procedure administered as a single dose about 16 hours before the procedures.**

Adults and children ( $\geq 12$  years): 15 - 60 ml; Children - 2 - 11 years: 5 - 15 ml; (< 2 years): 1 - 5 ml.

Note: – Drink increased fluid. Take each dose with a full glass of water or other liquid.

**Storage:** -at room temperature in a tight container and in dry place. Protect from freezing



**Glycerin (Glycerol)***Suppository, 1 g, 1.346 g, 2 g, 2.76 g***Indications:** -constipation, especially in children.**Cautions:** -avoid habitual use.**Side effects:** -rectal discomfort such as irritation, burning and pain may occur rarely.**Dose and Administration:** *Rectally.*

The suppositories should be moistened with water before insertion.

Adults: 2 – 4g suppository. Children: 2g suppository. Infants: 1g suppository.

**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.

Note: should not be taken immediately before going to bed.

**Drug interactions:** - avoid concomitant administration of the oil with fat soluble vitamins (A,D,E,K), carotene, oral contraceptive, coumarin and indandione derivative anticoagulants.**Contraindications:** - acute abdominal pain, nausea, vomiting or other symptoms of appendicitis or undiagnosed abdominal pain. Also contraindicated in children younger than 3 years old.**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** - *orally*, 5-20ml, when required.**Storage** - at room temperature and protect from freezing.**Psyllium***Powder***Indications:** - constipation that occurs following bed rest or hospitalization.**Cautions:** - avoid prolonged use. Adequate fluid should be taken to avoid intestinal obstruction.**Drug interactions:** - anticoagulants, digitalis glycosides, and salicylates.**Contraindications:** - appendicitis, rectal bleeding, congestive heart failure, intestinal obstruction, esophageal obstruction (dysphagia).**Side effects:** - allergies to some vegetable components (difficulty in breathing, skin rash or itching), esophageal blockage or intestinal impaction.

**Dose and Administration** - *Orally*, Adults and children - 12 years and older - 30gm given daily in divided doses of 2.5 - 7.5gm per dose; Children 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.

### 1.5. Agents used in Diarrhea

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 for treatment aimed at the underlying disorder will often alleviate the diarrhea.

The main groups of antidiarrhoeal agents are the drugs which reduce intestinal motility such as Diphenoxylate, and Loperamide, and the adsorbents (such as attapulgitte and kaolin which may absorb bacterial toxins and act as mucosal protectants); these drugs are not available at Health center level. Bulk laxatives (see section 1.4) may also be used in the symptomatic treatment of diarrhoea.

#### Oral Rehydration salt

*Powder -each sachet for 1 liter contains*

*Sodium chloride ..... 3.5gm*

*Trisodium citrate Dihydrate ..... 2.9gm*

*Potassium chloride ..... 1.5gm*

*Glucose .....20.0gm*

**Indications:** -replacement of fluid and electrolyte loss in diarrhoea.

**Side effects:** - hypernatremia (dizziness, fast heartbeat, high blood pressure, irritability, muscle twitching)

**Contraindications:** - anuria, oliguria, severe dehydration with symptoms of shock, severe diarrhoea, glucose malabsorption, inability to drink, severe and sustained vomiting, intestinal obstruction, paralytic ileus, perforated bowel which may be irritated by ORS.

**Dose and Administration:** - reconstitute one sachet by adding sufficient water to make 1 liter Oral Rehydration Solution.

Dose - according to fluid loss, usually 200-400ml solution after ever loose motion, child - 200ml after every loose motion, infant1 - 1½ times usual feed volume.

**Storage:** - at room temperature.



### 1.6. Antiflatulants

#### Activated Charcoal

*Tablet, 125 mg, 250mg*

**Indications:** -flatulence, indigestion and intestinal distention.

**Cautions:** -advise patients not to take other medications orally with in two hours of the activated charcoal, except when inactivation of the medication is desired.

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

**Side effects:** -it colours the stool black.

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

**Storage:** -at room temperature, in airtight containers.

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### 1.7. Antihaemorrhoidal Agents

Haemorrhoids 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 haemorrhoids, 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.

Haemorrhoids 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*)<sup>4</sup>

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

*Ointment, 2.25% + 0.87% + 1.875% + 10.75%*

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

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<sup>4</sup> Any antihaemorrhoidal preparation proven to be therapeutically effective can be used.



**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:** *Rectally*, 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.



## 2.CARDIOVASCULAR DRUGS

### 2.1.Antihypertensives

#### *Management of hypertension*

Since treatment for hypertension is often life-long, it is important to integrate the treatment of hypertension into an overall program of management of associated risk factors and conditions, particularly in elderly patients who often have multiple associated disorders.

Mild hypertension is defined as 140 - 159 mmHg systolic blood pressure and 90-99 mmHg diastolic blood pressure. Moderate hypertension 160 - 180 mmHg systolic and 100 - 109 mmHg diastolic and severe hypertension more than 180 mmHg systolic and more than 110 mmHg diastolic.

Lifestyle changes should introduce for all patients; they include weight reduction, reduction in alcohol intake, reduction of dietary sodium, stopping tobacco smoking, and reduction in saturated fat intake. The patient should eat a healthy nutritious diet including adequate fruit and vegetables and should exercise regularly. These measures alone may be sufficient in mild hypertension, but patients with moderate to severe hypertension will also require specific antihypertensive therapy.

#### *Drug treatment of hypertension*

The goal of treatment is to obtain the maximum tolerated reduction in blood pressure.

Drugs acting on the central nervous system are effective antihypertensive drugs. In particular, methyldopa is effective in the treatment of hypertension in pregnancy, and may also be used in asthma and heart failure. Reserpine is also used because of its effectiveness and low cost. It should be used in combination with diuretics and prescribed in much lower doses than were formerly used.

*Beta adrenoceptor antagonist (beta-blockers)* such as propranolol are also effective in all grades of hypertension, and are particularly useful in angina and following myocardial infarction; they should be avoided in asthma, chronic obstructive pulmonary disease, and heart block

#### *Hypertension in pregnancy*

Drug therapy for chronic hypertension during pregnancy remains controversial. If diastolic blood pressure is greater than 95 mmHg. Methyldopa is the safer drug. Beta-blockers should be used with caution in early pregnancy. Since they may retard fetal growth they are effective and safe in the third trimester. ACE inhibitors are contraindicated in pregnancy since they may damage fetal and neonatal blood pressure control and renal function. Women who are taking these drugs and become pregnant should have their antihypertensive therapy changed immediately.



**Methyldopa***Tablet, 250 mg, 500mg***Indications:** - moderate to severe hypertension, including that complicated by renal disease.**Drug interactions:** - alcohol, CNS depression producing medications, monoamine oxidase inhibitors including furazolidine, paragyline, procabazine; cocaine, norepinephrine, phenylepinephrine, anaesthetics, and lithium.**Contraindications:** - depression, active liver disease, phaeochromocytoma, haemolytic anemia.**Side effects:** - dry mouth, sedation, depression, drowsiness, diarrhoea, fluid retention, failure of ejaculation, liver damage, haemolytic anaemia, lupus erythematosus like syndrome, parkinsonism, rashes, nasal stuffiness edema (swelling of feet or lower legs).**Dose and Administration** - *orally*

Adult - 250mg 2-3 times daily gradually increased at intervals of two or more days to maximum daily dose 3gm.

Elderly- 120mg twice daily initially, gradually increased, maximum daily dose 2gm.

Note: - advice patients not to do activities requiring alertness (e.g. Car driving, machine operating).

**Storage:** - at room temperature.**Propranolol***Tablet, 10mg, 40mg**Injection, 1mg/ml in 1ml ampoule***Indications:** -for the treatment of hypertension.**Cautions:** - in late pregnancy and breast-feeding, liver disease, renal impairment diabetes, and myasthenia gravis. Avoid machine operating and car driving.**Drug interactions:** -antidiabetic agents, oral or insulin, calcium channel blocking agents, clonidine or diazoxide, guanabenz or reserpine, hypotension producing drugs, verapamil, cocaine, MAO inhibitor, alcohol, anaesthetics (hydrocarbon), nifedipine, amiodarone, lignocaine, fluvoxamine, terfenadine.**Contraindications:** -asthma, history of obstructive airways disease, uncontrolled heart failure, sinus, bradycardia, phaeochromocytoma, cardiac failure, cardiogenic shock, and heartblock.**Side effects:** - bradycardia, heart failure, conduction disorders, bronchospasm, peripheral vasoconstriction, gastrointestinal disturbances, fatigue, sleep disturbance, mental depression, decreased sexual ability, diarrhoea, dizziness, nausea, vomiting, numbness, trouble in sleeping, usual tiredness, weakness.

**Dose and Administration:** - *Orally*, 80mg twice daily increased at weekly intervals as required, maintenance 160-320mg daily.

*IV injection* - 1.3mg administered at a rate not to exceed 1mg/minute, repeated after two minutes and again after four hours if necessary (for Antiarrhythmic).

Storage: - at room temperature.

### Reserpine

*Tablet, 0.1mg, 0.25mg*

*Injection, 1mg/ml in 1ml ampoule*

**Indications:** - mild to moderate hypertension.

**Cautions:** - debilitated or elderly patients, during breastfeeding, in those patients with cardiac arrhythmias, myocardial infarction, severe cardiac damage, renal insufficiency, gallstones, epilepsy, or allergic conditions such as bronchial asthma. Advise patients not to operate machineries or drive vehicles

**Drug interactions:** - diuretic and hypotensive agents, cardiac glycosides or quinidine, monoamine oxidase inhibitors, CNS depressants.

**Contraindications:** - mental depression, active peptic ulcer, with ulcerative colitis and in patients receiving electroconvulsive therapy.

**Side effects:** - nasal congestion, CNS symptoms including depression, drowsiness, lethargy, nightmares, diarrhoea, abdominal cramp; nausea, vomiting and anorexia.

**Dose and Administration:** - *orally*, Adult, 0.1mg to 0.25mg a day.

Child dose- 0.005 to 0.02mg per kg of body weight a day in one or two divided daily doses.

Note: - Take with meals or milks.

**Storage:** - store below 40°C preferably between 15 and 30°C in tight, light-resistant containers.

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## 2.2.Diuretics

Diuretics promote the excretion of water and electrolytes by the kidneys. They are used in the treatment of heart failure or in hepatic, renal, or pulmonary disease when salt and water retention has resulted in oedema or ascites. Diuretics are also used, either alone, or in association with other agents, in the treatment of hypertension.

The principal groups of diuretics are thiazides, 'Loop' or 'high - ceiling' diuretics, potassium sparing diuretics, osmotic diuretics, mercurial diuretics and carbonic anhydrase inhibitors.

Thiazides such as hydrochlorothiazide are used to relieve oedema due to chronic heart failure and in lower doses, to reduce blood pressure.

Loop diuretics such as frusemide are used in pulmonary oedema due to left ventricular failure and in patients with chronic heart failure.



Although loop diuretics are the most potent their duration of action is relatively short, whilst thiazide diuretics are moderately potent but produce diuresis for a longer period.

#### *Adverse effects*

The adverse effect of diuretic therapy are mainly due to the fluid and electrolyte imbalance induced by the drugs. Hyponatraemia is an adverse effect of all diuretics. The risk of hypokalaemia, which may occur with both thiazide and loop diuretics, depends more on the duration of action than on potency and is thus greater with thiazides than with loop diuretics (when given in equipotent doses). Other electrolyte disturbances include hypercalcaemia (thiazides), hypocalcaemia (loop diuretics) and hypomagnesaemia (thiazide and loop diuretics).

Symptoms of fluid and electrolyte imbalance include dry mouth, thirst, gastrointestinal disturbances (including nausea, vomiting), weakness, lethargy, drowsiness, restlessness seizures, confusion, headache, muscle pains or cramps, hypotension (including postural hypotension), oliguria, arrhythmias.

#### *Elderly*

The elderly are more susceptible to electrolyte imbalance than younger patients; treatment should begin with a lower initial dose of the diuretic (commonly about 50 % of the adult dose) and then adjusted carefully according to renal function, plasma electrolytes and diuretic response.

#### **Furosemide/Frusemide**

*Tablet, 40 mg, 80 mg*

*Elixir, 10 mg/ml*

*Injection, 10 mg/ml in 2 ml ampoule*

**Indications:** -for the treatment of oedema, oliguria due to renal failure; mild to moderate hypertension, usually in combinations with other antihypertensive agents and as adjunct in the treatment of hypertensive crisis and for the treatment of hypercalcemia.

**Cautions:** - children, elderly patients, pregnancy (not used to treat hypertension in pregnancy) and breast feeding; hypotensive patients; correct hypovolaemia before using in oliguria. It may cause hypokalaemia and hyponatraemia, aggravates diabetes mellitus and gout, liver failure, prostatic enlargement, porphyria.

**Drug interactions:** - antibacterials like aminoglycosides, antidiabetics or insulin, antifungals like amphoterecin, cardiac glycosides, corticosteroids, lithium, ulcer-healing drugs, alcohol, anticoagulants (cumarin or indandion derivatives, or heparin), streptokinase, urokinase, indomethacin, hypokalaemia producing medication, chloralhydrate, probenecid.



**Side effects:** - hyponatraemia, hypokalaemia, hypomagnesaemia, hypochlorhaemic alkalosis, increased calcium excretion, hypotension, less commonly nausea, gastro-intestinal disturbances, hyperuricemia and gout, hyperglycemia, temporary increase in plasma cholesterol and triglyceride concentrations, photosensitivity and bone marrow depression, pancreatitis, tinnitus and deafness, orthostatic hypotension as a result of massive diuresis (dizziness or light-headedness when getting up from sitting position).

**Contraindications:** - precomatose states associated with liver cirrhosis, renal failure with anuria.

**Dose and Administration:** -

**Oedema, by mouth,** Adult initially 40 mg daily on rising, maintenance, 20 mg daily or 40 mg on alternate days, may be increased to 80 mg daily in resistant oedema; CHILD 1 - 3 mg/kg body weight daily (maximum 40 mg daily).

**Acute Pulmonary Oedema, by slow intravenous injection,** adult 20-50 mg, if necessary increase by 20 mg steps every 2 hours; if effective single dose is more than 50 mg, consider using slow intravenous infusion at a rate not exceeding 4 mg/minute, CHILD 0.5-1.5 mg/kg body weight daily (maximum 20 mg daily).

**Oliguria (glomerular filtration rate less than 20 ml/minute), by slow intravenous infusion** at a rate not exceeding 4mg/minute, Adult initially 250 mg over 1 hour; if urine output not satisfactory during hour after first dose, infuse 500 mg over 2 hours then, if no satisfactory response during hour after second dose, infuse 1 g over 4 hours; if no response after third dose, dialysis probably necessary.

**Hypertension, Orally** - initially 40mg two times a day; the dosage being adjusted according to patient's need. **Intravenously,** Hypertensive crisis in patients with normal renal function, *IV* 40 to 80mg. Hypertensive crisis accompanied by pulmonary edema or acute renal failure *IV* 100-200 mg.

**Antihypercalcemic - Orally,** 120mg a day a single dose or divided into two or three doses.

*-IM or IV,* Adult, 80-100mg in severe cases, the dosage being repeated if necessary every one to two hours until the desired response is obtained. In less severe cases smaller doses may be given every two or four hours. CHILD, *IM or IV* 25 to 50mg, the dosage being repeated if necessary every four hours until the desired response is obtained.

**Storage:** -at room temperature in a well closed container, protect from freezing and light.



**Hydrochlorothiazide***Tablet, 2.5 mg***Indications:** - treatment of oedema, hypertension.**Cautions:** - severe renal disease, impaired hepatic function or progressive liver disease; elderly patients, during pregnancy and breast-feeding. It may cause hypokalaemia, aggravates diabetes and gout, and may exacerbate systemic lupus erythematosus.**Drug interactions:** - lithium, antidiabetic agents, hypotensive agents, probenecid, NSAIDs, drugs causing potassium depletion.**Contraindications:** - refractory hypokalaemia, hyponatraemia, hypercalcemia, severe renal and hepatic impairment, and symptomatic hyperuricemia, Addison's disease, anuria.**Side effects:** - postural hypotension and mild gastrointestinal effects, impotence (reversible), hypokalaemia, hypomagnesaemia, hyponatraemia, hypercalcemia, hypochloraemic alkalosis, hyperuricemia, gout, hyperglycemia, and increased in plasma cholesterol concentrations, less commonly rashes, photosensitivity, blood disorders (including neutropenia and thrombocytopenia), pancreatitis, intrahepatic cholestasis, hypersensitivity reaction.**Dose and Administration****Hypertension, *by mouth*,** Adult 12.5, 25 mg daily; elderly initially 12.5 mg daily.**Oedema, *by mouth*,** Adult initially 25 mg daily on rising increasing to 50 mg daily if necessary, elderly initially 12.5 mg daily.**Severe Oedema in patients unable to tolerate loop diuretics, *by mouth*,** Adult up to 100 mg either daily or on alternate days (maximum 100 mg daily).**Nephrogenic diabetes insipidus, *by mouth*,** Adult initially up to 100 mg daily.

Note: - Take with meals or milk.

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**2.3. Drugs used in vascular shock**

Shock is a medical emergency associated with a high mortality. The underlying causes of shock such as haemorrhage, sepsis or myocardial insufficient should be corrected. The profound hypotension of shock must be treated promptly to prevent tissue hypoxia and organ failure. Volume replacement is essential to correct the hypovolaemia associated with haemorrhage and sepsis but may be detrimental in cardiogenic shock. Successful correction of hypovolaemia may alleviate hypotension in some cases. However, blood pressure in shock can be extremely low (sometimes a systolic pressure of less than 70 mmHg) and such profound hypotension (despite fluid replacement) and/or the presence of a low cardiac output will often necessitate additional measures.



Sympathomimetic agents are usually employed. They act as presser agents by producing vasoconstriction and also possess positive inotropic activity thus increasing cardiac out put. If hypotension is profound (for example systolic pressure less than 70 mmHg) noradrenaline is usually used; adrenaline or dopamine (not available at health center level) may be alternatives. If moderate hypotension exists (systolic pressure of about 70 to 100 mmHg) with hypoperfusion, dopamine is usually preferred.

The use of sympathomimetic inotropes and vasoconstrictors should therefore preferably be confined to the intensive care setting and under taken with invasive haemodynamic monitoring.

### **Adrenaline (Epinephrine)**

*Injection, 0.1 % in 1 ml ampoule*

**Indications:** correction of hypotension, unresponsive to adequate fluid volume replacement, as part of shock syndrome caused by myocardial infarction, trauma, bacteremia, open-heart surgery, renal failure, chronic cardiac decompensation, drug overdose, or other major systemic illness; also severe anaphylactic shock, severe angioedema, cardiac arrest.

**Cautions:** -hyperthyroidism, hypertension, diabetes mellitus, ischaemic heart disease, arrhythmias, cerebrovascular disease, and elderly.

**Drug interactions:** -amitriptyline, clomipramine, atenolol, ether (Anesthetic), halothane, propranolol, timolol.

**Contraindications:** -asymmetric septal hypertrophy, pheochromocytoma, tachyarrhythmias.

**Side effects:** - tachycardia and arrhythmia, hypertension, tremor, anxiety, sweating, nausea, vomiting, weakness, dizziness, pulmonary oedema, headache.

### **Dose and Administration**

Note: Different dilutions of epinephrine injection are used for different routes of administration.

*Intramuscular or Subcutaneous injection,* use 1:1000 epinephrine injection.

*Slow intravenous injection;* use 1:10000 epinephrine injection.

This route should be reserved for severely ill patient when there is doubt about the adequacy of circulation and absorption from the intramuscular site.

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



### 3. RESPIRATORY DRUGS

#### 3.1. Antitussives/Expectorants

Cough is an important physiological protective mechanism, but may also occur as a symptom of an underlying disorder. Treatment of the disease should be the first step in therapy to stop the cough. Upper respiratory tract infections often produce a self-limiting non-productive cough which serves no useful purpose and cough suppressants such as Dextromethorphan may provide the patient with relief, although they control the cough rather than eliminate it. Codeine may be effective but it is constipating and can cause dependence; Dextromethorphan and Pholcodine (not described here) have fewer side effects.

Cough suppressants must not be used to treat productive cough, which is considered to be a useful protective mechanism. Therapy is directed at modifying the mucus secretions to facilitate their removal, and the drugs mainly used are expectorants and mucolytics.

Cough suppressants containing codeine or similar opioid are not recommended for administration to children, and should be avoided altogether in those under 1 years of age.

Cough suppressants should not be combined with expectorants (such as Guaifenesin) in the treatment of cough since the combination is illogical and there is little evidence for their efficacy, but patients may be exposed to unnecessary adverse effects. Inhibition of cough reflex will lead to retention of phlegm.

#### Codeine Phosphate

*Tablet, 30 mg*

*Linctus, 15 mg/5ml*

**Indications:** - dry or painful cough.

**Cautions:** -caution should be taken in patients with asthma, hepatic and renal impairment, history of drug abuse and also in children (The use of cough suppressants containing codeine or similar opioid analgesics is not generally recommended in children). It may cause drowsiness. Avoid alcoholic beverages.

**Drug interactions:** – alcohol, CNS depressants, buprenorphine, monoamine oxidase (MAO) inhibitors, naltrexone.

**Side effects:** - constipation particularly troublesome in long term use; dizziness, nausea, vomiting; difficulty with micturation; ureteric or biliary spasm; dry mouth, headaches, sweating, facial flushing; in therapeutic doses, codeine is much less liable than morphine to produce tolerance, dependence, euphoria, sedation or other adverse effects.

**Contraindications:** - liver disease, ventilatory failure. It is also contraindicated in children under 1 year old.



**Dose and Administration:** -

**Tablet, *by mouth***, Adult - 10-20mg every 4 -6 hours. Maximum, 120mg in twenty-four hours. Children - (6-12), 5 to 10mg every four to six hours, not to exceed 60mg per day

**Linctus, *by mouth***, Adult -5-10ml 3 - 4 times daily, Child (but not generally recommended) 5-12 years, 2.5 - 5ml 3 - 4 times daily.

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

**Dextromethorphan Hydrobromide**

*Tablet, 15mg*

*Drops, 15mg/ml*

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

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

**Cautions:** - in atopic children, sedated or debilitated patients and in patients confined to the supine position. Advise patients not to operate machineries or driving vehicles.

**Drug interactions:** - CNS depressants, monoamine oxidase inhibitors including furazolidine and procarbazine.

**Contraindications:** - asthma, in children up to two years of age.

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

**Dose and Administration** - *Orally*, Adult, 10 to 20mg every 4 hours, or 30mg every 6 to 8 hours, to a usual maximum of 120mg in 24 hours; children (6-12 years), 5 to 10mg every 4 hours or 15mg every 6 to 8 hours to a maximum of 60mg in 24 hours, and children (2 to 6 years) 2.5 to 5mg every 4 hours, or 7.5 every 6 to 8 hours, to a maximum of 30mg in 24 hours.

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

**Guaifenesin**

*Tablet, 100mg, 200mg*

*Capsules, 200mg*

*Syrup, 100mg/5ml*

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

**Cautions:** - guaifenesin should not be used for persistent or chronic cough such as that occurring with smoking, asthma, chronic bronchitis, or emphysema, or for cough accompanied by excessive phlegm.

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

**Contraindications:** - sensitive to guaifenesin.



**Dose and Administration** - *Orally*, Adult, 200-400mg every 4 hours. Children (6 to 12 years), 100 to 200mg every 4 hours, and children (2 to 6 years), 50 to 100mg every 4 hours.

**Storage:** - at room temperature in a tight container

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### 3.2. Bronchodilators /Antiasthmatics

Asthma is a chronic inflammatory disease characterized by episodes of reversible airways obstruction due to bronchial hyper-responsiveness, inflammation may lead to irreversible obstruction in a few patients. A classification based on severity before the start of treatment and disease progression is of importance when decisions have to be made about management. It can be divided by severity into intermittent, mild persistent, moderate persistent and severe persistent. The level of therapy is increased at the severity of the asthma increases with stepping - down if control is sustained.

#### *Administration*

Medications for asthma can be administered in several different ways, including inhaled, oral and parenteral (subcutaneous, intramuscular or intravenous).

Initially, therapy is usually administered by inhalation to deliver the drugs to the desired site of action. The doses are thus smaller than would be required with oral administration, although in severe asthma that route may also be necessary. Spacing devices can be fitted to some metered - dose inhalers to act as reservoirs for the drug to make it easier for the patient (especially if a child) to inhale each dose. A large volume spacer device is recommended for the inhalation of high doses of corticosteroids to reduce oropharyngeal deposition any systemic absorption.

#### *Pregnancy*

Poorly controlled asthma in pregnant women can have an adverse effect on the fetus, resulting in perinatal mortality, increased prematurity and low birth - weight. For this reason using medications to obtain optimal control of asthma is justified. Administration of drugs by inhalation during pregnancy has the advantage that plasma drug concentrations are not likely to be high enough to have an effect on the fetus. Acute exacerbations should be treated aggressively in order to avoid fetal hypoxia.

The standard drugs employed in the management of asthma are the beta-adrenergic agonists and corticosteroids (not described here). Beta - adrenergic drugs (beta agonists) relax the bronchial smooth muscle to produce bronchodilation by stimulating beta<sub>2</sub>-adrenergic receptors.



Short-acting selective beta<sub>2</sub> agonists such as Salbutamol or Terbutaline are the initial drugs of choice; if inhaled they can have an almost immediate bronchodilating effect.

In addition, Xanthines such as aminophylline or theophylline may be given for their bronchodilating properties.

The use of epinephrine (adrenaline) in asthma has generally been superseded by beta<sub>2</sub>-selective adrenoceptor agonists.

### **Adrenaline (Epinephrine)**

*Injection, 0.1 %, 1 ml (1mg/ml)*

**Indications:** - for acute bronchial asthma, and acute anaphylactic reactions; see section 2.3

**Cautions, Drug interactions, Contraindications, Side effects;** see under Adrenaline, section 2.3

**Dose and Administration:** *Subcutaneously or intramuscularly.*

Acute bronchial asthma –

Adults: *S.C.* initially, 0.2–0.5mg (0.2-0.5ml), repeated every 20 minutes - 4 hours as necessary; Children: *S.C.* 0.01mg (0.01ml)/ kg of body weight, up to a maximum of 0.5mg(0.5ml)/dose.

Note: If there is no response after 2 adrenaline injections, or if the attack worsens after the first injection, aminophylline should be given intravenously.

Acute anaphylactic reactions –

Adults: *S.C., or I.M.*, initially 0.2 – 0.5mg (0.2ml-0.5ml) repeated as necessary. Maximum – 1mg (1ml) /dose if necessary. Children: *S, C.*, 0.01mg (0.01ml)/kg of body weight repeated every 15 minutes for 2 doses, then every 4 hours as necessary. Maximum – 0.5mg (0.5ml)/ dose

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

### **Theophylline**

*Tablet (anhydrous theophylline), 100mg, 200mg, 200mg (s/r)*

*Elixir, 33mg in each 15 ml (anhydrous theophylline)*

**Indications:** - reversible airways obstruction, acute severe asthma.

**Cautions:** - peptic ulcer, hyperthyroidism, hypertension, cardiac arrhythmias or other cardiovascular disease, or epilepsy (as these conditions may be exacerbated); 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); see also Interactions.

**Drug interactions:** - other xanthine medications; cimetidine, disulfiram, fluvoxamine, macrolide antibiotics and quinolones, oral contraceptives, thiabendazole, and viloxazine (necessitating dosage reduction); phenytoin and some other anticonvulsants, rifampicin, sulphinpyrazone, and cigarette smoking (necessitating an increase in dose or dosing frequency). Xanthines can potentiate hypokalaemia associated with the



administration of beta<sub>2</sub>-agonists, corticosteroids, and diuretics and hypokalaemia due to hypoxia.

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

**Dose and Administration –**

Theophylline Elixir, Tablet

Usual adult dose

*Loading dose -*

For patients not currently receiving theophylline preparation:

*Oral*, the equivalent of 5 mg of anhydrous theophylline per kg of lean (ideal) body weight as a single dose to provide an average peak serum concentration of 10 mcg per ml, ranges 5 to 15 mcg per ml.

For patients currently receiving theophylline preparations:

The loading dose for theophylline is based on the principle that each 0.5 mg of theophylline per kg of lean (ideal) body weight will result in a 1 mcg per ml increase in serum theophylline concentration.

*Maintenance -*

*Oral*, the equivalent of anhydrous theophylline, initially, 300 mg per day. After three days, the dosage may be increased, if tolerated to 400 mg per day. After three more days, the dosage may be increased, if tolerated, to 600 mg per day with out measurement of serum concentration.

The total daily adult dose is administered in three or four divided doses given about six to eight hours apart.

Usual pediatric dose:

Loading dose: - see usual adult dose

Maintenance -

Children 1 year of age and older (weighing less than 45 kg), *oral*, the equivalent of anhydrous theophylline, 12 to 14 mg per kg of body weight, up to a maximum of 300 mg, per day in divided doses. The dosage may be increased. If tolerated, after three days to 16 mg per kg of body weight, up to a maximum of 400 mg per day. After three more days, if tolerated, the dosage may be increased to 20 mg per kg of body weight up to a maximum of 600 mg, per day. The total daily dose is administered in four to six divided doses given every four to six hours.

Children weighing more than 45 kg - see usual adult dose.

Theophylline elixir is not recommended in children due to the high alcohol content.

Theophylline sustained release tablet

Usual adult dose: see theophylline tablet; under maintenance dose (adult dose)



Usual pediatric dose: see theophylline tablet; under maintenance dose (pediatric dose).

One-half of the daily theophylline dose may be given at twelve - hour intervals.

Note - Due to the significant variability in extended release product characteristics, pharmacists should not substitute one brand for another without consulting the prescribing physician unless the product has proven bioequivalence. So that theophylline serum concentrations can be appropriately monitored.

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

### **Aminophylline (Theophylline and Ethylenediamine)**

*Tablet, 100mg, 200mg*

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

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

**Indications:** - reversible airways obstruction, acute severe asthma.

**Cautions, Drug interactions, Contraindications;** see under theophylline

**Side effects:** - see under theophylline; also allergy to ethylenediamine can cause urticaria, erythema, and exfoliative dermatitis.

Note: aminophylline is a stable mixture or combination of theophylline and Ethylenediamine; the Ethylenediamine confers greater solubility in water.

**Dose and Administration:** -

Tablet, *by mouth*, 100-300mg, 3-4 times daily, after food.

Tablet (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 over 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.

*By slow intravenous injection or preferably by slow intravenous infusion.*

Avoid rapid intravenous injection. It should be given cautiously, particularly in patients who have previously been taking theophylline and/or ephedrine.

Adults: 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.

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

Maintenance-If required, 6 months-9 years-1mg/kg of body weight per hour by slow intravenous infusion.

10-16 years—0.8mg/kg of body weight per hour by slow intravenous infusion.

Note: aminophylline is a stable mixture or combination of theophylline and Ethylenediamine; the Ethylenediamine confers greater solubility in water.

**Storage:** at room temperature protect from light.

Note: The injection should not be used if crystallization has occurred.



**Theophylline and 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, Drug interactions:** - see notes under theophylline

**Side effects:** -gastroesophageal reflux: See notes under Theophylline

**Dose and Administration:** -see notes under Theophylline

**Storage:** –guaifenesin preparations should be stored in tight containers at room temperature.

**Ephedrine + Theophylline**

*Tablet, 11mg + 120mg*

*Syrup, 2.24% + 0.30%*

*Elixir, 6mg + 30mg in each 5ml*

**Salbutamol (Albuterol)**

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

*Syrup, 2mg/5ml*

*Oral inhalation (aerosol), 0.1mg per dose*

**Indications:** -symptomatic treatment of bronchial asthma. It is also indicated for the treatment of reversible bronchospasm associated with bronchitis, pulmonary emphysema, bronchiectasis, and other pulmonary disease.

**Cautions:** - pregnancy, breastfeeding

**Drug interactions:** - anaesthetics such as enflurane, isoflurane, methoxyflurane, maprotiline; beta adrenergic blocking agents, antihypertensives, CNS stimulants, cocaine, digitalis glycoside, levodopa, monoamine oxidase inhibitor, nitrates, ritodrine, sympathomimetics, thyroid hormones, xanthenes such as aminophylline, caffeine, dyphylline, otriphylline, theophylline.

**Contraindications:** - cardiac arrhythmias, coronary insufficiency, hypertension, ischemic heart diseases, diabetes mellitus, and hyperthyroidism.

**Side effects:** - fast heartbeat, nausea, nervousness or restlessness, pounding heartbeat, trembling, chest discomfort or pain, hallucinations.

**Dose and Administration -**

*Tablets -Adults, Oral, 2 to 6mg (base) - three or four times a day initially, the dosage being increased and tolerated up to a maximum of 8mg four times a day.*



Children (6-12 years) - *Oral*, 2mg (base) - three or four times a day initially, the dosage being increased and tolerated up to a maximum of 24mg per day in divided doses.

*Syrup* - Adult, *Oral*, 2 to 6mg (base) three or four times a day initially, the dosage being increased as needed and tolerated up to a maximum of 8mg four times a day.

Children (2-6 years) - *Oral*, 0.1mg(base) per kg of a body weight three times a day initially, the dosage being increased as needed and tolerated up to 0.2mg per kg of body weight, not to exceed 4mg three times a day. Children (6-14 years) - *Oral*, 2mg (base) three or four times a day initially, the dosage being increased as needed and tolerated up to a maximum of 24mg per day in divided doses.

*Inhalation (aerosol)* - Adult, *oral inhalation*, 0.18 to 0.2mg (2 inhalations) every four to six hours.

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.



## 4. CENTRAL NERVOUS SYSTEM DRUGS

### 4.1. 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-opioid analgesics are particularly suitable for pain in musculoskeletal conditions where as the opioid analgesics are more suitable for moderate to severe visceral pain. Those non-opioid analgesics which also have anti-inflammatory actions include salicylates and NSAIDS (Nonsteroidal anti-inflammation drugs), they can 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.

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 non-opioid analgesics such as aspirin, other NSAIDs, or paracetamol (preferably in a soluble or dispersible form) taken at the earliest signs of an attack concomitant anti-emetic treatment may be required.

#### **Non - opioid analgesics**

Paracetamol, aspirin, and other non steroidal anti-inflammatory drugs (NSAIDs) are the first choice for treating mild or moderate pain and are used in moderate or severe pain to potentate the effects of opioids. They are suitable for use in acute or chronic pain.

#### *Acetylsalicylic acid*

Aspirin is indicated for headache, transient musculoskeletal pain, dysmenorrhoea and pyrexia. In inflammatory conditions, most physicians prefer anti-inflammatory treatment with another NSAID which may be



better tolerated and more convenient for patient. Acetylsalicylic Acid is also used for its antiplatelet 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 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).

#### *Paracetamol*

Paracetamol is similar in analgesic and antipyretic efficacy to acetylsalicylic acid. Unlike acetyl salicylic acid and other NSAIDs, paracetamol has little anti-inflammatory activity which limits its usefulness for long-term treatment of pain associated with inflammation; however it is useful in the management of osteoarthritis, a condition with only a small inflammatory component.

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.

Dipyrrone, a sodium sulphonate of amidopyrine, is a nonsteroidal anti-inflammatory drug. Because of the risk of serious adverse effects its use is justified only in severe pain where no alternative is available or suitable. Administration of Dipyrrone is associated with an increased risk of agranulocytosis and with shock. In Ethiopia, only the Parenteral form of Dipyrrone is available, which is to be used in place of narcotic analgesics.

#### **Acetyl Salicylic Acid**

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

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).

**Indications:** -to relieve mild to moderate pain (e.g. headache, toothache, menstrual cramps) and to reduce fever.



**Cautions:** -caution in patients with gastritis, peptic ulcer, asthma and mild sensitivity reactions to acetylsalicylic acid, children under 12 years of age.

**Drug interactions:** alcohol, or chronic high-dose of magnesium containing antacids.

**Side effects:** gastrointestinal irritation and an acute intolerance to acetylsalicylic acid and hypersensitivity reactions such as bronchospasm and rashes may occur in very few patients.

**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).

**Dose and administration:** *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.

Adults: 300 – 600mg every 4—6 hours daily as necessary.

Maximum – 4g daily.

Children: 1—2 years - 75 – 150mg every 6 hours daily.

3 – 5 years – 225 – 300mg every 8 hours daily.

6—12 years- 300 – 400mg every 6 hours daily.

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

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

### **Paracetamol**

*Tablet, 100mg, 500mg*

*Suppository, 125mg, 250mg*

*Syrup, 120mg/5ml*

*Drops, 100mg/ml*

**Indications:** - mild to moderate pain including dysmenorrhoea, headache; pain relief in osteoarthritis and soft tissue lesions; pyrexia including post immunization pyrexia, also acute migraine attack.

**Cautions:** caution in alcoholics, and in patients with hepatic diseases, and severe renal function impairment.

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

**Side effects:** rare in therapeutic doses. Allergic reactions such as skin rashes may occur rarely.

### **Dose and Administration**

Mild to moderate pain, pyrexia,

*By mouth*, Adult 0.5 - 1g every 4-6 hours, maximum 4g daily; child months-1 year 60-120mg, 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).

*By rectum*, Adult 0.5 - 1g, child 1 - 5 years 125 - 250mg, 6 - 12 years 250 - 500mg; doses inserted every 4 - 6 hours if necessary, maximum & doses in 24 hours.

*Post* - immunization pyrexia, *by mouth*, 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.

### **Dipyrrone**

*Injection, 500mg/ml in 1ml ampoule*

**Indications:** -severe pain where no alternative is available or suitable

#### **Adverse effects and precautions**

The risk of agranulocytosis in patients taking Dipyrrone is sufficiently great to render this drug unsuitable for use. Onset of agranulocytosis may be sudden and unpredictable.

#### **Dose and Administration**

*IM or IV injection* in doses of up to 7.5g daily in divided doses.

### **Opioid analgesics**

Morphine and **pethidine** are opioid analgesics which are effective in relieving moderate to severe pain, particularly of visceral origin; there is a large variation in patient response. Weaker opioids such as codeine are suitable for mild to moderate pain. **Pethidine** produces prompt but short-acting analgesia, it is less constipating than morphine, but even in high doses it is less effective. A neurotoxic metabolite, norpethidine, accumulates during repeated administration and can cause central nervous system excitation, including myoclonus and seizures. These adverse effects together with the short duration of analgesic action make pethidine unsuitable for severe, continuing pain. It is used for analgesia in labor; however other opioid analgesics such as morphine are often preferred.

### **Pethidine Hydrochloride**

*Tablet, 50mg*

*Injection, 50mg/ml in 1 and 2ml ampoules*

**Indications:** -moderate to severe pain, obstetric analgesia, peri-operative analgesia.

**Cautions:** -hypotension, hypothyroidism, asthma (avoid during attack) and decreased respiratory reserve, prostatic hypertrophy; pregnancy and breast-feeding; may precipitate coma in hepatic impairment; reduce dose or avoid in renal impairment, elderly and debilitated (reduce dose); convulsive disorders, dependence (severe withdrawal symptoms if



withdrawn abruptly); use of cough suppressants containing opioid analgesics not generally recommended in children and should be avoided altogether in those under at least 1 year. Patients should be advised to avoid drinking alcohol and to avoid operate machineries or car driving. It may be habit forming. Avoid prolonged use.

**Drug interactions:** - alcohol, CNS depressants, amphetamines, anticholinergics, buprenorphine, monoamine oxidase inhibitor including furazolidine, paragyline and procarbazine; naltrexone, metoclopramide, hypotension producing medications or diuretics or antihypertensives such as guanadrel, guanethidine, mecamylamine, antidiarrhoeals such as difenoxin and atropine, kaolin, pectin, belladonna alkaloids.

**Side effects:** -histamine release (decreased blood pressure fast heart beat, increased sweating, redness or fleshing of the face, wheezing or troubled breathing), constipation, dizziness, feeling faint or light-headedness, drowsiness, hypotension, nausea or vomiting, unusual tiredness or weakness, ureteral spasm (difficult or painful urination), dry mouth, headache, stomach cramp or illness, blurred or double vision, fast or pounding heartbeat, convulsions.

**Contraindications:** - avoid in acute respiratory depression, acute alcoholism and where risk of paralytic ileus; also avoid in raised intracranial pressure or head injury (in additional to interfering with respiration, affect pupillary responses vital for neurological assessment); avoid injection in phaeochromocytoma (risk of pressor response to histamine release); severe renal impairment.

**Dose and Administration:** -

*By mouth*, 50 - 150mg every 4 hours; CHILD 0.5 - 2mg/kg.

*IM (preferred), Sc*; Adult -50 -150mg (usually 100mg) every three to four hour as needed; CHILD -1.1 to 1.76mg per kg of body weight, not to exceed 100mg, every three to four hours as needed.

**Storage:** - at room temperature protect from light and freezing.

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#### 4.2.Sedative, Hypnotics and Tranquillizers

The drugs in this section include sedative agents used in the management of anxiety disorders (anxiolytic sedatives or minor tranquillizers), as well as those used to produce sleep (hypnotics). There is no sharp distinction between sedatives and hypnotics; the difference in action is mainly one of degree and the same drug or group of drugs can have both effects, larger doses being necessary to produce a state of sleep. Prescribing of these drugs is widespread but dependence (both physical and psychological) and tolerance occurs. This may lead to difficulty in withdrawing the drug after the patient has been taking it regularly for more than a few weeks. Hypnotics and Anxiolytics should therefore be



reserved for short courses to alleviate acute conditions after causal factors have been established.

The benzodiazepines have largely replaced the barbiturates and related sedatives as the major group of drugs used as anxiolytics and hypnotics. Since benzodiazepine-induced disinhibition may precipitate suicide or aggressive behavior, it is advised against the use of benzodiazepines alone to treat depression or anxiety associated with depression, and recommended care when used in patients with personality disorders. Hypnotics and Anxiolytics may impair judgment and increase reaction time and so affect ability to drive or operate machinery. They increase the effects of alcohol. More over the hangover effects of a night dose may impair driving on the following day.

If used for longer periods, withdrawal should be gradual by reduction of the dose over a period of weeks or months, as abrupt discontinuation may produce confusion, toxic psychosis, convulsions or a condition resembling delirium tremens. The benzodiazepine withdrawal syndrome may not develop until up to three weeks after stopping a long - acting benzodiazepine but may occur within a few hours in the case of a short-acting one. The syndrome is characterized by insomnia, anxiety, loss of appetite and body-weight, tremor, perspiration, tinnitus and perceptual disturbances. These symptoms may be similar to the original complaint and encourage further prescribing.

Chlorpromazine is still widely used despite the wide range of adverse effects associated with it. It is generally characterized by pronounced sedative effects and moderate antimuscarinic and extrapyramidal side effects.

### **Hypnotics**

Hypnotic drugs should be reserved for the acutely distressed patient where non-pharmacological approaches (such as counseling, behavioral therapy, development of relaxation techniques and avoidance of stimulant substances) have failed, although they should be avoided in the elderly, and their use is rarely justified in children. They should be avoided in patients with sleep apnea or other sleep-related breathing disorders.

Benzodiazepines are generally regarded as the hypnotic of choice. Among the benzodiazepines, the long acting agent, diazepam is described here as hypnotics

Barbiturates have been used for the short-term treatment of insomnia; however, they generally have been replaced by benzodiazepines. If barbiturates are used, they are not recommended for long-term use since they appear to lose their effectiveness in sleep induction and maintenance after 2 weeks or less.



Antihistamines have weak hypnotic properties and some including promethazine, diphenhydramine have been used as alternatives to benzodiazepines particularly in children with pruritus. They may, however, cause troublesome antimuscarinic effects and those with longer half-lives may cause hangover effects.

Antidepressants and Antipsychotics with sedative effects are indicated only when insomnia is a symptom of an underlying psychiatric disorder.

### **Sedatives**

Benzodiazepines are more preferred than barbiturates for the management of anxiety and tension, because benzodiazepines have a relatively low abuse potential produce less sedation with effective anxiolytic dose, and produce less toxicity with acute overdose.

Anxiolytics, particularly the benzodiazepines, have been termed 'minor tranquillizers'. This term is misleading because not only do they differ markedly from the antipsychotic drugs ('Major tranquillizers') but also their use is by no means minor. Antipsychotics, in low doses, are also sometimes used in severe anxiety for their sedative action but long-term use should be avoided in view of possible risk of tardive dyskinesia.

Some antidepressants are licensed for use in anxiety and related disorders. The use of antihistamines for their sedative effect in anxiety is not considered to be appropriate.

### **Diazepam**

*Tablet, 2mg, 5mg, 10mg*

*Suppository, 5mg, 10mg*

*Syrup, 2mg/5ml*

*Injection, 5mg/ml in 2ml ampoule*

**Indications:** - short-term treatment of anxiety and insomnia; status epilepticus, recurrent alcohol withdrawal; premedication.

**Cautions:** - impaired liver or kidney function, muscle weakness; elderly or debilitated patients; respiratory disease, history of alcohol abuse marked personality disorder; pregnancy; breastfeeding; avoid prolonged use and abrupt withdrawal; porphyria; see also notes above, and also interactions.

**Drug interactions:** - alcohol, antidepressants, antihistamines, antipsychotics, general anaesthetics, other hypnotics or sedatives, and opioid analgesics (sedation or respiratory and cardiovascular depression may be enhanced); fluvoxamine, ketoconazole, nefazodone (concurrent use may inhibit the hepatic metabolism of benzodiazepines that are metabolized by oxidation); plastic infusion tubing (diazepam may adhere to plastic infusion tubing).

**Side effects:** - drowsiness and light headedness the next day; confusion and ataxia (especially in the elderly); amnesia; dependence; paradoxical



increase in aggression; muscle weakness; occasionally headache, vertigo, salivation changes, gastrointestinal disturbances, visual disturbances, dysarthria, tremor, changes in libido, incontinence, urinary retention, blood disorders and jaundice, skin reactions raised liver enzymes.

**Contraindications:** - preexisting CNS depression or coma, acute pulmonary insufficiency, or sleep apnea, severe hepatic impairment; myasthenia gravis; respiratory depression; diazepam should not be used for the treatment of chronic psychosis or for phobic or obsessional states.

**Dose and Administration**

*By mouth*, anxiety, 2mg 3times daily increased if necessary to 15 - 30 mg daily in divided doses; elderly (or debilitated) half adult dose

Insomnia associated with anxiety, 5- 15 mg at bedtime.

Child night terrors and somnambulism, 1 - 5 mg at bedtime.

*By intramuscular injection or slow intravenous injection* (into a large vein, at a rate of not more than 5mg/minute), for severe acute anxiety, control of acute panic attacks, and acute alcohol withdrawal, 10mg, repeated if necessary after not less than 4 hours.

Note: - Only use intramuscular route when oral and intravenous routes not possible.

*By rectum* as suppositories, anxiety when oral route not appropriate, 10 - 30mg (higher dose divided), dose form not appropriate for less than 10mg.

**Storage:** - At room temperature in light resistant container protect from freezing.

**Phenobarbitone (pentobarbital)**

*Tablet 10mg, 15mg, 30mg, 60mg, and 100mg*

*Capsule, 50mg*

*Suppository (Sodium), 30mg, 60mg*

*Elixir, 20mg/ 5ml*

*Injection (Sodium), 25mg/ml, 50mg/ml, 100mg/ml, 4%*

**Indications:** - used as sedative-hypnotic

**Cautions:** -caution should be taken in pediatric, elderly, and debilitated patients.

**Drug interactions:** - alcohol, CNS depressants, adrenocorticoids, glucocorticoids and mineralocorticoids; or chloramphenicol; corticotropin; cumarin or indandione - derivative anticoagulants, carbamazepine, estrogen-containing contraceptives; valproic sodium or valproic acid; vitamin D; xanthines such as aminophylline, caffeine, oxtriphylline, theophylline, rifampin; monoamine oxidase inhibitors including furazolidone, paragyline and procarbazine; doxycycline.

**Contraindications:** - pregnancy and breastfeeding, and in patients with acute intermittent or variegated or history of porphyria, insomnia caused



by pain, drug abuse or dependence (history of), hepatic coma or hepatic function impairment, acute or chronic pain; respiratory disease involving dyspnea or obstruction, particularly status asthmaticus; sensitivity to barbiturates.

**Dose and Administration:**

**Hypnotic** - *Oral*, Adult, 100 to 320mg (base) at bedtime; *Intramuscular or intravenous*, 100 to 325mg. Child, dosage must be individualized by physician.

**Sedative**- *Oral*, Adult, daytime- 30-120mg (base) in two or three divided doses a day; Child, daytime, 2mg (base)/kg of body weight three times a day; Preoperative, 1 to 3mg (base) per kg of body weight.

-*Intramuscular or intravenous*, Adult, daytime, 30 to 120mg a day in two or three divided doses, *preoperative (IM)*, 130-200mg sixty to ninety minutes before surgery. Child, *preoperative*, 1 to 3mg per kg of body weight, sixty-ninety minutes prior to surgery.

**Storage:** - at room temperature in a tight container protect from freezing.

**Promethazine**

*Tablet, 25mg*

**Indications:** - night sedation and insomnia or it is indicated as sedative hypnotic.

**Cautions:** - epilepsy, prostatic hypertrophy, urinary retention, glaucoma, hepatic disease, jaundice, also during pregnancy and breast-feeding, in children and elderly. It causes drowsiness. Patients should be advised to avoid car driving, machine operating or doing activities requiring alertness.

**Drug interactions:** - alcohol, CNS depressants, anticholinergics, antithyroid, epinephrine, extrapyramidal reaction causing medication, levodopa, metrizamide, monoamine oxidase inhibitors including furazolidone and procarbazine.

**Contraindications:** - porphyria.

**Side effects:** - drowsiness, headache, psychomotor impairment, urinary retention, dry mouth, blurred vision, gastrointestinal disturbances, rashes, photosensitivity reactions, palpitation, and arrhythmias, hypersensitivity reaction (including bronchospasm, angioedema, and anaphylaxes), convulsions, sweating, myalgia, paraesthesia, blood disorders, tremor, liver dysfunction, sleep disturbance, depression, hypotension, and hair loss, extra pyramidal effects.

**Dose and Administration**- *orally*

Adults - *oral*, 25mg at bedtime, increased to 50mg if necessary. Children (2-5 years) - 15 to 20mg; 5-10 years - 20 to 25mg at bedtime.

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



**Chlorpromazine Hydrochloride***Tablet, 25 mg, 50mg, 100mg**Syrup, 25mg/5ml**Drop, 25mg/ml in 10ml bottle, 40mg/ml in 10ml and 30ml bottles.**Injection, 25mg/ml in 1 and 2ml ampoules, 50mg/ml in 2ml ampoule.*

**Indications:** - symptomatic management of psychotic disorders in non-hospitalized patients with relatively mild symptomatology and for the management of excessive anxiety, tension, and agitation.

**Cautions:** - cardiovascular and cerebrovascular disease, respiratory disease, parkinsonism, epilepsy, acute infection, pregnancy, breast-feeding, renal and hepatic impairment, history of jaundice, leucopenia, hypothyroidism, myasthenia gravis, prostatic hypertrophy, closed-angle glaucoma. Caution also in elderly particularly in very hot or cold weather.

Note: -Avoid abrupt withdrawal. Avoid direct contact with chlorpromazine for it causes contact sensitization. Advise patients not to drive cars or operate machineries or do activities requiring alertness.

**Drug interactions:** - alcohol, CNS depressants, tricyclic antidepressants such as amitriptyline, antithyroid agents, epinephrine, extra pyramidal reaction causing medication, hypotension producing medication, levodopa, lithium, metrizamide, amphetamines, anticonvulsants including barbiturates.

**Side effects:** - akathisia (restlessness or need to keep moving) blurred vision associated with anticholinergic effects; deposition of opaque material in lens, cornea and retina (blurred vision), diatonic extrapyramidal effects (muscle spasms of the face, neck, and back; tic-like or twitching movements; twisting movements of the body; inability to move eyes; weakness of arms and legs); parkinsonian extrapyramidal effects (difficulty in speaking or swallowing; loss of balance control; mask like face; shuffling walk; stiffness of arms or legs; trembling and shaking of hands and fingers); hypotension (fainting), pigmentary retinopathy (blurred vision, defective colour vision, difficulty seeing at night); tardive dyskinesia (lip smacking or puckering; putting of cheeks, rapid or work-like movements of tongue; uncontrolled chewing movements; uncontrolled movements of arms and legs); amenorrhea and galactorrhea (female), gynecomastia and impotence (in male), hypothermia (decrease body temperature below normal); dry mouth; tachycardia, urinal retention; increased appetite and weight gain, cholestatic jaundice, corneal capacity.

**Contraindications:** - severe cardiovascular disease, severe CNS depression, and comatose states.

**Dose and Administration** - *orally and IM*

Adults -

Psychotic disorder -



*Orally*, 10 to 25mg (base) two or four times a day, the dosage being increased by 20 - 50mg a day over 3 or 4 days as needed or tolerated.

*IM* (sever) - 25 to 50mg (base), the dosage being repeated in one hour if needed and every three to twelve hours thereafter as needed and tolerated. The dosage may be gradually increased over several days as needed and tolerated.

Children (6 and older) -

**Psychotic disorders -**

*Oral*, 0.5mg per kg of body weight every four to six hours, the dosage being adjusted as needed and tolerated.

*IM* - 0.55 mg per kg of body weight one or two hours before surgery.

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

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#### **4.3. Anticonvulsants**

Treatment should always be started with a single drug, but the choice of an anticonvulsant can only be made on an individual basis and will depend on the efficacy of the drug and the patient's tolerance of treatment.

Barbiturates are used as antiepileptic agents. They can, however, produce central sedation, although they may produce paradoxical excitement and hyperactivity in children. The elderly are particularly sensitive to central depressant adverse effects and may experience confusion. Phenobarbitone is used in all forms of epilepsy with the exception of absence seizures. It has been widely used in children and neonates in particular, perhaps because of convenience of administration and linear pharmacokinetics, but there is concern about its effects on cognition.

The use benzodiazepines for the long-term treatment of epilepsy is limited by problems of tolerance, sedation, and the development of dependence; withdrawal seizures are also a problem. Diazepam is not used in the prophylaxis of epileptic seizures but is of value in the treatment of febrile convulsions.

**Withdrawal:**

Treatment is normally continued for a minimum of two years after the last seizure. Withdrawal should be extended over a period of several months since abrupt withdrawal can lead to complications such as status epilepticus. Abrupt discontinuation is therefore never warranted. Many adult patients relapse once treatment is withdrawn and it may be justified to continue treatment indefinitely, particularly when the patient's livelihood or lifestyle can be endangered by recurrence of a seizure.

**Pregnancy and Breastfeeding;**



Antiepileptic treatment may be teratogenic, the risk being increased when several drugs are given. However, generalized convulsions may be harmful or fatal to both foetus and mother and epilepsy if untreated has been associated with an increased incidence of foetal abnormalities; therefore there is no justification for abrupt withdrawal of treatment although withdrawal of therapy may be an option if the patient has been seizure free for at least 2 years; resumption of treatment antiepileptics are continued in pregnancy, mono therapy with the lowest effective dose is preferred, with adjustment made to take account of changes in plasma levels associated with pregnancy. The risk of teratogenicity with phenobarbitone appears to be lower than other antiepileptic agents, although with phenobarbitone there may be neonatal sedation and drug dependence if given close to term. In view of the risk of neonatal bleeding associated with phenobarbital, prophylactic phytomenadione (vitamin k1) is recommended for the neonatal and the mother before delivery. Anti-epileptic drugs can be continued during breastfeeding.

### **Diazepam**

*Suppository, 5mg, 10mg*

*Injection, 5mg/ml in 2ml ampoule*

**Indications:**- as adjunct in static epilepticus and severe recurrent convulsive seizures.

**Cautions, Drug interactions, Contraindications, & Side effects;** see notes on diazepam section 4.2

#### **Dose and Administration:**

Adult - Anticonvulsants - *IV*, 5-10mg initially, the dosage being repeated, if necessary, at 10-15 minutes interval up to a maximum dose of 30mg.

Child - Anti convulsant - status epilepticus and severe recurrent convulsive seizures.

- Infants over 30 days of age and children up to 5 years of age -

*IV* (slow) -0.2 to 0.5 mg every 2-5 minutes up to a maximum of 5mg. If necessary, therapy should be continued.

Children 5 and older - *IV* (*slow*) - 1mg every two to five minutes up to a maximum of 5mg. If necessary, therapy may be repeated in two or four hours.

Elderly - Anticonvulsant - *IM or IV*, initially, 2 to 5 mg per dose, the dosage being increased gradually as needed and tolerated.

**Storage:** - Store at room temperature. Protect from light and freezing.



**Phenobarbitone (Phenobarbital)**

Tablets, 15mg, 30mg, 100mg.

Elixir, 20mg/5ml

Injection (sodium), 25mg/ml in 1ml ampoule; 100mg/ml in 2ml ampoule;  
4%

**Indications:** - for the control of seizures (epilepsy).

Long - acting barbiturate is indicated as long-term anticonvulsant therapy for the treatment of generalized tonic-clonic and simple partial (cortical focal) seizures.

**Cautions:** - liver or renal diseases, acute or chronic pain, in weak patients, in children and the elderly, during pregnancy, labour, delivery, and breast-feeding. It has a sedative effect, and driving and operating machines should be avoided.

Also treatment should not be stopped abruptly as rebound seizures may occur.

**Drug interactions:** central nervous system (CNS) depressants (e.g. alcohol), paracetamol, isoniazid, and choramphenicol; and oral contraceptives containing estrogens.

**Contraindications:** respiratory depression.

**Side effects:** drowsiness or sedation, respiratory depression, and a hangover effect may occur more frequently.

Unusual excitement may occur in children, the elderly, and in patients with severe pain. It should be discontinued if severe skin reactions with fever occur.

Continued use may result in psychic or physical dependence. With excessive doses in coordination of muscular motion and continuous rolling movement of eyeball may also occur.

**Dose and Administration:** *Orally*. Several weeks (2—3) of therapy may be required to achieve maximum antiepileptic effect.

Adults :*Oral*, 50 – 100mg every 12 hours daily.

Children: *Oral*, 15 – 50 mg every 12 hours daily. Or 1 –2mg/kg of body weight every 8 hours daily.

Anticonvulsant, Adult, *Oral*, 60-250mg per day as a single dose - or in divided dose; *IV* -100-320mg, repeated if necessary up to a total dose of 600mg during a 24 hour period; Children, *Oral*, 1 to 6mg per kg of body weight per day as a single dose or in divided doses.

Status epilepticus - *IV (slow)*, 10 to 20mg per kg of body weight, repeated, if necessary.

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



## 5. DRUGS USED IN ANESTHESIA

### 5.1. General Anesthetics

General anesthetics depress the central nervous system and produce loss of consciousness. An ideal anesthetic agent would produce unconsciousness, analgesia, and muscle relaxation suitable for all surgical procedures and be metabolically inert and rapidly eliminated. No single agent in safe concentrations fulfills all these requirements and it is customary to employ a number of agents to produce the required conditions.

#### **Intravenous anaesthetics**

Intravenous anesthetics may be used either to induce anesthesia or for maintenance of anesthesia throughout surgery. They can produce apnea and hypotension and thus facilities for adequate resuscitation must be available. They are contraindicated if the anaesthetist is not confident of being able to maintain an airway. Before intubation is attempted, a muscle relaxant must be given. Individual requirements vary considerably; lesser dosage is indicated in the elderly, debilitated or hypovolaemic patients.

Anaesthesia with ketamine persists for up to 15 minutes after a single intravenous injection and is characterized by profound analgesia. It may be used as the sole agent for diagnostic and minor surgical interventions. Subanaesthetic concentrations of ketamine may be used to provide analgesia for painful procedures of short duration such as the dressing of burns, radio therapeutic procedures, marrow sampling and minor orthopedic procedures. It is of particular value in children.

#### **Ketamine Hydrochloride**

*Injection, 10 mg/ml in 20ml, 50 mg/ml in 20 mg.*

**Indications:** - anesthesia for short diagnostic and surgical procedures that do not require skeletal muscle relaxation; to induce anaesthesia prior to administration of other general anaesthesia. It is also used to supplement low potency anaesthetic such as nitrous oxide.

**Cautions:** - warn the patient not to drive or operate machinery for about 24 hours of post anaesthesia or avoiding alcohol and other CNS depressants within 24 hours following anaesthesia; pregnancy.

**Drug interactions:** - anaesthetics such as enflurane, isoflurane, methoxyflurane, antihypertensives; CNS depressants, thyroid hormones.

**Contraindications:** - ketamine is contraindicated in any condition in which significant elevation of blood pressure would be hazardous such as severe cardiovascular disease, heart-failure, severe-hypertension, myocardial infarction, stroke (history); cerebral trauma, intracerebral mass or hemorrhage; eye injury, increased cerebrospinal fluid pressure



and increased intraocular pressure; psychiatric disorders such as schizophrenia or acute psychosis, thyrotoxic states.

**Side effects:** - increased blood pressure, tachycardia, tonic or clonic muscle movements, emergence reaction (alteration in mood or body image, delirium, dissociative or floating sensation), vivid dreams or illusions, visual hallucinations.

**Dose and Administration:**

Adult -Induction: *IV*, 1 to 2mg per kg of body weight administered as a single dose or by *IV* infusion at a rate of 0.5mg per kg of body weight per minute.

*IM*- 5-10mg per kg of body weight.

Maintenance: *IV*-0.01-0.05mg (base) per kg of body weight by continuous infusion at a rate of 1-2mg per minute.

Children and Elderly - Same as adult

**Storage:** - at room temperature, protect from light and heat and from freezing

**Volatile inhalation agents**

One of the volatile anesthetics, ether, halothane (with or without nitrous oxide), must be used for induction when intravenous agents are contraindicated and particularly when intubations is likely to be difficult. Full muscle relaxation is achieved in deep anesthesia with ether. Excess bronchial and salivary secretion can be avoided by premedication with atropine. Laryngeal spasm may occur during induction and intubations. Localized capillary bleeding can be troublesome and postoperative nausea and vomiting are frequent; recovery time is slow particularly after prolonged administration.

If intubation is likely to be difficult, halothane is preferred. It does not augment salivary or bronchial secretions and the incidence of postoperative nausea and vomiting is low. Severe hepatitis, which may be fatal, sometimes occurs; it is more likely in patients who are repeatedly anaesthetized with halothane with in a short period of time.

**Ether, anesthetic**

*Inhalation, 100gm, 250gm*

**Indications:** - general anesthesia before surgery.

**Cautions:** - ether is explosive. Mixture of its vapor with oxygen, nitrous oxide or air at certain concentration causes explosion and hence it should be avoided. It should not be used in the presence of open flame or any electrical appliances liable to produce a spark.

Premedication with atropine is necessary to inhibit bronchial and gastric secretion induced by ether.



**Drug interactions:** - avoid concomitant use of ether with competitive muscle relaxants.

**Side effects:** - irritation on the mucous membrane of the respiratory tract, pharyngeal spasm, decreased blood pressure, capillary bleeding, malignant hyperpyrexia (in some individuals), convulsions in children and young adults.

**Contraindications:** - diabetes mellitus, impaired kidney function, severe liver disease.

**Dose and Administration**

Induction, *inhalation*, Adult, & child, up to 15 % in impaired gases. Maintenance of light anesthesia, 3 - 5 % in air (with or without muscle relaxants); up to 10 % for deep anesthesia.

**Halothane**

*Inhalation, 250 ml*

**Indications:** - induction and maintenance of general anesthesia.

**Cautions:** - during pregnancy, breast-feeding, in children and elderly patients.

**Drug interactions:** - sympathomimetics, specially catecholamines such as dopamine, epinephrine, norepinephrine; or cocaine, ephedrine, levodopa, metraminol, methenamine, nephrotoxic agents, xanthines; alcohol, aminoglycosides; capreomycin, citrate-anticoagulated blood, lincomycin (systemic), neuromuscular blocking agents (non depolarizing), polymyxins (systemic). Amiodarone, cumarine or indandione derivative anticoagulants; antihypertensives, especially diazoxide or ganglionic blockers such as guanidrel, guanethidine, mecamlamine or trimethaphan, neostigmine and pyridostigmine.

**Side effects:** - hepatotoxicity, impairment of psychomotor skills, emergence delirium (postanaesthesia), shivering or trembling, nausea or vomiting (mild).

**Contraindications:** - malignant hyperthermia, biliary tract disease or hepatic function impairment, jaundice or acute hepatic damage; cardiac arrhythmias, head injury or increased intracranial pressure, myasthenia gravis, pheochromocytoma, sensitivity to halothane.

**Dose and Administration** - inhalation

Adult -Induction: *inhalation*, 1.5 to 3%

Maintenance: *inhalation*, 1 to 3.5%

Child -Dosage must be individualized

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

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**5.2.Neuromuscular Blockers**

These drugs affects transmission at the neuromuscular junction and are used as adjuncts to general anesthesia, particularly to enable adequate



muscle relaxation to be achieved with light anesthesia. There are 2 main types of neuromuscular blocking agents: competitive or non-depolarizing agents and depolarizing agents.

Generally, the competitive neuromuscular blocking agents, having a longer duration of action, are used in major operations, while the depolarizing agents, with a much shorter effects, are used for minor operations or manipulations and particularly for intubations. Following administration of a depolarizing agent, such as suxamethonium, to aid incubation, a longer acting competitive agent may be given to maintain muscle relaxation throughout an operation.

Suxamethonium is the only widely used depolarizing muscle relaxant. It produces rapid, complete paralysis, which is very short-lasting in most patients and is of particular value for laryngoscopy and intubation. Prolonged paralysis may occur in those with low or atypical plasma cholinesterase. Assisted ventilation should be continued until muscle function is restored. Suxamethonium normally produces a phase I (depolarizing) neuromuscular block. After high dose or prolonged use, the nature of the block changes to a phase II (non-depolarizing) block; this phase II block (also known as dual block) is associated with prolonged neuromuscular blockade and apnoea.

Gallamine is competitive (non-depolarizing) muscle relaxant and has vagolytic and sympathomimetic properties and frequently increases pulse rate and blood pressure. It is rarely used since the other neuromuscular blocking drugs have a more predictable response and it should be avoided in patients with renal impairment.

### **Gallamine Triethiodide**

*Injection, 40mg/ml in 2 and 3ml ampoule*

**Indications:** - as adjunct to anaesthesia to induce skeletal muscle relaxation and to facilitate the management of patients undergoing mechanical ventilation.

**Cautions:** - children, during pregnancy and in children with pre-existing hypotension.

**Drug interactions:** - aminoglycosides, local and parental anaesthetics, capreomycin, citrate -anticoagulated blood, clindamycin or lidocaine, lincomycin, polymyxins or procaine, trimethaphan (large doses), analgesics (opiod, narcotic), especially those used as adjuncts to anaesthesia such as alfentanil, fentanyl, sufentanil; quinidine, calcium salts and succinylecholine.

**Side effects:** - increased blood pressure, tachycardia.

**Contraindications:** - renal function impairment, shock, cardiac condition in which tachycardia would be undesirable.

**Dose and Administration:**



Adult -*IV*, initially 1mg per kg of body weight, not to exceed 100mg per dose, then 0.5mg to 1mg per kg of body weight after an interval of thirty to forty minutes, if necessary, for prolonged procedure. Child - same as adult.

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

### **Suxamethonium Chloride (succinylcholine)**

*Powder for injection, 100 mg, 500 mg in vial*

**Indications:** - as adjunct to anaesthesia to induce skeletal muscle relaxation and to facilitate the management of patients undergoing mechanical ventilation.

**Cautions:** - children, during pregnancy, and cardiovascular function impairment.

Caution is also required:

In conditions that may be adversely affected by increased potassium concentrations (severe burns, digitalis toxicity, or recent digitalization, degenerative or dystrophic neuromuscular disease, paraplegia, pre-existing hyperkalemia, spinal cord injury, severe trauma).

Conditions that may lead to low plasma pseudocholine esterase activity (severe anemia, dehydration, exposure to neurotoxic insecticides or other cholinesterase inhibitors, severe hepatic disease or cirrhosis, malnutrition, recessive hereditary trait).

Conditions that may be adversely affected by increase in intraocular pressure (open eye injury, glaucoma, ocular surgery).

Fracture or muscle spasm and malignant hyperthermia.

**Drug interactions:** - cholinesterase inhibitor specially echothiopate, demecarium, isofluorophate, cyclophosphamide. Avoid exposure to insecticides such as Malathion. Avoid also simultaneous use of digitalis glycosides, procainamide, physostigmine, calcium salts, and succinylcholine.

**Contraindications:** - allergic to succinylcholine, pulmonary function impairment or respiratory depression, renal function impairment.

**Side effects:** - increased intra ocular pressure, muscle pain and stiffness (post operative), excessive salivation, cardiac arrhythmias, bradycardia.

### **Dose and Administration:**

Adult - For short surgical procedures. *IV* usually 0.6mg per kg of body weight, initially.

Repeated doses may be administered, if necessary, calculated on the basis of response to the first dose.

*IM* - 3 to 4 mg per kg of body weight, not to exceed a total dose of 150mg.

Child - Endotracheal intubation



*IM* - up to 2.5mg per kg of body weight, not to exceed, a total dose of 150mg.

*IV* - 1 to 2mg per kg of body weight. Repeated on the basis of response to the first dose.

**Storage:** - Store between 2 and 8°C. Protect from freezing.

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### 5.3. Anesthetic Adjuncts and Adjuvants

A balance combination of agents with different actions is often used to provide the various components of general anesthesia including hypnosis muscle relaxation. This technique has been reported to minimize intra-operative cardiovascular depression, to facilitate a rapid return of consciousness, and to have a low incidence of postoperative adverse effects such as nausea, and vomiting, and excitation.

Antimuscarinics, including atropine, and hyoscine have been used as pre-operative medication to inhibit salivation and excessive secretions of the respiratory tract. This use is less important now that less irritating anesthetics are used. Atropine and hyoscine are also given as premedications to reduce intra-operative bradycardia and hypotension induced by agents such as suxamethonium, halothane, or following vagal stimulation.

At the end of surgery drugs are sometimes administered to accelerate recovery from the effects of the various agents used during anesthesia. Non-depolarizing muscle relaxants may be reversed with anticholinesterases such as neostigmine but concomitant administration of atropine is required to prevent bradycardia and other muscarinic actions developing.

Oxygen should be added routinely during anesthesia with inhalational agents, even when air is used as the carrier gas, to protect against hypoxia.

Atropine is now rarely used for premedication but still has an emergency role in the treatment of vagotonic side effects.

Hyoscine effectively reduces secretion and also provides a degree of amnesia, sedation and anti-emesis. Unlike atropine it may produce bradycardia rather than tachycardia. In some patients, especially the elderly, hyoscine may cause the central anti-cholinergic syndrome (excitement, ataxia, hallucinations, behavioral abnormalities and drowsiness).

Neostigmine is the specific drug for reversal of non-depolarizing (competitive) blockade. It acts within one minute of intravenous injection and lasts for 20 to 30 minutes; a second dose may then be necessary. Atropine should be given before or with neostigmine in order to prevent bradycardia, excessive salivation; and other muscarinic actions of neostigmine.



**Atropine Sulphate***Injection, 1 mg/ml in 1 ml ampoule***Indications:** - as antisialagogue pre-anaesthetic medication to prevent or reduce salivation and respiratory tract secretions.**Cautions:** - pregnancy, breastfeeding, in children and elderly patients. Caution is also needed in patients with hyperthyroidism, hepatic or renal disease, hypertension, tachyarrhythmias, congestive heart failure, coronary artery disease, gastric ulcer, esophageal reflex, and cardiac insufficiency. Extreme caution is required in patients with known or suspected GI-infection and with autonomic neuropathy. There should be caution also in debilitated patients with chronic pulmonary disease. Advise patients not to drive vehicle or operate machineries**Drug interactions:** - atropine with antacids, antidiarrhoeals (adsorbent), other anticholinergic, cyclopropane anaesthesia, ketoconazole.**Side effects:** - dryness of mouth, nose and throat, skin; constipation decreased sweating, redness or other signs of irritation at injection site, blurred vision, decreased salivary secretion (difficulty in swallowing), mydriatic effect (increased sensitivity of eyes to light), increased intraocular pressure, bradycardia followed by tachycardia, palpitation and arrhythmias.**Contraindications:** - severe ulcerative colitis, obstructive disease of the GI tract e.g. pylorodeudonal stenosis, achalasia, cardiospasm, paralytic ileus or intestinal atony (especially in geriatric or debilitated patients), known hypersensitivity, angle-closure glaucoma, obstructive uropathy, myasthenia gravis.**Dose and Administration:**Adult - *IV* 0.3-0.6mg immediately before induction of anaesthesia.*IM* 0.3-0.6, 30-60 minutes before inductionChildren - *IM* 20 micrograms per kg of body weight**Storage:** - store at room temperature protect from freezing.**Hyoscine Hydrobromide***Injection, 0.4 mg/ml, 0.6 mg/ml in 1 ml ampoule***Indications:** - as antisialagogue preanaesthetic medication to prevent or reduce salivation and respiratory tract secretion.

Parenteral administration of scopolamine in combination with morphine or mepridine is indicated in pre-anaesthesia to reduce excitement and produce amnesia.

**Cautions:** - pregnancy and breast-feeding, in children and elderly patients. Advise patients to avoid alcohol, driving vehicle and operating machineries.

**Drug interactions:** - antacids, antidiarrhoeals (adsorbents), other anticholinergics, cyclopropane anaesthesia, CNS depressants.

**Contraindications:** - angle closure glaucoma, pyloric obstruction, urinary bladder neck obstruction, tachycardia, paralytic ileus, hypersensitivity to the drug, ulcerative colitis.

**Side effects:** - constipation, decreased sweating, drowsiness, dryness of mouth, skin, throat and nose, loss of memory, redness or other signs of irritation at injection site.

**Dose and Administration:**

Adult -Prophylaxis of excessive salivation and respiratory tract secretion in anaesthesia: *IM* 0.2-0.6mg, 30 minutes to 1 hour before induction of anaesthesia.

Anaesthetic Adjunct - sedation - hypnosis: *IM, IV* or *SC* 0.6mg three or four times a day.

-Amnesia: *IM, IV, SC* 0.32 to 0.05mg

Child- Prophylaxis of excessive salivation and respiratory tract secretion in anaesthesia: *IM*, administered 45 minutes - 1 hour before induction of anaesthesia. Children (4-7 months) - 0.1mg. Children (7months - 3 years) - 0.15mg, children (3-8 years) - 0.2mg, Children (8-12 years) - 0.3mg

**Storage:** - store at room temperature in light-resistant container, protect from light.

**Neostigmine**

*Injection (Methylsulphate), 0.5 mg/ml, 2.5 mg/ml in 1 ml ampoule*

**Indications:** for reversal of the effects of Non-depolarizing Neuromuscular blocking agents (e.g. tubocurarine, metocurine, gallamine or pancuronium) after surgery.

It is also indicated in the treatment of post-operative non-obstructive urinary retention.

It may be indicated for prevention and treatment of post-operative gastro intestinal ileus and prevention of postoperative distention and urinary retention.

**Cautions:** - caution should be taken during near term pregnancy, in elderly and in those patients with epilepsy, bronchial asthma, bradycardia, recent coronary occlusion, vagotonia, hyperthyroidism, cardiac arrhythmias, or peptic ulcer.

**Drug interactions:** - anticholinergics especially atropine and related compounds, local and some general anaesthetics such as chloroform, cyclopropane, enflurane, halothane, lidocaine; systemic aminoglycosides, succinylcholine or decamethonium; other cholinesterase inhibitors including demecarium, echothiopate isophlurophate, edrophonium; ganglionic blocking agents such as guanethidine, mecamlamine, trimethaphan; procainamide.



**Side effects:** - diarrhoea, increasing sweating, increasing of watering of mouth, nausea, vomiting, stomach cramp, frequent urge to urinate, increased bronchial secretion, miosis, bradycardia, bronchospasm, weakness, muscle cramp, fasciculation, hypotension.

**Contraindications:** - intestinal or urinary tract obstruction (mechanical), hypersensitivity to the drug or bromide, peritonitis, urinary tract infection.

**Dose and Administration:**

Adult -Antidote (to non-depolarizing neuromuscular blocking agents) after surgery - *IV*- 0.5mg - 2mg administered slowly, repeated as required up to a total dose of 5mg.

**Note:** -0.6mg - 1.2mg of atropine is administered prior to or concurrently with neostigmine to counteract its muscarinic side effect.

- Prevention of post-operative distention or retention - *IM or SC* - 0.25mg immediately following surgery, repeated every four to six hours for 2 or 3 days.
- Prevention of post-operative distention - *IM or SC* - 0.5mg as needed.
- Prevention of urinary retention - *IM or SC* - 0.5mg; dose repeated every 3 hours for at least five doses after patient has voided or the bladder has been emptied.

**Note:** - If urination doesn't occur within one hour following the initial - 0.5mg per dose, the patient should be catheterized.

Child - Antidote (to non-depolarizing Neuromuscular blocker) after surgery - *IV*, 0.04mg per kg of body weight administered with 0.02mg of atropine per kg of body weight.

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

**Oxygen (white-colored cylinder)**

**Indications:** - oxygen is given by inhalation to correct hypoxia in conditions causing under ventilation of the lungs, such as exacerbations of chronic bronchitis, pneumonia, or pulmonary oedema, where bronchospasm causes hypoxia, as in asthma, in extensive fibrosing alveolitis after general anaesthesia and in conditions where the oxygen content of the air breathed is inadequate as at high altitudes.

**Cautions:** - any fire or spark is highly dangerous in the presence of increased oxygen concentrations especially when oxygen is used under pressure.

Metal cylinders containing oxygen should be fitted with a reducing valve by which the rate of flow can be controlled.



**Side effects:** - CNS, toxicity (nausea, mood change, vertigo, twitching, convulsions, loss of consciousness), pulmonary toxicity (decrease in vital capacity, cough, substernal distress, and later atelectasis), retinopathy of prematurity.

**Dose and Administration:** - *by inhalation*. It is administered by means of nasal catheter, facemask, endotracheal tube, or oxygen tent. Concentration of oxygen in inspired anesthetic gases should never be less than 21 % sideline (carbondioxide absorbent).

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#### 5.4. Local Anesthetics

The local anesthetics are compounds which produce reversible loss of sensation by preventing or diminishing the conduction of sensory nerve impulses near to the site of their application or injection. Local anesthetics could also be described as local analgesics as they are most often used to produce loss of pain without loss of nervous control. Also because their mode of action is to decrease permeability of the nerve cell membrane to sodium ions they are considered to have a membrane stabilizing effect.

Local anesthetics are used very widely indented practice, for brief and superficial interventions for obstetric procedures, and for specialized techniques of regional anesthesia calling for highly developed skins. Where patient cooperation is required the patient must be psychologically prepared to adept the proposed procedure. Facilities and equipment for resuscitation should be readily available at all times care must always be taken to avoid inadvertent intravascular injection.

The drugs used vary widely in their potency, toxicity, duration of action, stability in water, and ability to penetrate mucous membranes. These variations determine their suitability for use by various routes, e.g. topical (surface), infiltration, plexus, epidural (extradural) or spinal block.

The cold sensation produced by ethyl chloride spray is used to test the onset of regional an aesthesia.

*Local infiltration anesthesia.* Many simple surgical procedures that neither involve the body cavities nor require muscle relaxation can be performed under local infiltration anesthesia. Lower segment caesarean section can also be performed under local infiltration anesthesia. The local anesthetic drug of choice is lidocaine 0.5 % with or without epinephrine. No more than 4 mg/kg of plain lidocaine or 7 mg/kg of lidocaine with epinephrine should be administered on any one occasion. The addition of epinephrine (adrenaline) diminishes local blood flow.



Slows the rate of absorption of the local anesthetic, and prolongs its effect. Care is necessary when using epinephrine for this purpose since, in excesses, it may produce ischaemic necrosis.

*Surface anesthesia.* Topical preparations of lidocaine are available and topical eye drop solutions of tetracaine are used for local anaesthesia of the cornea and conjunctiva.

*Regional Block.* A regional nerve block can proceed safe and effective anesthesia but its execution requires considerable training and practice. Nevertheless, where the necessary skills are available, techniques such as axillary's or ankle block can be invaluable. Either lidocaine 1 % or bupivacaine 0.5 % is suitable. Bupivacaine has the advantage of a longer duration of action.

*Spinal Anesthesia.* This is one of the most useful of all anaesthetic techniques and can be used widely for surgery of the abdomen and the lower limbs. It is a major procedure requiring considerable training and practice. Either lidocaine 5 % in glucose or bupivacaine 0.5 % in glucose can be used but the latter is often chosen because of its longer duration of action.

### **Ethyl Chloride**

*Spray, 50ml*

**Indications:** -as a local anaesthetic in minor operative procedures such as incision of boils and removal of localized growths.

**Cautions:** - during application, the skin adjacent to the area being treated should be covered with vaseline to protect against tissue sloughing. Inhalation of ethyl chloride should be avoided.

**Side effects:** - freezing may injure cells, decrease resistance to infections, and delay healing. The frozen tissue may be painful, as it gets warm. And cutaneous sensitization may occur rarely.

**Contraindications:** broken skin or mucous membrane.

**Dose and Administration:** -the container should be held about 12 inches (30 cm) from the area being treated and the spray directed downward until light frosting appears. Because the local anaesthetic effect is very brief, incision should be made as soon as the tissue become white.

**Storage:** -at room temperature, in tight containers, away from fire. Protect from light.

### **Lidocaine Hydrochloride**

*Ointment, 5 % in 10 g*

*Jelly, 2% in 30 ml*

*Cartridge, 2% in 1.8 ml ampoule*

*Injection, 0.5 %, 1 %, 2 % in 2 and 20 ml vials*

*Injection Heavy, 5 % in 2 ml ampoule*



*Spray, 4 %, 10 % in 80 g*

*Viscous, 2 % in 100 ml*

**Indications:** - surface anaesthesia of mucous membranes; infiltration anesthesia; peripheral and sympathetic nerve block; dental anaesthesia; spinal anaesthesia; intravenous regional anaesthesia; arrhythmias.

**Cautions:**- caution in patients with inflammation and/or infections at site of injection, and in very young, the elderly acutely ill, or weak patients.

**Drug interactions:** -avoid simultaneous use of lidocaine with vasoconstrictors (e.g. adrenaline) on the extremities such as the finger, toes...etc.

**Contraindications:** known hypersensitivity.

**Side effects:** a transient burning sensation may occur at the site of injection.

**Dose and Administration:**

Note: - *Intradermally, subcutaneously, or submucosally* (local infiltration). Inject indirectly in to the tissue to be incised or in the immediate area surgery. It should be injected slowly, with frequent aspirations before and during the injection, to reduce the risk of inadvertent intravascular administration.

The total dose should not exceed 300mg/dose (4.5mg/kg of body weight). Children should receive smaller amounts of lidocaine, generally in lower concentration than adults.

*By injection*, infiltration anesthesia, according to patient's weight and nature of procedure, max, 300 mg.

Ointment, *Topical*, adult and child 2 years of age and older as a 5 % ointment, to the affected area three or four times a day as needed.

Jelly, *Topical*, Adult, to the affected area three or four times a day as needed

Spray, *Topical*, Adult, sprayed and/or applied to affected area three or four times a day as needed.

**Storage:** -at room temperature. Protect from freezing.

**Lidocaine Hydrochloride + Adrenaline**

*Injection, 1 % + 1:200,000 in 30 ml Vial*

*Injection, 2 % + 1:200,000 in 20 ml vial*

See under Lidocaine Hydrochloride

**Dose and Administrations**

Dental Anesthesia (for infiltration or nerve block)

Adult, 20 to 100 mg (1 to 5 ml) of lidocaine hydrochloride as 2 % solution with epinephrine 1:2000,000; Child, 4 to 5 mg of Lidocaine Hydrochloride per kg of body weight or 100 to 150 mg as a single dose.

Local infiltration or nerve block 7 mg of lidocaine hydrochloride per kg of body weight as a 0.25 to 1 % solution with epinephrine 1:200,000.

**Storage:** - at room temperature protect from light and freezing.



## 6.DRUGS USED IN MUSCULOSKELETAL AND JOINT DISEASE

### 6.1.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 a 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, 75 mg, 100 mg (soluble), 300 mg, 324 mg (microfined), 500 mg (enteric coated)*

See section 4.1 and notes above.

**Diclofenac sodium**

*Tablet (e/c), 25 mg, 50 mg*

*Suppository, 100 mg*

*Injection, 25 mg/ml, 3 ml ampoule*

**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.

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

**Contraindications:** - see notes above, porphyria.

**Dose and Administration**

Adult,



*By mouth*, 75 – 150 mg daily in 2 – 3 divided doses.

*By deep intramuscular 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.

*By intravenous 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.

*By 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, *by mouth* or *by 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**

*Tablet, 200 mg, 400 mg*

*Capsule, 300 mg*

*Syrup, 10 mg/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, Side effects, Contraindications:** - see notes above.

**Drug interactions:** - coumarine 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.

### **Dose and Administration**

Mild to moderate pain, pyrexia, inflammatory musculoskeletal disorders, *by mouth* with or after food, ADULT 1.2–1.8 g daily in 3–4 divided doses, increased if necessary to maximum 2.4 g daily; maintenance dose of 0.6–1.2 g daily may be sufficient

Juvenile arthritis, *by mouth* with or after food, CHILD over 7 kg, 30–40 mg/kg body weight daily in 3–4 divided doses

Fever and pain in children (not recommended for child under 7 kg body weight), *by mouth* with or after food, 20–30 mg/kg body weight daily in divided doses *or* 1–2 years 50 mg 3–4 times daily, 3–7 years 100 mg 3–4 times daily, 8–12 years 200 mg 3–4 times daily

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



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

**Indomethacin**

*Capsule, 25 mg, 50mg, 75mg*

*Suppository, 100 mg*

*Syrup, 25mg/5ml*

**Indications:** - acute or chronic rheumatoid arthritis, for relief of acute or chronic osteoarthritis and for relief of acute or chronic ankylosing spondylitis; acute gout (section 6.2). It is also indicated for relief of acute or chronic juvenile arthritis and in the treatment of psoriatic arthritis.

**Cautions:** - see notes above, also epilepsy, parkinsonism, psychiatric disturbances, during prolonged therapy ophthalmic and blood examinations particularly advisable; avoid rectal administrations in proctitis and haemorrhoids. Dizziness may affect performance of skilled tasks (e.g. driving)

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

**Side effects:** -see notes above; frequently gastrointestinal disturbances (including diarrhea, headache, dizziness, and light - headedness; also gastro-intestinal ulceration and bleeding; rarely, drowsiness, confusion, insomnia, convulsions, psychiatric disturbances, depression, syncope, blood disorders (particularly thrombocytopenia), hypertension, hyperglycaemia, blurred vision, corneal deposits, peripheral neuropathy, and intestinal strictures; suppositories may cause rectal irritation and occasional bleeding.

**Contraindications:** - see notes above

**Dose and Administration:** -

Adult -Anti-rheumatic - *oral*, initially 25 to 50mg two or four times a day, if well tolerated, the dosage per day may be increased by 25 or 50mg at weekly intervals until a satisfactory response is obtained or up to a maximum dose of 200mg per day.

- *Rectal*, 50mg four times a day

Child - Anti-rheumatic - *oral*, 1.5 to 2.5mg per kg of body weight, per day, administered in three or four divided doses, up to a maximum of 4mg per kg of body weight per day or 150 to 200mg per day, which ever is less.

*Rectal* - same as oral (for children)

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



### 6.2. Drugs used for gout

It is important to distinguish drugs for the treatment of acute attacks of gout from those used in the long-term control of the disease. The latter exacerbate and prolong the acute manifestations if started during attack.

#### *Acute gout*

Acute attacks of gout are usually treated with high doses of NSAIDs such as indomethacin (150 - 200 mg daily in divided doses), ibuprofen has weaker anti-inflammatory properties than other NSAIDs and is therefore unsuitable for treatment of gout. Salicylates, including acetylsalicylic acid are also not suitable because they may increase plasma-urate concentrations.

#### *Chronic gout.*

If the Patient suffers recurrent attacks or develops gouty nephropathy or urolithiasis, then the hyperuricaemia will need to be treated, but not until 2 to 3 weeks after the patient has recovered from the latest acute attack. There are two approaches to this drug treatment (known as interval treatment) of hyperuricaemia: inhibiting the production of uric acid with allopurinol (not available at health center level) or enhancing the urinary excretion of uric acid with a uricosuric agent such as probenecid.

#### **Ibuprofen**

*Tablet - 200 mg, 400 mg*

**Indications:** - For relief of the pain and inflammation of acute gout arthritis.

**Cautions, Drug interactions, Contraindications, Side effects, storage** See under section 6.1

#### **Dose and administrations:**

Treatment of acute migraine attack, *by mouth* preferably with or after food, ADULT 400–600 mg at first sign of attack, may be repeated every 6–8 hours if necessary, maximum 2.4 g daily; CHILD 8–12 years 200 mg at first sign of attack, may be repeated every 6–8 hours if necessary

#### **Indomethacin**

*Capsule, 25 mg*

*Suppository, 100 mg*

**Indications:** - for relief of the pain and inflammation of acute gouty arthritis.

**Cautions, Drug interactions, Contraindications, Side effect, and Storage** - see under indomethacin above, section. 6.1

**Dose and Administration:** -Adult - Antigout- *Oral*, 100mg initially, then 50mg three times aday until pain is relieved, with the dosage then being reduced until medication is discontinued.



*Rectally*, 50mg up to four times a day. A daily dose more than 150 to 200 mg may increase the risk of adverse effects without providing additional clinical benefit.

Child dose not recommended.

### **Probenecid**

*Tablet, 500 mg*

**Indications:** - long-term management of hyperuricemia associated with chronic gout.

Note: - It is not effective in the treatment of acute gout attacks and does not eliminate the need to use colchicine or non-steroidal anti-inflammatory drugs to relieve an attack.

**Cautions:** - children (younger than 2 years of age), in patients with peptic ulceration, renal function impairment, blood dyscrasias.

**Drug interactions:** - antineoplastic (rapidly cytolytic), zidovudine, indomethacin, ketoprofen, aspirin or other salicylates (including bismuth subsalicylate), cephalosporines or penicillines, heparin, and nitrofurantoin.

**Side effects:** - acute gout, arthritis attack (joint pain, redness, swelling), headache, loss of appetite, nausea or vomiting (mild), dizziness, flushing or redness of face, urinary frequency, sore gums, aplastic anaemia, nephrotic syndrome (cloudy urine, swelling of face).

**Contraindications:** - probenecid is contraindicated in any condition in which there is an increased risk of uric acid renal calculi formation or urate nephropathy such as cancer chemotherapy with rapidly cytolytic antineoplastic agents, radiation therapy for malignancy, moderate to severe renal function impairment, history of blood dyscrasias nephrolithiasis, porphyria, acute gout attacks.

#### **Dose and Administration:**

Adult - Antigout: Initial - *oral*, 250mg two times a day for one week

Maintenance - *oral*, 500mg two times a day.

Child - dosage has not been established.

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

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### **6.3.Skeletal Muscle Relaxants**

Skeletal muscle relaxants such as diazepam are indicated as adjuncts to other measures, such as rest and physical therapy, for the relief of muscle spasm associated with acute, painful musculoskeletal conditions. They act principally on the central nervous system. They differ in action from the muscle relaxants used in anaesthesia which block transmission at the neuromuscular junction.

The major disadvantage of treatment with these drugs is that reduction in muscle tone can cause a loss of splinting action of the spastic leg and trunk muscles and sometimes lead to an increase in disability



**Diazepam***Tablet, 2 mg, 5 mg, 10 mg**Syrup, 2 mg / 5 ml**Injection, 10 mg/ml, in 2 ml ampoule***Indications:** - muscle spasm of varied aetiology, including tetanus; other indications (section 4.2, section 4.3).**Cautions:** see section 4.2; special precautions for intravenous injection.**Contraindications; Side effects,** see section 4.2; also hypotonia**Dose and Administrations***By mouth,* 2 - 15 mg daily in divided doses, increased if necessary in spastic conditions to 60 mg daily according to response.

Cerebral spasticity in selected cases, child 2 - 40 mg daily in divided doses.

*By intramuscularly or by slow intravenous injection* (into a large vein at a rate of not more than 5 mg/minute), in acute muscle spasm, 10 mg repeated if necessary after 4 hours.

Note: Only use IM route when oral and IV routes not possible.

Tetanus, Adult and Child, *by intravenous injection*, 100 - 300 micrograms/kg repeated every 1 - 4 hours; *by intravenous infusion (or by nasoduodenal tube)*, 3 - 10 mg/kg over 24 hours, adjusted according to response

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**6.4. Cholinergic and Anticholinesterase Agents****Neostigmine***Tablet (Bromide), 15 mg**Injection (Methylsulphate), 0.5 mg/ml, 2.5 mg/ml in 1 ml ampoules***Indications:** - in the treatment of conditions such as myasthenia gravis and to reverse muscle relaxation produced by competitive (non-depolarizing) muscle relaxant**Cautions, Contraindications, Drug interactions, Side effects,** see section 5.3 under neostigmine.**Dose and Administrations***By mouth,* neostigmine bromide 15 - 30 mg at suitable intervals throughout day, total daily dose 75 - 300 mg; Neonate 1 - 5 mg every 4 hours, half an hour before feeds; Child up to 6 years initially 7.5 mg, 6-12 years initially 15 mg, usual total daily dose 15 - 90 mg.*By subcutaneous or intramuscular injection* - neostigmine methylsulphate 1 - 2.5 mg at suitable intervals throughout day (usual total daily dose 5 - 20 mg); Neonate 50 - 250 micrograms every 4 hours half an hour before feeds; Child 200 - 500 micrograms as required.

## 7.ANTI-INFECTIVE

### 7.1.Antibacterials

#### 7.1.1.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 influenza*. 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. Amoxycillin, 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.

### **Penicillin G, Sodium crystalline**

*Injection, 1 million IU, 10 million IU, 20 million IU in vial*

**Indications:** throat infections, pneumonia, otitis media, lyme disease in children; streptococcal endocarditis; meningococcal meningitis; necrotizing enterocolitis, necrotizing fascitis; leptospirosis, neurosyphilis, anthrax; actinomycosis; brain abscess; gas gangrene; cellulitis; osteomyelitis.

**Cautions:** history of allergy (see notes above); renal failure; heart failure; pregnancy and breastfeeding.

**Drug interactions:** methotrexate

**Side effects:** - hypersensitivity reactions including anaphylaxis, serum sickness – like reactions, hemolytic anemia and interstitial nephritis; neutropenia, thrombocytopenia, coagulation disorders and central nervous system toxicity including convulsions reported (especially with high doses or in severe renal impairment), paraesthesia with prolonged use; diarrhea and antibiotic associated colitis; see also notes above.

**Contraindications:** - penicillin hypersensitivity (see notes above); avoid intrathecal route

### **Dose and Administration**

Mild to moderate infections due to sensitive organisms, *by intramuscularly injection or by slow intravenous injection or by intravenous infusion*, Adult, 0.6 – 2.4 g daily in 2 – 4 divided doses, with higher doses in severe infections and duration of treatment depending on disease; Neonate, 50 mg/kg daily in 2 divided doses; Infant 1 to 4 weeks, 75 mg/kg daily in 3 divided doses; Child 1 month to 12 years, 100 mg/kg daily in 4 divided doses, with higher doses in severe infections.



**Bacterial endocarditic**, *by slow intravenous injection or by intravenous infusion*, Adult up to 7.2g daily in 6 divided doses.

**Meningococcal meningitis**, *by slow intravenous injection or by intravenous infusion*, Adult up to 14.4 g daily in divided doses; Premature infant and Neonate 100 mg/kg daily in 2 divided doses; Infant 150 mg/kg daily in 3 divided doses. Child 1 month to 12 years, 180 – 300 mg/kg daily in 4 – 6 divided doses.

**Suspected meningococcal disease** (before transfer to hospital), *by intramuscularly injection or by slow intravenous injection*, Adult and child over 10 years, 1.2 g; Child 1 to 9 years, 600 mg; Child less than 1 year, 300 mg.

**Neurosyphilis**, *by slow intravenous injection*, Adult 1.8 – 2.4 g every 4 hours for 2 weeks.

**Congenital syphilis**, *by intramuscularly injection or by slow intravenous injection*, Child up to 1 years, 30 mg /kg daily in 2 divided doses for 10 days, Child over 2 years, 120 – 180 mg/Kg (to maximum of 1.44g) daily in divided doses for 14 days.

**Reconstitution and Administration.** According to manufacturer's directions

**Storage:** - at room temperature. Prior to reconstitution.

### **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:** - see under penicillin G, sodium crystalline

### **Dose and Administrations**

**Streptococcal pharyngitis;** primary prophylaxis of rheumatic fever, *by deep intramuscular injection.* 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,** *by deep intramuscular injection,* 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,** *by deep intramuscularly injection,* Adult 1.8 g as a single dose, divided between 2 sites.



Late syphilis, *by deep intramuscularly injection*, Adult 1.8 g divided between two sites, once weekly for 3 consecutive weeks.

Congenital syphilis (where no evidence of CSF involvement), *by deep intramuscular injection*, child up to 2 years, 37.5 mg/kg as a single dose.

Yaws, Pinta, and bejel, *by deep intramuscularly injection*, 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

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

*Oral suspension, 125 mg/5ml, 50000 IU/ml*

**Indications:** tonsillitis, otitis media, erysipelas; rheumatic fever and pneumococcal infection prophylaxis.

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

### Dose and Administration

Infections due to sensitive organisms, *by mouth*, Adult 500 – 750 mg every 6 hours; 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, *by mouth*, adult 500 mg twice daily; child 1 – 5 years, 125 mg twice daily; Child 6 – 12 years, 250 mg twice daily.

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

**Storage:** -at room temperature in a tight container.

### Procaine Penicillin, Fortified

*Injection (buffered), 4,000,000 IU in Vial, Dry Powder.*

*Penicillin G sodium -1,000,000 IU*

*Penicillin G procaine -3,000,000 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:** - see under penicillin G, sodium crystalline

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

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

**Dose and Administration:** - *Intramuscular injection* only.

Adults:



**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**-Adults and children (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.

Children (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 with in 14 days provided it is stored between 2-4°C or within 4 days at about 20°C.

### **Phenoxymethyl penicillin, potassium**

*Suspension, 195 mg/5ml*

*Tablet, 390 mg*

See under Phenoxymethyl penicillin

### **Ampicillin**

*Capsule, 250 mg, 500 mg*

*Oral suspension, 125 mg/5ml, 250 mg/5ml*

*Drop, 100 mg/ml*

*Injection, (sodium), 250 mg, 500 mg, 1 g in vial*

**Indications:** -for treatment of genitourinary tract infection including gonorrhoea in female and urethritis in males and females, meningococcal meningitis, acute otitis media, paratyphoid fever, pharyngitis, pneumonia, bacterial septicemia (IV only), sinusitis, and for skin and soft tissue infections including burn wound infections.

**Cautions:** - caution in patients with history of allergy, renal function impairment, GIT disease especially ulcerative colitis, regional enteritis, or antibiotic associated colitis mononucleosis infections.

**Drug interactions:** -probenecid (except in cases of gonorrhoea and other STD), allopurinol, erythromycin, sulfonamides, tetracyclines and estrogen containing contraceptives.

**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).

**Contraindications:** - known hypersensitivity (allergy) to any penicillines.

**Dose and Administration**

*By mouth*, usual adult dose, 0.25 – 1 g every 6 hours, at least 30 minutes before food; Child under 10 years, half adult dose.

Urinary – tract infections, 500 mg every 8 hours; Child under 10 years, half adult dose

*By intramuscular injection or intravenous injection or infusion*, 500 mg every 4 – 6 hours; Child under 10 years, half adult dose.

Meningitis (in combination with another antibiotic if necessary), *by intravenous infusion*, 2 g every 4 hours for 5 days in meningococcal disease or for 10 – 14 days in listerial meningitis.

**Storage:** - at room temperature.

**Amoxicilline**

*Capsule, 250 mg, 500 mg*

*Injection, 250 mg, 500 mg in vial*

*Syrup, 250 mg/5ml*

**Indications:** - see under Ampicillin, and under dose and administration; also endocarditis prophylaxis and treatment, meningococcal disease and adjunct in listerial meningitis; *Helicobacter pylori* eradication

Cautions, Contraindications and Side effects; see under Ampicillin

**Dose and Administrations**

Infections due to sensitive organisms, *By mouth*, 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.

*Short Course Oral therapy*

Dental abscess, 3 g repeated after 8 hours

Urinary – tract infections, 3 g repeated after 10 – 12 hours.

Otitis media, Child 3 – 10 years, 750 mg twice daily for 2 day.

*By intramuscularly injection*, 500 mg every 8 hours; Child, 50 – 10 mg/kg daily in divided doses

*By intravenous 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), *by intravenous 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), *by intravenous infusion*, 2 g every 4 hours.

**Storage:** – at room temperature in a tight container.



**Cloxacilline sodium***Capsule, 250mg, 500mg**Syrup, 125mg, 250mg in each 5ml**Injection, 250mg, 500mg in vial***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 function impairment, GIT disease especially ulcerative colitis, regional enteritis, antibiotic associated colitis.**Drug interactions:** - probenecid, chloramphenicol, erythromycin, sulfonamide, and tetracyclines.**Side effects:** - allergic reaction, specifically prophylaxis (bronchospasm, hypotension), skin rash, joint pain, fever, GIT reaction (mild diarrhoea, nausea, vomiting), oral candidiasis (sore mouth or tongue), pseudomembraneous colitis (sever abdominal or stomach cramp; and pain, abdominal teaderness, watery and severe diarrhoea)**Contraindications:** - known hypersensitivity or allergy to penicillines.**Dose and Administration**Usual adult and adolescent dose - *Oral*, 250 to 500mg (base) every six hours. Maximum dose up to 6gm. *IV* - 250 to 500mg (base) every six hours maximum - 6gms (base) dailyUsual pediatric dose- Infants and children up to 20kg of body weights - *Oral*, 6.25 to 12.5mg (base) per kg of body weight every six hours or *IV*, 6.25 to 12.5mg (base) per kg of body weight every six hours.**Storage:** - store at room temperature. The injectable should be stored at room temperature prior to reconstitution.**7.1.2. Other Antibacterials****Chloramphenicol***Capsules, 250mg**Suspension, oral (palmitate), 125mg/5ml; 60ml.***Indications:** -for the treatment of acute typhoid fever, and also typhus when tetracycline is contraindicated.**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.

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

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

**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** - Adults: 500mg every 6 hours daily for 14 days. Children: 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. Children: 50 – 75 mg/kg of body weight daily in divided doses every 6 hours for 10 days.

**Storage:** at room temperature, in a tight container.

### **Tetracycline**

*Capsules, 250mg.*

**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:** - aluminium and/or magnesium containing antacids, laxatives, calcium (e.g. milk or other dairy products, eggs) and/or iron supplements, penicillines, or streptomycin.

**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.

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

**Dose and Administration:** -*orally*, given 1 hour before or 2 hours after meals and/or milk with adequate amounts of fluid.

Reduce dosage in renal and hepatic function impairment.

Adults:

**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.



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

Relapsing fever-

Adults: 500mg – 1g every twelve hours.

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

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

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

### **Doxycycline**

*Tablet, 100mg*

*Capsule, 100mg*

**Indications:** -respiratory-tract infections, including pneumonia and chronic bronchitis; urinary-tract infections; syphilis; chlamydia, mycoplasma, and rickettsia; prostatitis; lymphogranuloma venereum; pelvic inflammatory disease (with metronidazole); Lyme disease; brucellosis (with rifampicin); leptospirosis, scrub typhus and travellers' diarrhoea; psittacosis; cholera; melioidosis; plague; anthrax; Q fever; malaria.

**Cautions:** - hepatic function impairment.

**Drug interactions:** - cyclosporin, oral contraceptives, warfarin.

**Side effects:** - nausea, vomiting, diarrhoea, erythema, headache, visual disturbance, hepatotoxicity, pancreatitis, pseudomembrane colitis, discolouration of infants and children's teeth, photosensitivity.

**Contraindications:** - pregnancy, and breast-feeding, in infants and children up to 8 years of age.

**Dose and Administration** -

Infections due to susceptible organisms, *by mouth*, ADULT and CHILD over 8 years, 200 mg on first day then 100 mg daily; in severe infections, 200 mg daily

Syphilis, *by mouth*, 200–300 mg daily in 1–2 divided doses

Uncomplicated genital chlamydia, non-gonococcal urethritis, *by mouth*, 100 mg twice daily

Louse and tick-borne relapsing fevers, *by mouth*, 100 mg or 200 mg as a single dose

Cholera, *by mouth*, ADULT 300 mg as a single dose; CHILD over 8 years, 100 mg as a single dose

PATIENT ADVICE. Capsules should be swallowed whole with plenty of fluid while sitting or standing to prevent oesophageal irritation. May be given with milk or food to counter gastric irritation

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



**Erythromycin***Tablet (stearate), 250mg, 500mg**Capsule, 250mg**Oral suspension, 125mg/5ml, 200mg/5ml, 250mg/5ml**Injection, 50mg/ml in 2ml ampoule*

**Indications:** for treatment of conjunctivitis in newborns, genitourinary tract infection during pregnancy, pneumonia in infants, prophylaxis of bacterial endocarditis, gonorrhoea, legionnaires disease, pharyngitis, sinusitis and for long term prophylaxis of rheumatic fever, syphilis.

**Cautions:** - pregnancy and breast-feeding, in patients with renal and hepatic function impairment, cardiac arrhythmias (prolongation of QT interval), porphyria.

**Drug interactions:** - alfentanil, carbamazepine, chloramphenicol, itraconazole, cyclosporins, terfenadin, warfarin, xanthines such as aminophylline, caffeine, oxtriphylline, and theophylline.

**Side effects:** - GIT disturbance (nausea, vomiting, diarrhoea, abdominal or stomach cramping and discomfort), reversible loss of hearing, recurrent fainting, sudden death (rare), hypersensitivity (skin rash, redness or itching), cholestatic jaundice (dark or amber urine, pale stools, stomach pains), inflammation or phlebitis at injection site (for parenteral erythromycin).

**Dose and Administration:** -

Adult:

**Antibacterial (systemic)** - *oral*, 250mg (base) every 6 hours, or 500mg every 12 hours if twice a day dosage is required. **Maximum:** - up to 4 grams (base) daily. *IV infusion*, 250-500mg (base) every 6 hours. **Maximum** - up to 4 grams.

**Endocarditis (prophylaxis)** - In patients with heart disease or rheumatic or other acquired valvular heart disease who undergo dental procedures or surgical procedure of the upper respiratory tract, *oral*, 1gm (base) one hour prior to the procedure, and 500mg 6 hours following the procedure.

**Genitourinary tract infection, including chlamydial**, *oral*, 500mg (base) every six hours for at least seven days. For patients unable to tolerate the higher dosage regimen, the dosage may be halved and given for at least fourteen days.

**Legionnaires' disease** - *oral*, 500mg (base) to 1gm(base) every six hours.

**Streptococcal (prophylaxis)** - continuous prophylaxis of streptococcal infections in patients with a history of rheumatic heart disease - *oral*, 250mg (base) every twelve hours.

Child:

**Antibacterial (systemic)** - *oral*, 7.5to 12.5 (base) per kg of body weight every 6 hours, or 17 to 25mg per kg of body weight every 12 severe infection, 15 to 25mg (base) per kg of body weight every six hours.



**Antibacterial (systemic) - *IV infusion***, 3.75 to 5mg (base) per kg of body weight every 6 hours.

**Conjunctivitis, chlamydial - *oral***, 12.5mg (base) per kg of body weight every 6 hours for at least two week.

**Endocarditis prophylaxis** - in patients with heart disease are rheumatic or other acquired valvular heart disease who undergo dental procedures or surgical procedures of the upper respiratory tract - *oral*, 20mg (base) per kg of body weight one hour prior to the procedure, and 10mg per kg of body weight six hours following the procedure.

**Pertusis - *oral***, 10 to 12.5mg (base) per kg of body weight every 6 hours for 14 days.

**Pneumonia, chlamydial - *oral***, 12.5mg (base) per kg of body weight every 6 hours for two weeks.

**Streptococcal pharyngitis - *oral***, 5-12.5mg (base) per kg of body weight every 6 hours for at least 10 days.

**Storage:** - at room temperature in tight container.

### **Gentamicin**

*Injection, 240mg/ml 2ml ampoule*

**Indications:** -biliary tract infection, bone and joint infection, meningitis, ventriculitis, urinary tract infection including peritonitis, bacterial septicemia.

**Cautions:** -pregnancy and breast-feeding, in premature infants and neonates, elderly, patients with renal function impairment or dehydration, and in those with eighth-cranial nerve impairment. Prolonged use should be avoided.

**Drug interactions:** -avoid concurrent and /or sequential use of two or more aminoglycosides or aminoglycosides with capreomycin, antimysthenic, methoxyflurane or polymyxin, cephalosporins, ciclosporin, cisplatin, neostigmine, pyridostigmine, suxamethonium, vecuronium, furosemide, penicillines and indomethacin.

**Side effects:** - nephrotoxicity (greatly increased or decreased frequency of urination or amount of urine; increased thirst, loss of appetite, nausea or vomiting); neurotoxicity (muscle twitching, numbness, seizures, tingling); ototoxicity, auditory damage (loss of hearing, ringing or buzzing a feeling of fullness in the ears), vestibular damage (clumsiness, dizziness, nausea, vomiting, unsteadiness)

**Contraindications:** - pregnancy, myasthenia gravis, previous allergic reaction to one aminoglycoside.

**Dosage and Administration:** -

Adult: -

**Antibacterial (systemic) - *IM or IV infusion***, 1-1.7mg (base) per kg of body weight every eight hours for seven to ten days or more.



Urinary tract infection (bacterial, uncomplicated) - *IM or IV infusion* - Adults (< 60kg body weight) - 3mg (base) per kg of body weight once a day, or 1.5mg per kg of body weight every 12 hours. Adults (>=60kg of body weight)- 160mg (base) once a day, or 80mg every 12 hours.

Usual adult prescribing limit - up to 8mg (base) per kg of body weight daily in severe, life threatening infections.

Child: -

Antibacterial (systemic) - *IM or IV infusion* - premature or full term neonates up to 1 week of age: 2.5mg (base) per kg of body weight every 12 or 24 hours for seven to ten days or more.

Older neonates and infants - 2.5mg (base) per kg of body weight every 8 to 16 hours for 7-10 days or more.

Children - 2 to 2.5mg (base) per kg of body weight every 8 hours for 7-10 days or more.

**Storage:** - at room temperature and protect from freezing.

### Metronidazole

*Tablet, 250mg*

*Intravenous infusion, 5mg/ml in 100ml*

**Indications:** - treatment of anaerobic infection, bone and joint infection, meningitis, bacterial endocarditis, prophylaxis of perioperative infection during colorectal surgery, lower respiratory tract infection including pneumonia, emphysema and lung abscess, bacterial septicemia, skin and soft tissue infection, inflammatory bowel disease, antibiotic associated colitis, *Helicobacter pylori* associated duodenal ulcer; see also section 7.4.2.

**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.

**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

**Contraindications:** -chronic alcohol dependence



**Dose and Administration-**

Adult: -

**Antibacterial** (systemic), anaerobic infections, *oral*, 7.5mg (base) per kg of body weight up to a maximum of 1 gm, every 6 hours for 7 days or longer; *IV-infusion*, 15mg (base) per kg of body weight initially, then 7.5mg per kg of body weight up to a maximum of 1gm, every six hours for seven days or longer;

Inflammatory bowel disease - *oral*, 500mg (base) four times a day.

Antibiotic associated colitis - *oral*, 500mg (base) three or four times a day.

*Helicobacter pylori* associated gastritis or duodenal ulcer, *oral*, 500mg (base) three times a day with amoxicilline for one to two weeks.

Perioperative infections, colonic (prophylaxis): - *IV infusion*, 15mg (base) per kg of body weight one hour prior to start of surgery and 7.5mg per kg of body weight six and twelve hours after the initial dose.

Child:-

Anaerobic infection - *oral*, 7.5mg (base) per kg of body weight every 6 hours, or 10mg per kg of body weight every 8 hours.

Anaerobic infection - for preterm infants - *IV infusion*, 15mg per kg of body weight (base) as an initial dose, then 7.5mg per kg of body weight every 12 hours starting 48 hours after the initial dose. Term infants, *IV infusion*, 15mg (base) per kg of body weight as an initial dose, then 7.5mg per kg of body weight every 12 hours starting 24 hours after the initial dose. Infants greater than 7 days of age and children - *IV infusion*, 15mg (base) per kg of body weight as an initial dose, then 7.5 mg per kg of body weight every 6 hours.

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

**Nitrofurantoin**

*Tablet, 50mg, 100mg*

*Capsule (macrocrystal), 50mg, 100mg*

*Oral suspension, 0.5%*

**Indications:** -prophylaxis and treatment of urinary tract infection.

**Cautions:** - hypersensitive to nitrofurantoin, diabetes mellitus, electrolyte imbalance, vitamin B and folate deficiency, pulmonary disease, hepatic impairment, peripheral neuropathy.

**Drug interactions:** - hemolytic, neurotoxic medication, probenecid, sulfinpyrazone.

**Side effects:** - pneumonitis (chills, chest pain, cough, fever, troubled breathing, abdominal or stomach pain or upset, diarrhoea, loss of appetite, nausea, vomiting), hematology reactions, specifically granulocytopenia (sore throat and fever) or megaloblastic anemia (unusual tiredness or weakness), neurotoxicity (dizziness, drowsiness,



headache, unusual tiredness or weakness), polyneuropathy (numbness or tingling, or burning of face or mouth, unusual muscle weakness, haemolytic anaemia (pale skin, unusual tiredness or weakness), hepatitis (yellow eyes or skin), hypersensitivities (skin rash, itching, arthralgia, fever, chills), rust yellow to brown discoloration of urine.

**Contraindications:** - pregnancy, in infants up to 1 month of age, during breastfeeding. And also in patients with renal function impairment, glucose 6 phosphate dehydrogenase (G6PD) deficiency, and in those with porphyria.

**Dose and Administration -**

Adult: - *Oral*, 50 to 100mg every 6 hours. Maximum up to 600mg daily, or up to 10mg per kg of body weight daily.

Note: - Prophylaxis - *oral*, 50 to 100mg once a day at bedtime.

Child: - infants and children 1 month of age and over, *Oral*, 0.75 to 1.75mg per kg of body weight every 6 hours.

Note: - Prophylaxis - *oral*, 1mg per kg of body weight once a day at bedtime. Continue medicine for full time of treatment.

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

**Sulphamethoxazole + Trimethoprim**

*Tablet (pediatric), 100mg + 20mg; (adult), 400mg + 80mg, 800mg+160mg Mixture, 200mg + 40mg in each 5ml*

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

**Indications:** - acute exacerbation of chronic bronchitis, otitis media (children), primary agent for pneumocystis carinii pneumonia (PCP) in immunocompromised patients including AIDS patients, urinary tract infection, biliary tract infection, bone and joint infection, chancroid, gonorrhoea, meningitis, bacterial septicemia, skin and soft tissue infection.

Note: - It is not indicated for prophylaxis or prolonged therapy for otitis media.

**Cautions:** - elderly, renal and hepatic function impairment, photosensitivity, Glucose-6-phosphate dehydrogenase (G6PD) deficiency. During treatment maintain adequate fluid intake.

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

**Contraindications:** - pregnancy, renal and hepatic function failure, jaundice, blood disorders, megaloblastic anemia, porphyria. Breast-feeding, 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: -**

Usual Adult and Adolescent dose: - Antibacterial (systemic)

- *Oral*, 160mg of trimethoprim and 800mg of sulphamethoxazole every 12 hours.
- *IV infusion* 2-2.5mg of trimethoprim and 10-12.5mg sulphamethoxazole per kg of body weight every six hours; 2.7 to 3.3mg of trimethoprim and 13.3-16.7mg sulphamethoxazole per kg of body weight every 8 hours, or 4-5mg of trimethoprim and 20-25mg of sulphamethoxazole per kg of body weight every 12 hours.

Pneumocystis carinii pneumonia

Treatment - *oral*, 3.75 - 5mg of trimethoprim and 18.75-25mg sulphamethoxazole per kg of body weight every 6 hours.

Prophylaxis - *oral*, 160mg of trimethoprim and 800mg of sulphamethoxazole once daily.

- *IV infusion* - pneumocystis carinii pneumonia - *IV infusion* 3.75-5mg of Trimethoprim and 18.75-25mg sulphamethoxazole per kg of body weight every 6 hours or 5.0-6.7mg of Trimethoprim and 25-33.3mg sulphamethoxazole per kg of body weight every 8 hours.

Usual child dose -

Antibacterial (systemic)

Infants 2months of age and over up to 40kg of body weight - *oral*, 4-6mg trimethoprim and 20-30mg sulphamethoxazole per kg of body weight every 12 hours.

Pneumocystis Carinii pneumonia

Treatment - *oral*, 3.75 - 5mg of trimethoprim and 18.75-25mg sulphamethoxazole per kg of body weight every 6 hours.

Prophylaxis - children 2 months of age and over: *oral*, 75mg trimethoprim and 375 of sulphamethoxazole per meter square two times a day, 3 times a week on consecutive days (e.g. Monday, Tuesday, Wednesday). *IV - infusion* for pneumocystis carinii pneumonia is same as adult's.



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.

### Quinolones

Nalidixic acid and Norfloxacin are effective in uncomplicated urinary – tract infections and, in the treatment of shigella in areas where it remains susceptible.

Ciprofloxacin is active against both Gram-Positive and Gram-Negative bacteria. .

**Cautions –** Quinolones should be used with caution in patients with a history of epilepsy or conditions predisposing to seizures; convulsions may be induced in patients with or without a history of convulsions; also, use with caution in G6PD deficiency, pregnancy or breast feeding; use in children or adolescents is generally not recommended (quinolones cause arthropathy in weight – bearing joints in young animals), although in some specific circumstances, shorter use may be justified. Exposure to sunlight should be avoided (discontinue if photosensitivity occurs).

**Side effects–** Adverse effects of quinolones include nausea, vomiting, dyspepsia, abdominal pain, diarrhoea, and rarely antibiotic associated colitis; headache, dizziness, sleep disorders, rash (rarely Stevens – Johnson Syndrome and toxic epidermal necrolysis), and pruritus; less commonly, anorexia, transient disturbances in liver enzymes and bilirubin and increases in blood urea and creatinine; drowsiness, restlessness, depression, confusion, hallucinations, convulsions, paraesthesia; photosensitivity; hypersensitivity reactions including fever, urticaria, angioedema, arthralgia, myalgia, and anaphylaxis, blood disorders, disturbances in vision, taste, hearing, and smell; isolated reports of tendon inflammation and damage; if psychiatric, neurological, or hypersensitivity reactions occur –discontinue the drug.

**Drug interactions –**Quinolones may interact with the various compounds including analgesics, anticoagulants, ciclosporin (increased risk of nephrotoxicity) and theophylline.

### Nalidixic acid

*Tablet, 500 mg*

*Oral suspension 300 mg/vial*

**Indications:** - urinary – tract infections

**Cautions:** - see notes above: avoid in porphyria; liver disease; renal impairment; false positive urinary glucose (if tested for reducing substances); monitor blood counts, renal and liver function if treatment exceeds 2 weeks.



**Drug interactions:** see notes above

**Side effects:** see notes above; also reported toxic psychosis, weakness, increased intracranial pressure, cranial nerve palsy, and metabolic acidosis.

**Dose and Administration**

1g every 6 hours for 7 days reduced in chronic infections to 500 mg every 6 hours; Child over 3 months max. 50 mg/kg daily in divided doses; reduced in prolonged therapy to 30 mg/kg daily.

**Storage:** - at room temperature (up to 25°C) in a tight container. Protect from freezing.

### 7.1.3. Antituberculars

Tuberculosis is a chronic infectious disease caused primarily by *Mycobacterium tuberculosis* or sometimes *M. bovis*; the closely related form *M. africanum* has occasionally been implicated as a cause of human tuberculosis. Infection is usually due to inhalation of infected droplet nuclei, and the lung is generally the first organ affected, but the primary infection is usually asymptomatic.

Drug treatment for clinical infection always involves multi drug regimens, chosen to provide early bactericidal activity (activity against actively dividing mycobacteria), and sterilizing activity (activity against non-dividing, semi-dormant organisms), and to prevent resistance. Treatment is divided into 2 phases, an initial intense phase involving daily administration of 3 or more drugs for 8 weeks, followed by a continuation phase for 4 or more months usually 2 drugs are used in the continuation phase and they may be administered daily or 2 or 3 times per week. The continuation phase may be extended beyond 4 months when treating extrapulmonary tuberculosis or AIDS – associated tuberculosis.

Direct observation of therapy (DOT) is considered essential to ensure compliance in the initial phase and also useful in the continuation phase if patients are receiving rifampicin. The six antituberculosis drugs, isoniazid, rifampicin, pyrazinamide, streptomycin, (which are bactericidal) ethambutol and thioacetazone (which are bacteriostatic) are used in various combinations as part of WHO recommended treatment regimens

In supervised regimens change of drug regimen should be considered only if the patient fails to respond after 5 months of DOTs.

Isoniazid, Rifampicin, and Pyrazinamide are components of all antituberculosis drug regimens currently recommended by WHO.



Unsupervised and alternative regimens as set out in the following tables may be administer as specified.

**Recommended 6-month treatment regimens for tuberculosis<sup>a</sup>**

<b>Drug</b>	<b>Initial phase (2 months)</b>	<b>Continuation phase (4 months)</b>
Isoniazid	5mg/kg daily	5mg/kg daily
Rifampicin	10mg/kg daily	10mg/kg daily
Pyrazinamide	25mg/kg daily	
<b>together with</b>		
Streptomycin	15mg/kg daily	
Or		
Ethambutol	<u>15mg/kg daily</u>	
Isoniazid	10mg/kg 3 times weekly	10mg/kg 3 times weekly
Rifampicin	10mg/kg 3 times weekly	10mg/kg 3 times weekly
Pyrazinamide	35mg/kg 3 times weekly	
<b>together with</b>		
Streptomycin	15mg/kg 3 times weekly	
Or		
Ethambutol	30 mg/kg 3 times weekly <sup>c</sup>	

**Recommended 8-month treatment regimen for tuberculosis<sup>a</sup>**

<b>Drug</b>	<b>Initial phase (2 months)</b>	<b>Continuation phase (6 months)</b>
Isoniazid	5mg/kg daily	5mg/kg daily
Rifampicin	10mg/kg daily	
Pyrazinamide	30mg/kg daily	
Thioacetazone		2.5mg/kg daily
<b>together with</b>		
Streptomycin	15mg/kg daily	
Or		
Ethambutol	25mg/kg daily <sup>b</sup>	

<sup>a</sup>Unless otherwise indicated, doses are suitable for both adults and children

<sup>b</sup>15mg/kg for children

<sup>c</sup>Not suitable for children

World wide, an important predisposing cause of immuno suppression leading to tuberculosis is human immunodeficiency virus (HIV) infection. It increases susceptibility to primary infection and increases



the reactivation rate of tuberculosis. Preventative antituberculosis therapy for such persons is recommended.

Chemoprophylaxis with isoniazid can prevent the development or clinically apparent disease in persons in close contact with infectious patients, and in other persons at high risk particularly those who are immuno deficient.

Monitoring: since isoniazid, rifampicin and pyrazinamide are associated with liver toxicity, hepatic function should be checked before treatment with these drugs. Those with preexisting liver disease or alcohol dependence should have frequent checks particularly in the first 2 months. If there is no evidence of liver disease (and pre-treatment liver function is normal), further checks are only necessary if the patient develops fever, malaise, vomiting, jaundice or unexplained deterioration during treatment.

Renal function should be checked before treatment with antituberculous drugs and appropriate dosage adjustments made. Streptomycin or Ethambutol should preferably be avoided in patients with renal impairment, but if used, the dose should be reduced and the plasma – drug concentration monitored. Visual acuity should be tested before Ethambutol is used.

*Isoniazid* is cheap and highly effective. It should always be indicated in any antituberculous regimen unless there is a specific contraindication. Its only common side effect is peripheral neuropathy which is more likely to occur where there are pre-existing risk factors such as diabetes, alcohol dependence, chronic renal failure, malnutrition and HIV infection. In these circumstances pyridoxine 10 mg daily (or 20 mg daily if suitable product not available) should be given prophylactically from the start of treatment. Other side effects such as hepatitis and psychosis are rare.

*Rifampicin*, a rifamycin, is a key component of any antituberculous regimen. Like isoniazid it should always be included unless there is a specific contraindication. During the first two months (initial phase) of rifampicin administration transient disturbance of liver function with elevated serum transaminases is common but generally does not require interruption of treatment. Occasionally more serious liver toxicity requires a change of treatment particularly in those with preexisting liver disease (important: see monitoring above). Rifampicin induces hepatic enzymes which accelerate the metabolism of several drugs including oestrogens, corticosteroids, phenytoin, sulphonylureas, and



anti-coagulants. The effectiveness of oral contraceptives is reduced and alternative family planning advice should be offered.

*Pyrazinamide* is a bactericidal drug only active against intracellular dividing forms of *Mycobacterium tuberculosis*; it exerts its main effect only in the first two or three months. It is particularly useful in tuberculous meningitis because of good meningeal penetration. It is not active against *M. Bovis*. Serious liver toxicity may occasionally occur.

*Ethambutol* is included in a treatment regimen if isoniazid resistance is suspected, it can be omitted if the risk of resistance is low.

Side effects of Ethambutol are largely confined to visual disturbances in the form of loss of acuity, colour blindness, and restriction of visual fields. These toxic effects are more common where excessive dosage is used or if the patients renal function is impaired. Early discontinuation of the drug is almost always followed by recovery of eyesight. Patients who cannot understand warnings about visual side effects should, if possible, be given an alternative drug. In particular, Ethambutol should be used with caution in children until they are at least 5 years old and capable of reporting symptomatic visual changes accurately.

### **Ethambutol**

*Tablet, 100mg, 400mg*

**Indications:** - tuberculosis, in combination with other drugs (see notes and tables above)

**Cautions:** - visual disturbances - ocular examination recommended before and during treatment; reduce dose in renal impairment and monitor plasma concentration: elderly; pregnancy; breastfeeding.

**Contraindications:** - optic neuritis, poor vision, children under at least 6 years of age.

**Side effects:** - optic neuritis, red/green colour blindness, peripheral neuritis, rarely rash, pruritus, urticaria, and thrombocytopenia.

### **Dose and Administration**

Tuberculosis (initial phase of combination therapy; see notes and tables above), *by mouth*, Adult 15mg/kg daily or 30 mg/kg 3 times a week; child 15mg/kg daily.

**Storage:** - at room temperature, in a well-closed containers. Protect from light, moisture, and excessive heat.

### **Isoniazid**

*Tablet, 100mg, 300mg*

*Injection, 100mg/ml in 10ml ampoule*

**Indications:** - tuberculosis treatment, in combination with other drugs (see notes and tables above); tuberculosis prophylaxis.



**Cautions:** - hepatic impairment; renal impairment; slow acetylator status (increased risk of side effects); epilepsy; history of psychosis; alcohol dependence, malnutrition, diabetes mellitus, HIV infection (risk of peripheral neuritis); pregnancy and breast-feeding; porphyria

**Drug interactions:** - carbamazepine, ethosuximide, phenytoin.

**Side effects:** - nausea, vomiting, constipation, dry mouth; peripheral neuritis with high doses (pyridoxine prophylaxis, see notes above), optic neuritis, convulsions, psychotic episodes, vertigo; hypersensitivity reactions including fever, erythema multiforme, purpura; blood disorders including agranulocytosis, haemolytic anaemia, aplastic anaemia; hepatitis (especially over age of 35 years); systemic lupus erythematosus-like syndrome, pellagra, hyperreflexia, difficulty with micturation, hyperglycaemia, and gynaecomastia reported.

**Contraindications:** - drug induced hepatic disease.

#### **Dose and Administration**

Tuberculosis, treatment (combination therapy; see also notes and tables), *by mouth*, Adult and Child 5mg/kg (4-6 mg/kg) daily (maximum, 300 mg daily), or 10mg/kg 3 times weekly.

Tuberculosis, treatment in critically ill patients unable to take oral therapy (combination therapy), *by intramuscular injection*, Adult 200 - 300 mg as single daily dose; Child 10 - 20 mg/kg daily.

Tuberculosis, prophylaxis, *by mouth*, Adult 300mg daily for at least 6 months; child 5mg/kg daily for at least 6 months.

Note: - isoniazid should be taken on an empty stomach; if taken with food to reduce gastrointestinal irritation, oral absorption and bioavailability may be impaired.

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

#### **Ethambutol + Isoniazid**

*Tablet, 400mg + 150mg*

**Indications:** - tuberculosis, in combination with other drugs (see notes and tables above)

**Cautions:** - see ethambutol, and isoniazid

**Drug interactions:** - see ethambutol, and isoniazid

**Side effects:** - see ethambutol, and isoniazid

**Contraindications:** - preparation not suitable for use in children; see ethambutol, and isoniazid.

#### **Dose and Administration**

Tuberculosis, continuation phase of 8-month regimen in place of thioacetazone with isoniazid (see notes and tables), *by mouth*, Adult ethambutol hydrochloride 800mg and isoniazide 300 mg daily.

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



**Pyrazinamide***Tablet, 500mg***Indication:** - tuberculosis, in combination with other drugs (see notes and tables above)**Cautions:** - hepatic impairment (monitor hepatic function); renal impairment; diabetes mellitus (monitor blood glucose - may change suddenly); increased uric acid level in urine; breast-feeding.

Note: - Patients or their carers should be told how to recognize signs of liver disorders and advised to discontinue treatment and seek immediate medical attention if symptoms such as persistent nausea, vomiting, malaise or jaundice develop.

**Drug interactions:** - uricosurics (probenecid, sulfinpyrazone)**Side effects:** - hepatotoxicity including fever, anorexia, hepatomegaly, jaundice, liver failure; nausea, vomiting; arthralgia; gout; sideroblastic anaemia; urticaria; skin flushing.**Contraindications:** - severe hepatic impairment; porphyria.**Dose and Administration**Tuberculosis (initial phase of combination therapy; see notes and tables above), *by mouth*, Adult and child 25-mg/kg daily or 35 mg/kg 3 times weekly.**Storage:** - at room temperature, in a well closed container.**Rifampicin***Capsule, 150mg, 300mg, 600mg**Syrup, 20mg/5ml**Powder for injection (sodium) 300mg, 600mg in vial***Indications:** - tuberculosis, in combination with other drugs (see notes and tables above); leprosy, see section 7.1.4**Cautions:** - reduce dose in hepatic impairment, liver function tests and blood counts required in liver disorders, elderly, and on prolonged therapy; renal impairment (if dose above 600 mg daily); pregnancy; breastfeeding; porphyria; discolour soft contact lenses.

Note: Advise patients on oral contraceptives to use additional means.

Resumption of rifampicin treatment after a long interval may cause serious immunological reactions, resulting in renal impairment, haemolysis, or thrombocytopenia. Discontinue permanently if serious adverse effects occur.

Patients or their carers should be told how to recognize signs of liver disorders and advised to discontinue treatment and seek immediate medical attention if symptoms such as persistent nausea, vomiting, malaise or jaundice develop.

**Drug interactions:** - azathioprine, ciclosporin, contraceptives, dexamethasone, fluconazole, fludrocortisone, glibenclamide, haloperidol, hydrocortisone, indinavir, saquinavir, lopinavir, nelfinavir, nifedipine, levonorgestrel, medroxyprogesterone, norethisterone, phenytoin, prednisolone, guanidine, verapamil, warfarin.**Contraindications:** - hypersensitivity to rifamycins, jaundice.

**Side effects:** - severe gastrointestinal disturbances including anorexia, nausea, vomiting and diarrhea (antibiotic associated colitis reported); rashes, fever, influenza-like syndrome and respiratory symptoms, collapse, shock, haemolytic anaemia, acute renal failure, and thrombocytopenic purpura-more frequent with intermittent therapy; alterations of liver function jaundice and potentially fatal hepatitis (dose related; do not exceed maximum dose of 600 mg daily); stains body fluid (urine, tears, saliva, and sputum) orange - red.

**Dose and Administrations**

Tuberculosis (combination therapy; see notes and tables above). *By mouth*, Adult and child 10mg/kg daily or 3 times weekly (maximum dose, 600mg daily)

Note: - take dose at least 30 minutes before a meal, as absorption is reduced when taken with food.

**Storage:** - below 40°C, in a tight, light - resistant container.

**Rifampicin + Isoniazid**

*Tablet, 150mg + 100mg, 300mg + 150mg*

*Capsule, 150mg + 100mg*

**Indications:** - tuberculosis (see notes and tables above)

**Cautions:** - preparation not suitable for use in children; see under rifampicin, and Isoniazid

**Drug interactions, Contraindications, Side effects:** see under rifampicin, and isoniazid

**Dose and Administration:** -

Tuberculosis, 6 - month regimen (combination therapy; see notes and tables), *by mouth*, Adult 10mg/kg (rifampicin) and 5mg/kg (isoniazid) daily.

Tuberculosis, 6-month regimen (combination therapy; see notes and tables), *by mouth*, Adult 10mg/kg (rifampicin) and 10mg/kg (isoniazid) 3 times a week.

**Rifampicin + Isoniazid + Pyrazinamide**

*Tablet, 150mg + 75mg + 400mg*

**Indications:** - tuberculosis, in combination with other drugs (see notes and tables above)

**Cautions; Side effects, Drug interactions:** see Rifampicin, Isoniazid, and Pyrazinamide

**Contraindications:** - preparations not suitable for use in children; see rifampicin, isoniazid, and pyrazinamide.

**Dose and Administrations**

Tuberculosis, initial phase of 6 - month treatment regimens (see notes and tables above), *by mouth*, Adult rifampicin 10mg/kg, isoniazid



5mg/kg, and Pyrazinamide 25 mg/kg daily or rifampicin 10mg/kg, isoniazid 10mg/kg and Pyrazinamide 35mg/kg 3 times a week.

#### **Rifampicin + Isoniazid + Pyrazinamide + Ethambutol**

*Tablet, 150mg + 75mg + 400mg + 275mg*

**Indications:** - tuberculosis (see notes and tables above)

**Cautions, Side effects, Drug interactions, Contraindications:** see rifampicin, isoniazid, Pyrazinamide and Ethambutol.

#### **Dose and Administrations**

Tuberculosis, induction phase of 6-month regimen (see notes and tables above), *by mouth*, Adult rifampicin 10mg/kg, isoniazid 5mg/kg, Pyrazinamide 25mg/kg, and Ethambutol hydrochloride 15mg/kg daily.

#### **Streptomycin Sulphate**

*Powder for injection - 1g, 5g bases in vial*

**Indications:** - tuberculosis, in combination with other drugs (see notes and tables above)

**Cautions:** -children - painful injection, avoid use if possible, renal impairment, infants, and elderly (dosage adjustment), and monitor renal, auditory, and vestibular function, and plasma streptomycin concentrations.

**Drug interactions:** - alcuronium, ciclosporin, cisplatin, furosemide, neostigmine, pyridostigmine, suxamethonium, and vecuronium.

**Side effects:** vestibular and auditory damage; nephrotoxicity; hypersensitivity reactions - withdraw treatment; paraesthesia of mouth, rarely, hypomagnesaemia on prolonged therapy; antibiotic associated colitis; also nausea, vomiting, rash; rarely, haemolytic anaemia, aplastic anaemia, agranulocytosis, thrombocytopenia; pain and abscess at injection site.

**Contraindications:** hearing disorders; myasthenia gravis, pregnancy.

#### **Dose and Administration**

Tuberculosis (initial phase of combination therapy; see notes and table above), *by deep intramuscular injection*, Adult and child 15mg/kg daily or 3 times a week (patients over 60 years or those weighing less than 50kg may not tolerate doses above 500 - 750mg daily)

**Storage:** - at room temperature protect from light.

Note: Reconstituted solutions may vary in colour from colourless to yellow and may darken on exposure to light but potency is not affected for 48 hours at room temperature and for up to 14 days when refrigerated.

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#### **7.1.4. Antileprotics**

Leprosy (Hansen's disease) is a chronic disease caused by *Mycobacterium leprae*; it affects the peripheral nervous system, the skin, and some other tissues. It is transmitted from person to person when bacilli are shed



from the nose and skin lesions of infected patients, but most individuals are naturally immune, and symptoms are suppressed. For treatment purposes patients may be classified as having paucibacillary (PB) or multibacillary (MB) leprosy. The 2 forms may be distinguished by skin smears, but facilities are not always available to process them and their reliability is often doubtful.

Drugs recommended are dapsons, rifampicin and clofazimine.

A three - drug regimen is recommended for multibacillary leprosy (lepromatus, borderline-lepromatous, and borderline leprosy) and a two - drug regimen for paucibacillary leprosy (borderline tuberculoid, tuberculoid, and indeterminate).

Any patient with a positive skin smear should be treated with the multidrug therapy regimen for MB leprosy. The regimen for PB leprosy should never be given to a patient with MB leprosy. If diagnosis in a particular patient is not possible the multi drug therapy regimen for MB leprosy must be used.

Multibacillary leprosy (3 - drug regimen)

Rifampicin 600mg once-monthly, supervised (450mg for adults weighing less than 35kg)

Dapsone 100mg daily, self administered (50mg daily or 1 - 2 mg/kg daily for adults weighing less than 35kg)

Clofazimine 300mg once - monthly, supervised, and 50mg daily (or 100mg on alternate days), self-administered.

Multibacillary leprosy should be treated for at least 2 years. Treatment should be continued unchanged during both type I (reversal) or type II (erythema nodosum leprosum) reactions. During reversal reactions neuritic pain or weakness can herald the rapid onset of permanent nerve damage. Treatment with prednisolone (initially 40 - 60mg daily) should be instituted at once. Mild type II reactions may respond to aspirin or chloroquine. Severe type II reactions may require corticosteroids; thalidomide is also useful in men and post menopausal women who have become corticosteroid dependent, but it would be used under specialist supervision and it should never be used in women of child bearing potential (significant teratogenic risk). Increase doses of clofazimine 100mg 3 times daily for the first month with subsequent reductions, are also useful but may take 4 - 6 weeks to attain full effect.



Paucibacillary leprosy (2 - drug regimen)

Rifampicin 600mg once - monthly, supervised (450mg for those weighing less than 35kg)

Dapsone 100mg daily, self - administered (50mg daily or 1-2 mg/kg daily for adults weighing less than 35kg)

Paucibacillary leprosy should be treated for 6 months. If treatment is interrupted the regimen should be recommended where it was left off to complete the full courses.

Neither the multibacillary nor the paucibacillary antileprosy regimen is sufficient to treat tuberculosis.

### Dapsone

*Tablet, 25mg, 50mg, 100mg*

*Injection, 20% in 50ml ampoule*

**Indications:** - paucibacillary (PB) and multibacillary (MB) leprosy (see notes above)

**Cautions:** - cardiac or pulmonary disease; anaemia (treat severe anaemia before starting); G6PD deficiency (including breastfeeding affected infants); pregnancy; breast-feeding; porphyria.

Note: - on long term treatment patients and their carers should be told how to recognize blood disorders and advised to seek immediate medical attention if symptoms such as fever, sore throat, rash, mouth ulcers, purpura, bruising or bleeding develop.

**Drug interactions:** - rifamycins, amprenavir, and probenecid.

**Contraindications:** - hypersensitivity to sulfones; severe anaemia.

**Side effects:** - (dose-related and uncommon at doses used for leprosy), haemolysis, methaemoglobinaemia, neuropathy, allergic dermatitis (rarely including toxic epidermal necrolysis and Stevens-Johnson syndrome), anorexia, nausea, vomiting, tachycardia, headache, insomnia, psychosis, hepatitis, agranulocytosis; dapsone syndrome (rash with fever and eosinophilia)-discontinue immediately (may progress to exfoliative dermatitis, hepatitis, hypoalbuminaemia, psychosis and death)

### Dose and Administration

Leprosy, 1 - 2mg/kg daily, see notes above

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

### Clofazimine

*Capsule, 50mg, 100mg*

**Indications:** - multibacillary (MB) leprosy; type II lepra reactions.

**Cautions:** - pre-existing gastrointestinal symptoms (reduce dose, increase dose interval or discontinue if symptoms develop during treatment); liver and renal impairment; pregnancy and breast-feeding; may discolour soft contact lenses.



Note: -Patients should be warned that Clofazimine might cause a reddish - brown discolouration of skin, conjunctiva, tears, sputum, sweat, urine, and faces.

**Side effects:** - reversible discoloration of skin, hair, cornea, conjunctiva, tears, sweat, sputum; symptoms including pain, nausea, vomiting and diarrhoea; severe mucosal and submucosal oedema with prolonged treatment with high doses - may be severe enough to cause subacute small bowel obstruction.

**Dose Administration**

Leprosy, see notes above

Lepromatous lepra reactions, dosage increased to 300mg daily for max. of 3 months.

**Rifampicin**

*Capsule, 150mg, 300mg, and 600mg*

**Indications:** -paucibacillary leprosy; multibacillary leprosy; tuberculosis (section 7.1.3)

**Cautions, Drug interactions, Side effects, Contraindications;** see under section 7.1.3.

**Dose and Administrations:** see notes above.

**7.2. Antifungals**

**Fungal Infections** may be classified as superficial, affecting only the skin, hair, nail, or mucous membranes, or systemic, affecting the body as a whole; systemic infections tend to occur more frequently in immunocompromised individuals such as those with AIDS.

**Drugs used in fungal infections at health center level:**

*Polyene antifungals* - The polyene antifungals include amphotericin (not described here) and Nystatin; neither drug is absorbed when given by mouth. They are used for oral, oropharyngeal, and perioral infections by local application in the mouth.

**Nystatin** is used principally for candida albicans infections of the skin and mucous membranes, including esophageal and intestinal candidiasis. Other Antifungals. **Griseofulvin** is effective for widespread or intractable dermatophyte infections but has been superseded by newer antifungals, particularly for nail infections. It is usually well tolerated and is licensed for use in children. Duration of therapy is dependent on the site of the infection and may be required for a number of months.

**Griseofulvin**

*Tablet, 125mg, 250mg, 500mg*

*Suspension, 125mg / 5ml*

**Indications:** - dermatophyte infections of the skin, scalp, hair and nail where topical therapy has failed or is inappropriate.



**Cautions:** - rarely aggravation or precipitation of systemic lupus erythematosus; breast-feeding; griseofulvin may impaired the ability to drive or operate machinery, see also drug interaction.

**Drug interactions:** - phenobarbitone, coumarin anticoagulants and oral contraceptives, aspirin.

**Contraindications:** - patients with porphyria and liver failure, lupus erythematosus and related conditions, pregnancy (avoid pregnancy during and for 1 month after treatment, men should not father children with in 6 months of treatment)

**Side effects:** - side effects are usually mild and transient and consist of headache, skin rashes, dryness of the mouth an altered sensation of taste, and gastro-intestinal disturbances; angioedema, erythemamultiforme, toxic epidermal necrolysis, proteinuria, leucopenia and other blood dyscrasias, candidacies, paraesthesia, photosensitization, and severe headache have been reported occasionally. Depression, confusion, dizziness, insomnia, and fatigue. Griseofulvin may precipitate or aggravate systemic lupus erythematosus.

**Dose and Administration**

Adult, *by mouth*, 500mg daily, in divided doses or as a single dose, in severe infection dose may be doubled reducing when response occurs; CHILD, 10mg/kg daily in divided doses or as a single dose.

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

**Nystatin**

*Tablet, 500,000IU*

**Indications:** - prophylaxis and treatment of candidiasis of skin and mucous membranes.

**Side effects:** - nausea, vomiting, and diarrhea; Steven Johnson syndrome, irritation.

**Dose and Administration**

Adult, *By mouth*, intestinal candidiasis 500, 000 unit every 6 hours, doubled in severe infections; CHILD 100,000 units 4 times daily prophylaxis, 1 million units once daily, NEONATE 100,000 units once daily.

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

**7.3. Antiviral**

**Acyclovir**

*Tablet, 200mg, 400mg*

*Powder for injection, 250mg, 500mg in vial*

**Indications:** - viral infections due to herpes simplex virus (types 1 and 2) and varicella-zoster virus (herpes zoster and chickenpox); see also under dose.



**Cautions:** - renal impairment (dose should be adjusted), rapid or bolus injection should be avoided and adequate hydration maintained; pregnancy and breast-feeding; see also interaction.

**Drug interactions:** - probenecid, any nephrotoxic drugs.

**Side effects:** - nausea, vomiting abdominal pain, diarrhea, headache, fatigue, rash urticaria, pruritus, photosensitivity; rarely hepatitis, jaundice, dyspnoea, angioedema, anaphylaxis, neurological reactions (including dizziness, confusion, hallucinations and drowsiness), acute renal failure, decreases in hematological indices; on intravenous infusion, severe local inflammation (sometimes leading to ulceration), fever, and rarely agitation, tremors, psychosis and convulsions.

**Dose and Administration:**

*By mouth,*

Herpes simplex, treatment, 200mg (400mg in the immunocompromised or if absorption impaired) 5 times daily, usually for 5 days; CHILD under 2 years, half adult dose, over 2 years, adult dose.

Herpes simplex, prevention of recurrence, 200mg 4 times daily or 400mg twice daily possibly reduced to 200mg 2 or 3 times daily and interrupted every 6-12 months.

Herpes simplex, prophylaxis in the immunocompromised, 200-400mg 4 times daily; CHILD under 2 years, half adult dose; over 2 years, adult dose

Varicella and herpes zoster, treatment, 800mg 5 times daily for 7 days; CHILD, varicella, 20mg/kg (max. 800mg) 4 times daily for 5 days or under 2 years 200mg 4 times daily, 2-5 years 400mg 4 times daily, over 6 years 800mg 4 times daily.

*Intravenous infusion,* treatment of herpes simplex in the immunocompromised, severe initial genital herpes, and varicella-zoster, 5mg/kg every 8 hours usually for 5 days, doubled to 10mg/kg every 8 hours usually in varicella-zoster in the immunocompromised and in simplex encephalitis (usually given for 10 days in encephalitis); prophylaxis of herpes simplex in the immunocompromised, 5mg/kg every 8 hours. NEONATE up to 3 months, herpes simplex, 10mg/kg every 8 hours usually for 10 days; CHILD 3 months-12 years, herpes simplex or varicella-zoster in immunocompromised and in simplex encephalitis (usually given for 10 days in encephalitis)

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## 7.4. Antiprotozoals

### 7.4.1. 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. It is now recognized that for many countries vector eradication is an unrealistic aim.

#### **Treatment of Malaria**

Blood Schizontocides are the mainstay of the treatment of acute malaria and some are used for prophylaxis. They include the 4- aminoquinolines (chloroquine), the related arylaminoalcohols (quinine and mefloquine), and artemisinin and its derivatives (not described here). They suppress malaria by destroying the asexual blood forms of the parasites but, because they are not active against intrahepatic forms, they do not eliminate infections by *P.vivax* and *P.ovale*.

Some antimetabolites act synergistically when given in combination. For example, pyrimethamine in combination with a sulfonamide or sulfone (sulfadoxine); and some antibiotics (tetracyclines particularly doxycycline). Because they act more slowly these substances are of little value when used alone. The tetracyclines are used primarily as adjuncts to quinine where multi-drug resistant *P. faciparum* is prevalent.

Chloroquine, a rapidly acting schizontocide, is well tolerated, safe and inexpensive. It should be used to treat malaria wherever the parasites remain susceptible. *P.malaria* and *P.ovale* remain fully sensitive to chloroquine where as wide spread chloroquine resistance strains of *P. falciparum* have been reported in many countries. Resistance in *P. vivax* has also become established in several parts of the world. Infections acquired in areas of known or unknown chloroquine resistance are treated now with quinine followed by pyrimethamine and sulfadoxine. Parenteral administration of chloroquine may be used when there is no expectation of resistance in cases of severe and complicated malaria, when the patient is unable to take oral medication and when neither quinine nor quinidine is available.



If subsequent relapse occurs in *P.ovale* and *P.vivax* infections primaquine should be administered, after a second course of chloroquine, to eliminate the intrahepatic injection. The combination of pyrimethamine with sulfadoxine is recommended for therapeutic use only in areas of high chloroquine resistance. A single dose of pyrimethamine with sulfadoxine is usually sufficient to eliminate infection; quinine should also be given for 3 days in patients in whom quinine may accelerate reduction of parasitaemia and in those patients with risk of fulminating disease. Because sulfonamides can induce hypersensitivity in pregnant women and possible kernicterus in the newborn, quinine should be used, whenever possible, to treat chloroquine resistant malaria during pregnancy.

Quinine, given orally, should be reserved for *P - falciparum* infections likely to be unresponsive to other drugs. Resistance to quinine was, until recently, rare. Doxycycline, which is an effective oral schizonticide should be given in combination with quinine except in pregnant women and children under 8 years.

Pregnancy: malaria is especially dangerous during pregnancy and the seriousness of the disease usually outweighs any potential risk from treatment.

For falciparum malaria, the adult treatment doses of oral and intravenous quinine can safely be given to pregnant women. Doxycycline should be avoided in pregnancy.

The adult treatment doses of chloroquine can be given for benign malaria. In the case of *P.vivax* or *P.ovale*, however, the radical cure with primaquine should be postponed until the pregnancy is over; instead chloroquine should be continued at a dose of 600mg each week during the pregnancy.

#### **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.malariae*, 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. Proguanil is used for prophylaxis with chloroquine in areas where there is resistance to chloroquine but a low risk of infection as it may give some protection against *P.falciparum* and may alleviate symptoms if an attack occurs.

**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.

### **Chloroquine Phosphate**

*Tablets, 250mg (equivalent to 150 mg chloroquine base)*

*Syrup, 80mg/5ml (equivalent to 50 mg chloroquine base)*

*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.

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

**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).

**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 –

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

Children :*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 -

Adults – Initially, 1g (600mg base).

Children – Initially, 16.7mg/kg (10mg base/kg) of body weight.

Note: The initial dose is given in 2 equally divided doses 6 hours 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	STAT
	40 mg ¼ tab	6 hours later
	75mg ½ tab	2 <sup>nd</sup> . Day
	75mg ½ tab	3 <sup>rd</sup> . day
1 -5 years	150mg 1 tab	STAT
	75mg ½ tab	6 hours later
	75mg ½ tab	2 <sup>nd</sup> . Day
	75mg ½ tab	3 <sup>rd</sup> . day
6 - 9 years	300mg 2 tab	STAT
	150mg 1 tab	6 hours later
	150mg 1 tab	2 <sup>nd</sup> . Day
	150mg 1 tab	3 <sup>rd</sup> . day
10 -15 years	450mg 3 tab	STAT
	225 mg 1 ½ tab	6 hours later
	225 mg 1 ½ tab	2 <sup>nd</sup> . Day
	225 mg 1 ½ tab	3 <sup>rd</sup> . day
ADULT (16 years and over)	600mg 4 tab	STAT
	300 mg 2 tab	6 hours later
	300 mg 2 tab	2 <sup>nd</sup> . Day
	300 mg 2 tab	3 <sup>rd</sup> . day

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.

### **Primaquine phosphate**

*Tablet, 7.5mg (base), 15mg (base)*

**Indications:** -for the prevention of relapses (radical cure) of malaria caused by *Plasmodium vivax* and *Plasmodium ovale*. It is also effective against the gametocytes of *Plasmodium falciparum*.

**Cautions:** - G6PD deficiency, history of acute hemolytic anemia, systemic disease associated with agranulocytopenia (e.g. rheumatoid arthritis), and in those patients who are hypersensitive to primaquine. Caution is also required during breast-feeding.

**Drug interactions:** - bone marrow depressants, and other drugs that cause hemolysis (e.g dapsone).

**Side effects:** - haemolytic anemia especially in G6PD deficiency, leucopenia, abdominal pain or cramps, nausea, vomiting, methemoglobinemia (cyanosis - bluish fingernails, lips, or skin, dizziness or light headedness, difficult breathing, unusual tiredness or weakness).

**Contraindications:** -during pregnancy and in patients with Glucose 6 phosphate dehydrogenase (G6PD) deficiency.

#### **Dose and Administration-**

Adult - Malaria, *Oral*, 26.3mg (15mg base) once a day for 14 days.

Child - Malaria, *Oral*, 0.68mg (0.39mg base) per kg of body weight once a day for 14 days.

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

### **Quinine Dihydrochloride**

*Tablet, (Dihydrochloride or sulphate), 300mg, 600mg*

*Injection, 300mg/ml in 1ml ampoule*

**Indications:** -quinine is indicated concurrently with tetracycline, doxycycline, clindamycin, pyrimethamine plus sulfadiazine, or pyrimethamine + sulfadoxine in the treatment of chloroquine resistant malaria.

**Cautions:** - during pregnancy and breast feeding, in patients with atrial fibrillation, conduction defects, heart block and glucose 6 phosphate dehydrogenase (G6DP) deficiency.

**Drug interactions:** - mefloquine, quinidine, cimetidine, halofantrine, digoxin, antacids, other hemolytics.

**Side effects:** - cinchonism (blurred vision or change in colour vision, severe headache, nausea or vomiting, ringing or buzzing in ears or transient loss of hearing), GIT disturbances (abdominal or stomach



cramps or pain, nausea, vomiting, diarrhoea), confusion, hypersensitivity reaction (fever, angioedema, blood disorder including thrombocytopenia and intravascular coagulation), acute renal failure, hypoglycemia.

**Contraindications:** - haemoglobinuria, optic neuritis and in patients hypersensitive to quinine or quinidine.

**Dose and Administration-**

Usual Adult and Adolescent dose:

*Oral*, malaria- for chloroquine resistant *Plasmodium falciparum* malaria- *oral*, 600-650mg every 8 hours for at least 3 days in most areas of the world, with concurrent administration of 250mg of tetracycline every 6 hours for seven days, or concurrent administration of 100mg of doxycycline every 12 hours for seven days, or concurrent administration of 1.5gm of sulfadoxine and 75mg of primethamine combination as a single dose, or concurrent administration of 900mg of clindamycin, 3 times a day for three days.

*Intravenous* (if an infusion pump is available), 7 mg per kg of body weight over thirty minutes followed immediately by 10 mg per kg of body weight diluted in 10ml per kg isotonic fluid over four hours; repeated every eight hours until oral treatment can be instituted.

or

*Intravenous* (if an infusion pump is not available), 20mg per kg of body weight over four hours followed immediately by 10mg per kg of body weight diluted in 10ml per kg isotonic fluid over four hours; repeated every eight hours until oral treatment can be instituted.

Usual child dose:

*Oral*, Malaria-for chloroquine resistant *P.falciparum*: - oral 8.3mg per kg of body weight every 8 hours for at least 3 days in most areas of the world, with concurrent administration of 5mg per kg of body weight of tetracycline every 6 hours for seven days in children over 8 years of age or concurrent administration of 6.7 - 13.3mg per kg of body weight of clindamycin 3 times a day for 3 days or concurrent administration of 1.25mg per kg of body weight of pyrimethamine in combination with 25mg per kg of body weight of sulfadoxine as a single dose.

*Intravenous*, see usual Adult and Adolescent dose

**Storage:** - at room temperature in a well closed container (for tablet)

**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, *by mouth*, 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.

**Sulfadoxine and Pyrimethamine**

*Tablet, 500mg + 25mg*

*Injection, 500mg + 25mg in 2.5ml ampoule*

**Indications:** - treatment of malaria due to susceptible *P.falciparum* in areas of high chloroquine resistance and in patients who have not responded to chloroquine; additionally quinine may be given for 3 days (see notes above)

Note: - It is not recommended for prophylaxis use for severe occurrence of side effects.

**Cautions:** - anemia, bone marrow depression, hepatic and renal function impairment. Women of child bearing potential who travel to areas where chloroquine resistant malaria is endemic should be warned not to become pregnant.

**Drug interactions:** - anticoagulants (cumarine or indandione derivatives), hydantoin, bone marrow depressants, other haemolytics, hepatotoxic medications.

**Side effects:** - atrophic glossitis (pain, burning, or inflammation of the tongue, change in or loss of taste) due to folic acid deficiency with high doses, blood dyscrasias, specifically agranulocytosis (fever, sore throat), megaloblastic anaemia (usual tiredness or weakness), or thrombocytopenia (unusual bleeding or bruising), hypersensitivity (skin rash, fever), photosensitivity (increased sensitivity of skin to sunlight), hepatitis (yellow eyes or skin), Stevens' Johnson syndrome (aching of joints and muscles, redness, blistering, peeling, or loosening of skin, unusual tiredness or weakness).

**Contraindications:** - breastfeeding; infants under two months of age; pregnancy; allergy to sulfonamides, pyrimethamine, furosemide, thiazide diuretics, sulfonyleureas, carbonic anhydrase inhibitors.

**Dose and Administration:**

Usual Adult and Adolescent dose: -

Malaria - treatment - chloroquine resistant plasmodium falciparum malaria - *Oral*, 3 tablets as a single dose on day three of quinine therapy.

Usual child dose: -

Malaria treatment - chloroquine resistant *Plasmodium falciparum* malaria - children 2 months of age and over - *Oral*, 1.25mg per kg of body weight pyrimethamine in combination with 25mg per kg of



body weight of sulfadoxine as a single dose on day three of quinine therapy.

Note: - continue medicine for full time of treatment.

**Storage:** - at room temperature in a well closed, and light-resistant containers.

#### 7.4.2. Amoebicides and Antigiardial Agents

**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-interstitial 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**

*Tablet, 250mg*

*Syrup 4% w/v, 250mg/5ml*

*Suspension (oral), 125mg/5ml*

*Intravenous infusion, 5mg / ml in 100ml*

**Indications:** invasive amoebiasis and giardiasis, trichomoniasis, tissue nematode infections, bacterial infections (section 7.1.2); *Helicobacter pylori* eradication.

**Cautions, Drug interactions, Contraindications, Side effects** -see section 7.1.2 under metronidazole.

#### **Dose and Administration**

Invasive amoebiasis, *by mouth*, Adult and Child 30mg/kg daily in 3 divided doses for 8 - 10 days; subsequent course of luminal amoebicide.

Invasive amoebiasis; (if oral administration not possible), *by intravenous infusion*, Adult and patient able to complete course with oral drugs), subsequent course of luminal amoebicide.

Giardiasis, *by mouth*, Adult 2g once daily for 3 days, child 15mg/kg daily in divided doses for 5 - 10 days.

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

#### **Tinidazole**

*Tablet, 150mg, 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

**Dose and Administration:** *Oral*

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.

Giardiasis, single 2gm dose; CHILD single dose of 50 - 75 mg/kg (repeated once if necessary)

### **Diloxanide Furoate**

*Tablet, 500mg*

**Indications:** - chronic amoebiasis, intestinal amoebiasis. It is a drug of choice for asymptomatic patients with *E.histolytica* cysts in the faeces.

**Side effects** - flatulence, vomiting, urticaria, pruritus

**Dose and Administration:** -

Adult - *oral*, 500mg 3 times daily for 10 days

Child - *oral*, 20mg daily in 3 divided doses

## **7.5. Anthelmintics**

### **7.5.1. Filaricides**

Filarial nematode infections are endemic in large areas of the tropics and produce considerable morbidity. These are loiasis (arises from infections with loa loa), lymphatic filariasis (by *wuchereria bancrofti*, *brugia malayi*, or *B.timori*), onchocerciasis (river blindness, is caused by infection with the filarial nematode *onchocerca volculus*), mansonella infections.

**Ivermectin** is very effective in onchocerciasis and it is now the drug of choice. A single dose of 150 micrograms/kg by mouth produces a prolonged reduction in microfilarial levels. Retreatment at intervals of 6 to 12 months depending on symptoms must be given until the adult worms die out. Reactions are usually slight and most commonly take the form of temporally aggravation of itching and rash.

### **Ivermectin**

*Tablet, 3mg, 6mg (scored)*

**Indications:** - suppressive treatment of onchocerciasis; as a secondary agent in the treatment of bancroftian filariasis caused by wucheria bancrofti.

**Cautions:** - breast-feeding (avoid treating mother until infant is 1 week old).



**Side effects:** - Mazotti like reaction, specifically arthralgia or myalgia (joint or muscle pain), dizziness, fever, headache, lymphadenopathy (painful and tender nodes in necks, armpits, or groin), skin rash or itching - due to death of microflaria in skin; or unusual tiredness or weakness; postural hypotension (light headedness while standing).

**Contraindications:** - pregnancy (delay treatment until after delivery), hypersensitivity to ivermectin.

**Dose and Administration:**

Bancroftian filariasis, *by mouth*, Adult, 200mcg (0.2mg) per kg of body weight as a single dose. Suppression of microfilariae, *by mouth*, Adult and Child over 5 years (and weighing over 15kg), 150mcg/kg as a single dose once a year.

Note: - avoid food or alcohol for at least 2 hours before and after a dose.

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

### 7.5.2.Schistosomicides

Schistosomiasis, a waterborne parasitic infection, is caused by several species of trematode worms (blood flukes).

Intestinal schistosomiasis is caused principally by *schistosoma mansoni* as well as *S.japonicum*, *S.mekongi*, and *S.intercalatum*. Urinary schistosomiasis is caused by *S.haematobium*. The latter is an important predisposing cause of squamous cell cancer of the bladder.

Praziquantel is used for the treatment of chronic schistosomiasis and is effective against all species of schistosomes. Metrifonate and oxamniquine are also used but are only effective against *S.haematobium* and *S.mansoni* respectively. Antischistosomal drugs may cause clinical deterioration if used during the acute phase of infection; treatment is either delayed or given in conjunction with a corticosteroid.

**Praziquantel**

*Tablet, 600mg*

**Indication:** - schistosomiasis caused by *Schistosoma mekongi*, *Schistosoma japonicum*, *Schistosoma mansoni*, and *Schistosoma haematobium*.

**Cautions:** - moderate to severe liver disease and in those hypersensitive to praziquantel; pregnancy and breast-feeding, nursing mothers. The drug causes drowsiness that patients are to be advised not to drive vehicles or operate machineries.

**Side effects:** -CNS effects (dizziness, drowsiness, headache, malaise), fever, GIT effects (abdominal cramps or pain, loss of appetite, nausea or vomiting, bloody diarrhoea), increased sweating, skin rash, hives or itching.



**Dose and Administration -**

Adult and Child (above 4), *S. haematobium*, *S.mansoni* - oral, 20mg per kg of body weight two times a day for 1 day. *S.Japonium*, *S. mekongi* - oral, 20mg per kg of body weight 3 times a day for 1 day.

**Storage:** - store below 30°C

**7.5.3. Other Anthelmintics****Albendazole**

*Tablet, 200mg*

*Oral Suspension, 100mg/5ml*

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

**Cautions:** - breast-feeding. 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 children over 2 years - with ascariasis, enterobiasis, hookworm infection, or trichuriasis, *by mouth*, 400mg as a single dose.

Strongyloidiasis, *by mouth*, Adult and Child over 2 years, 400mg given daily for 3 consecutive days.

**Storage:** at room temperature.

**Levamisole**

*Tablet, 40mg*

**Indications:** treatment of ascariasis and other worm infections.

**Cautions:** - sensitive to levamisole

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

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

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

**Dose and Administration: -**

Adults, *by mouth*, 120mg (3 tablets) as a single dose

Children, *by mouth*, 3mg per kg of body weight as a single dose.



**Mebendazole***Tablets, 100mg**Syrup, 100mg/5ml*

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

**Cautions:** ulcerative colitis, liver diseases, hypersensitivity, in children under 2 years, during pregnancy and in nursing women. In hookworm and whip worm 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:** - *orally*, preferably with meals.

Adults and children:

Pinworm -100mg as a single dose. It should be repeated in 2 – 3 weeks.

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

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

**Niclosamide***Tablet (chewable), 500mg.*

**Indications:** tapeworm infections.

**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:** *Orally*, 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 grounded 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.

Adults: 2g

Children: 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

*Tablet (Adipate), 300mg*

*Elixir (Citrate), 500mg/5ml, 622.5mg/5ml, 750mg/5ml, 706mg/5ml, 937.5mg/5ml, 1gm/5ml*

**Indications:** for the treatment of roundworm (*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:** orally, 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)-**

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

Children: 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)**

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

Children: 65mg/kg of body weight as a single dose for 7 days. Or,

1 –5 years 750mg (7.5ml) once daily for 7 days.

6 –12 years –11/2g (15ml) once daily for 7 days.

Maximum – 2.5g once daily.

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

### Pyrantel Pamoate

*Tablet, 125mg base*

*Oral suspension, 250mg base in each 5ml*

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



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

**Drug interactions:** - piperazine

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

**Contraindications:** - hypersensitivity to the drug

**Dose and Administration:** -

Usual Adult and Adolescent dose

**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.

**Trichostrongliasis** - *oral* 11mg (base) per kg of body weight as a single dose. Maximum - up to 1 gm (base)

Usual Child dose - children 2 years and over - same as adults

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

### **Thiabendazole**

*Tablet, 500mg*

*Oral suspension, 500mg/ml*

**Indications:** -for treatment of strongyloidiasis, cutaneous and visceral larva migrans, dracontiasis, 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.

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

**Contraindications:** - pregnancy, breast-feeding.

**Dose and Administration:** -

Adult -

Cutaneous Larva migrans - *oral*, 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 - *oral*, 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 - *oral*, 25mg per kg of body weight 2 times a day for two days.

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

**Trichinosis** - *oral*, 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 dose - (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.



## 8.DRUGS USED IN ENDOCRINE DISORDERS AND CONTRACEPTIVES.

### 8.1.Insulin and oral antidiabetic agents.

Diabetes mellitus is a disorder of carbohydrate metabolism in which the action of insulin is diminished or absent through altered secretion, decreased insulin activity, or a combination of both factors. There are two principal classes of diabetes (and many sub types not listed here):

Type I diabetes: Type I diabetes, also referred to as insulin dependent diabetes mellitus (IDDM), is due to a deficiency of insulin following autoimmune destruction of pancreatic beta cells. Patients with type I diabetes require administration of insulin.

Type II diabetes: Type II diabetes, also referred to as non-insulin dependent diabetes (NIDDM), is due to reduced secretion of insulin or to peripheral resistance to the action of insulin. Although patients may be controlled on diet alone, many require administration of oral antidiabetic drugs or insulin to maintain satisfactory control.

The aim of treatment is to achieve the best possible control of plasma glucose concentration and prevent or minimize complications including microvascular complications (retinopathy, albuminuria, neuropathy).

Diabetes mellitus is a strong risk factor for cardiovascular disease. Other risk factors such as smoking, hypertension, obesity and hyperlipidaemia should also be addressed.

**Insulin:** Insulin plays a great role in the regulation of carbohydrate, fat and protein metabolism. It is a polypeptide hormone of complex structure. There are differences in the amino acid sequence of animal insulin's, human insulin's and the human insulin analogues.

Insulin may be of beef or pork origin or it may be human insulin produced by gene technology or by modification of porcine insulin.

All insulin preparations are to a greater or lesser extent immunogenic in man but immunological resistance to insulin action is uncommon. Human and Porcine insulin are less immunogenic than bovine insulin and where possible most newly diagnosed IDDM patients are now given human insulin.

Insulin is inactivated by gastro-intestinal enzymes, and must therefore be given by injection; the subcutaneous route is ideal in most circumstances. It is usually injected in to the upper arms, thighs, buttocks, or abdomen; there may be increased absorption from a limb site if the limb is used in strenuous exercise following the injection. Generally subcutaneous insulin injections cause few problems; fat hypertrophy does however occur but can be minimized by rotating the



injection site. Local allergic reactions are now rare. The various types of insulin may also be given intramuscularly when the onset of action is faster than with the subcutaneous route. An even faster onset may be achieved with intravenous administration, but this route is only suitable for fast-acting or soluble insulin.

Most patients can and should monitor their own blood glucose concentrations using blood glucose strips. Since blood glucose levels vary throughout the day, it is best to recommend that patients should maintain blood glucose concentrations of between 4 and 10 mmol/litre for most of the day while accepting that on occasions levels will be higher; strenuous efforts should be made to prevent blood glucose concentrations falling below 4 mmol/litre. Patients should be advised to look for troughs and peaks of blood glucose and to adjust their insulin dosage only once or twice a week. Insulin doses are determined on an individual basis, by gradually increasing the dose but avoiding hypoglycemic reactions.

In the absence of blood glucose monitoring strips, urine glucose can be tested to ensure glucose levels are not too high. It is the method of personal choice for many patients with type II diabetes mellitus. It is less reliable than blood glucose but is easier and costs much less. All patients should monitor either blood or urine glucose level daily.

**Hypoglycemia:** The most frequent complications of insulin therapy is hypoglycemia and patients taking insulin should be educated about its cause, symptoms, and treatment. Most patients can recognize the early warning signs of hypoglycemic and by taking sugar immediately they can prevent more serious symptoms developing. Comatose patients should be given intravenous glucose or, if this is not practicable, subcutaneous or intramuscular glucagons. Hypoglycemia can also develop in patients taking oral hypoglycemic, notably the sulphonylureas. Some patients may no longer be able to recognize the warning signs of hypoglycemia after transferring from animal to human insulin and these patients, if appropriate, should be transferred back to porcine insulin.

Car drivers need to be particularly careful to avoid hypoglycemia. They should check their blood glucose concentrations before driving and, on long journeys, at intervals of approximately two hours; they should ensure that a supply of sugar is always readily available. If hypoglycemia occurs the driver should switch off the ignition until recovery is complete (may be 15 minutes or longer). Driving is not permitted when hypoglycemic awareness has been lost. For sporadic physical activity departing from the patients usual daily routine extra



carbohydrate may need to be taken to avert hypoglycemia. Blood glucose should be monitored before, during and after exercise.

**Diabetic Ketoacidosis.** Diabetic ketoacidosis results from a lack of insulin due to a number of factors and the onset may be over hours or days. It is characterized by hyperglycemia, hyperketonaemia, and acidaemia and is a medical emergency which should be treated promptly with fluid and electrolyte replacement and insulin. However, over vigorous fluid replacement without severe dehydration carries the risk of precipitating cerebral oedema.

#### **Isophane/NPH insulin (HPB)\***

*Injection 100units/ml in 10ml vial*

**Indications:** - diabetes mellitus

**Cautions:** -see notes above; reduce dose in renal impairment; occasionally insulin resistance necessitating large doses; pregnancy and breastfeeding; see also interactions.

**Drug interactions:** - analgesics, antibacterials, antifungals, uricosurics.

**Side effects:** -hypoglycaemia in overdose; localized and rarely generalized, allergic reactions; lipoatrophy at injection site; insulin resistance. Protamine may cause allergic reactions

#### **Dose and Administrations**

*By subcutaneous injection, according to requirements.*

Intravenous injection is contraindicated.

**Storage:** - unopened vials of insulin should be stored at 2<sup>0</sup>C to 8<sup>0</sup>C and should not be subjected to freezing. The vial in use may be stored at room temperature; exposure to extremes in temperature or direct sunlight should be avoided.

#### **Insulin Zinc suspension/Insulin Lente (HPB)\***

*Injection 100 units/ml in 10ml vial*

**Indications:** -diabetes mellitus (long acting)

**Cautions, Drug interactions, Side effects:** see notes above and under Isophane insulin.

#### **Dose and Administrations**

By subcutaneous injection, according to requirements

**Storage:** -store between 2<sup>0</sup>C and 8<sup>0</sup>C protect from freezing.

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\* HPB stands for Human, porcine, and Bovine



**Oral antidiabetic drugs.** If patients with NIDDM have not achieved suitable control after about 3 months old dietary modification and increased physical activity, then oral hypoglycemic may be tried.

The two major classes of oral hypoglycemic agents are the sulphonylureas and the biguanides.

Sulphonylureas act mainly by augmenting insulin secretion and therefore only effective if there is some residual pancreatic beta-cell activity. They may occasionally lead to hypoglycaemia 4 hours or more after food. This may be dose related and usually indicates excessive dose and it occurs more frequently with long-acting sulfonylureas such as Glibenclamide and occurs particularly in the elderly. The sulphonylureas have the disadvantage that they may encourage weight gain. They should not be used during breast-feeding and caution is required in the elderly and those with renal or hepatic insufficiency because of the risk of hypoglycaemia. Insulin therapy is generally required during intercurrent illness, during surgery and also during pregnancy.

### **Glibenclamide**

*Tablet, 5mg*

**Indications:** type II diabetes mellitus

**Cautions:** -renal impairment, hepatic impairment, elderly, substitute insulin during severe infection, trauma, surgery.

**Drug interactions:** - Analgesics (azapropazone, phenylbutazone and possibly other NSAIDs enhance effect of sulphonylureas), Antibacterial, Antifungals, uricosurics.

**Side effects:** - mild and infrequent, including gastrointestinal disturbances and headache; hypersensitivity reactions; hypoglycaemia, particularly in the elderly.

**Contraindications:** -ketoacidosis; porphyria; pregnancy; breastfeeding.

**Dose and Administrations:** -Initially 5mg daily with or immediately after break fast (Elderly 2.5mg, but avoid - see notes above), adjusted according to response, maximum 15mg daily.

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## **8.2. 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: 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 (avoid if over 50 years), obesity and migraine.

If 2 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

Estrogen - containing oral contraceptives should be discontinued four weeks prior to major elective surgery and all surgery to the legs. When



discontinuation is not possible consideration, should be given to the prophylactic use of subcutaneous heparin.

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: 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 (ED) 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); advice on the possibility of interaction with newer antiretroviral drugs should be sought from HIV specialists: 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 (ED) tablets omitting the inactive ones).

After childbirth: start any time after 3 weeks postpartum (increased risk of breakthrough bleeding if started earlier) - lactation is not affected.

Emergency contraception. Emergency contraception can be obtained using levonorgestrel, one tablet of 750 micrograms should be taken as soon as possible after unprotected intercourse followed 12 hours later by another 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.

### 8.2.1. Combined Oral Contraceptives

*Tablet, levonorgestrel (D-Norgestrel)+Ethinylestradiol and Iron tablets\**  
(0.15mg + 0.03mg; 0.25mg + 0.05mg; 0.5mg + 0.005mg; 0.3mg + 0.003mg)

*Tablet, Norethindrone (Norethisterone) + Ethinylestradiol\** (0.5mg + 0.03mg)

*Tablet, Norethindrone (Norethisterone) + Mestranol and iron tablets\**  
(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; inflammatory bowel disease including crohn disease; see also interactions

**Drug interactions:** see notes above

**Side effects:** - nausea, vomiting, headache, breast tenderness, increase in body weight, thrombosis, changes in libido, depression, chorea, 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; 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)

**Contraindications:** - pregnancy; twenty-one days post partum; breastfeeding until weaning or for first 6 months post partum; 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

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\* Each iron Tablet contains: Ferrous fumarate 75 mg



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)

**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 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.

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**8.2.2. Progestogen - only contraceptives**

**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.

Breast cancer: There is 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 wholly or partly be due to an earlier diagnosis. The most important risk factor appears to be the age at which the contraceptive is stopped rather than the duration of use; the



risk disappears gradually during the 10 years after stopping and there is no excess risk by 10 years.

**Dose and Administrations:** - see under preparation

Oral Preparations

**Ethinodiol Diacetate**, *Tablet, 0.5mg*

**Levonorgestrel (D-Norgestrel)** - *Tablet, 0.03 mg*

**Lynestrenol**, *Tablet 0.5mg*

**Norethindrone (Norethisterone)** - *Tablet, 0.35mg*

Dose: - 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 preparations

**Medroxyprogesterone Acetate**, *injection (aqueous suspension), 150mg/ml in 1 ml vial*

Dose: - *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).

**Norethindrone (Norethisterone) Enanthate**, *injection (oily), 200mg/ml in 1 ml ampoule.*

Dose: *by deep intramuscular injection* given very slowly into gluteal muscle, short-term contraception, 200mg with in first 5 days of cycle or immediately after parturition (duration 8 weeks); may be repeated once after 8 weeks (withhold breast-feeding for neonates with severe or persistent jaundice requiring medical treatment).

Implants

**Etonogestrel**, *Implant (subdermal) 68 mg/capsule, pack of 1 capsule.*

Dose: -*by subdermal implantation*, no previous hormonal contraceptive, 1 implant inserted during first 5 days of cycle; parturition or abortion in second trimester, 1 implant inserted between days 21 - 28 after delivery or abortion (if inserted after 28 days additional precautions necessary for next 7 days); abortion in first trimester, 1 implant inserted immediately; changing from an oral contraceptive, consult product literature; remove within 3 years of insertion.

**Levonorgestrel (D-Norgestrel)**; *Implant capsule (subdermal); 36mg/capsule pack of 6 capsules, 108mg/capsule pack of 2 capsules; 75mg/capsule pack of 2 capsules.*

Dose: - *Implant capsule -by subdermal implantation*, set of 6 implant capsules inserted within first 5 days of cycle (preferably on 1<sup>st</sup> day after 1<sup>st</sup> day additional precautions necessary for following 7 days) or 21<sup>st</sup> day



after parturition (after this any additional, precautions necessary for following 7 days), remove within 5 years of insertion.

### 8.2.3. Contraceptive Devices, Barriers, and Spermicides

#### Condoms - *Latex condoms*

- *Lamb CECUM condoms*

**Indications:** -Condoms is used 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:** -caution 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.

**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

**Contraindication:** - sensitivity to latex condom

#### Copper T 380 A

**Indications:** -Copper T 380 A is an intra-uterine device used for prevention of pregnancy, most suitable in parous women but should be a last-resort contraceptive for young nulliparous women because of the increased risk of pelvic inflammatory disease and infertility.

**Cautions:** -caution should be taken in those with anaemia, heavy menses, history of pelvic inflammatory disease, diabetes, valvular heart disease (antibiotic cover needed) - avoid if prosthetic valve or past attack of infective endocarditis; epilepsy, increased risk of expulsion if inserted before uterine involution; there should be gynaecological examination before insertion, 6 weeks after (or sooner if there is a problem), then after 6 months, then yearly. The IUD should be removed if pregnancy occurs.

**Side effects:** - uterine or cervical perforation, displacement, pelvic infection may be exacerbated, heavy menses, dysmenorrhoea, allergy, some pain on insertion (pain helped by giving NSAIDs half an hour before insertion) bleeding, occasionally, epileptic seizures, vasovagal attack.

**Contraindications** - pregnancy, severe anaemia, known HIV infection very heavy menses, history of ectopic pregnancy or tubal surgery, distorted or small uterine cavity, genital malignancy, pelvic



inflammatory disease, immunosuppressive therapy, copper allergy, Wilson's disease, medical diathermy.

Note: -Copper T 380A should be fitted into uterine cavity after the end of menstruation and before the calculated time of implantation.

An intrauterine device should not be removed in mid cycle unless an additional contraceptive was used for the previous 7 days.

### **Diaphragm with spermicides**

**Indications:** -Diaphragm is a mechanical barrier method of contraception designed to hold spermicides near the cervical os, which is particularly important in the event that the diaphragm is dislodged or does not form a complete seal around the cervix.

**Cautions:** - caution is required in cases where there was recent abortion or parturition, in chronic allergic conditions, in genital contact dermatitis.

**Drug interactions:** - avoid use of diaphragm (with spermicides) with vaginal or topical medications, and vaginal douch products.

**Contraindications:** - allergy to spermicides (Nonoxinol, octoxinol), menstruation, toxic-shock syndrome.

**Side effects:** - vulvovaginal candidiasis (thick, white or curd like vaginal discharge), toxic shock syndrome (dizziness, fever, lightheadedness, chills, sunburn-like rash followed by peeling of the skin, muscle aches, hypotension, unusual redness of the mucous membrane inside of the mouth, nose, throat, vagina or conjunctiva; confusion)

### **Dose and Administration -**

*Nonoxinol 9 vaginal cream with diaphragm* - Intravaginal, Initially 1 applicatorful (approximately 1 teaspoonful of 0.5% cream placed into cup (diaphragm) and additional spermicides spread along the rim of diaphragm just before insertion of diaphragm and not longer than six hours prior to intercourse. An additional applicatorful should be inserted into the vagina just prior to each repeat act of intercourse or if intercourse occurs later than six hours after initial diaphragm placement.

*Nonoxinol 9 vaginal foam with diaphragm* - Intravaginal, initially 1 applicatorful placed into vagina and additional spermicide spread along the rim of diaphragm just before insertion of diaphragm and not longer than one hour prior to intercourse. An additional applicatorful should be inserted into vagina just prior to, and not longer than one hour before, each repeat of intercourse.

*Nonoxinol 9 vaginal gel with diaphragm* - Intravaginal, initially 2 teaspoonful of a 2% gel placed into cup and additional spermicide spread along the rim of diaphragm just before insertion of diaphragm and not longer than six hours prior to intercourse. An additional applicatorful should be inserted into vagina, just prior to each repeat act of intercourse



or if intercourse takes place later than six hours after initial diaphragm placement.

*Octoxinol 9 vaginal cream with diaphragm - Intravaginal*, initially 2 teaspoonful placed into cup and additional spermicide spread along the rim of diaphragm just before insertion of diaphragm and not longer than six hours prior to intercourse. An additional applicatorful should be inserted into vaginal just prior to each repeat act of intercourse or if intercourse occurs later than six hours after initial diaphragm placement.

*Octoxinol 9 vaginal jelly with diaphragm - Intravaginal*, initially 1 applicatorful placed into cup and additional spermicide spread along the rim of diaphragm just before insertion of diaphragm and not longer than six hours prior to intercourse. An additional applicatorful should be inserted into vagina just prior to each repeat act of intercourse or if intercourse occurs later than six hours after initial diaphragm placement.

**Storage:** - at room temperature

### **Spermicides**

*(Menfegol), tablet (foaming), 60mg*

*(Non oxinol, octoxinol), Creams, Foams, Gels*

**Indications:** - vaginal spermicides are used as chemical barrier contraceptive for prevention of pregnancy.

Also used for prevention of sexually transmitted diseases when used in combination with latex condoms.

**Cautions:** - Caution is required in chronic allergy (local), genital contact dermatitis, in medical or psychosocial conditions where a critical need exists for highly effective contraception. Caution should also be taken in recent parturition or abortion.

**Drug interactions** - vaginal or topical medication, especially those containing aluminium, citrate, cotton dressing, hydrogen peroxide, iodide, lanolin, nitrates, permanganates, salicylates, silver salts, sulfonamides. Avoid also use of spermicides with vaginal douche products or other vaginal or local cleansing products.

**Side effects** - burning, stinging, warmth, itching, or other irritation of the skin, penis, rectum, or vagina, vaginal discharge (transient), vaginal dryness or odor, allergic vaginitis (persistent vaginal redness, irritation, rash, dryness, or whitish discharge), contact dermatitis (persistent skin rash, redness, irritation or itching), urinary tract infection (female) - due to change in vaginal flora.

**Contraindications** - allergy to octoxinol, nonoxinol, and benealleonium chloride, menstruation, history of toxic-shock syndrome, genital ulcer, vaginal epithelial irritation.



**Dose and Administration -**

*Nonoxinol 9 vaginal cream - Intravaginal*, 1 applicatorful of 5% cream inserted just prior to intercourse. An additional applicatorful should be inserted into vagina just prior to each repeat act of intercourse.

*Nonoxinol 9 vaginal Foam - Intravaginal*, 1 applicatorful of inserted just prior to and not longer than one hour prior to each act of intercourse.

*Nonoxinol 9 vaginal Gel - Intravaginal*, 1 applicatorful of a 4% gel inserted just prior to and not longer than one hour prior to intercourse.

**Storage:** - at room temperature, in a well-closed container (cream and gel), protect from freezing.



## 9. 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 and beta<sub>2</sub>-adrenoceptor agonists used to relax the uterus and prevent premature labour.

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. High doses of both substances produce sustained tonic contractions. Oxytocin is now recommended for routine use in postpartum and post-abortion haemorrhage since it is more stable than ergometrine. However, ergometrine may be used if oxytocin is not available or in emergency situations.

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. Imidazole drugs (clotrimazole, miconazole) are effective in short courses of 3 to 14 days according to the preparation used; single dose preparations after an advantage when compliance is a problem. Vaginal applications may be supplemented with antifungal cream for vulvitis and to treat other superficial sites of infection.

Nystatin is a well established treatment (but stain clothing yellow). One or two pessaries are inserted for 14 to 28 nights; they may be supplemented with cream for vulvitis and to treat other superficial sites of infection.

Recurrence is common if the full course of treatment is not completed and is also particularly likely if there are predisposing factors such as antibacterial therapy, pregnancy, diabetes mellitus and possibly oral contraceptive use. Possible reservoirs of infection may also lead to recontamination and should be treated. These include other skin sites such as the digits, nail beds, and umbilicus as well as the gastro-intestinal tract and the bladder. The partner may also be the source of re-infection and, if symptomatic, should be treated with cream at the same time. Other infections such as trichomonal infections and bacterial infections can be treated with Metronidazole.



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 gynaecological 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.

Note: - It is not effective in the treatment of vulvovaginitis caused by other common pathogens such as *Trichomonas vaginitis*.

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

**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.

**Contraindications** - hypersensitivity to clotrimazole

### **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



**Metronidazole***Tablet, 250mg**Tablet (vaginal), 500mg**Intravenous infusion, 5mg/ml in 100ml**Syrup, 4% w/v, 250mg/5ml*

**Indications:** - used orally or intravaginally for the treatment of bacterial vaginosis (formerly called, *Haemophilus vaginitis*, *Gardnerella vaginitis*, non-specific vaginitis, *Carynebacterium vaginitis*, or anaerobic vaginosis) which is a non-inflammatory vaginal syndrome characterized by replacement of the normal vaginal flora (predominantly hydrogen producing lactobacillus) with a mixed flora including *Gardnerella vaginalis*.

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*. See also section 7.1.2 & 7.4.2 for other uses.

**Cautions:** -abnormal neurologic symptoms, history of blood dyscrasias. Caution and reduce dosage in patients with such hepatic impairment. Use of the drug during pregnancy with caution when it is clearly needed. Breastfeeding should be interrupted in nursing mothers.

**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 -**

Usual Adult and Adolescent dose:

Vaginosis (bacteria) - *by mouth*, 500mg (base) two times a day for seven days, or 2gm as single dose; *Intravaginal*, 500mg placed high into the vagina every night for ten or twenty consecutive days. *IV-infusion*, 15mg (base) per kg of body weight initially, then 7.5mg per kg of body weight up to a maximum of 1gm, every six hours for seven days or longer

Pelvic inflammatory disease - *by mouth*, 500mg of metronidazole twice daily with ofloxacin given orally in a dosage of 400mg twice daily. Therapy should be continued for 14 days.

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

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



**Miconazole Nitrate**

*Tablet (vaginal), 200mg, 400mg*

*Cream (vaginal), 2%*

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

**Cautions, Contraindications, Side effects** - Same as clotrimazole

**Dose and Administration** - usual Adult and Adolescent dose

Vaginal cream - *Intravaginal*, one applicatorful once a day at bed time for seven or fourteen days. May be repeated if needed.

Vaginal tablets - *Intravaginal*, 100mg once a day at bedtime for seven days. May be repeated for seven days if needed or 200mg or 400mg once a day at bedtime for three days. May be repeated if needed.

**Storage:** - at room temperature in a tight container.

**Nystatin**

*Cream (vaginal), 100,000 units in 4g*

*Pessary (ovules), 100,000 units*

**Indications:** - local treatment of vulvovaginal candidiasis caused by *Candida (monilia) albicans* and other candida species.

Note: - It is not effective against *Trichomonas Vaginalis* or *Gardnerella vaginalis* (*Haemophilus Vaginalis*).

**Cautions:** - discontinue treatment with nystatin therapy if irritation or sensitization occurs. They are also advised against interrupting or discontinuing, vaginal nystatin therapy during a prescribed regimen, even during menstruation or if symptomatic relief occurs after only a few days of therapy, unless otherwise instructed by their physician.

**Side effects:** - vaginal irritation not present before therapy

**Contraindications** - sensitivity to nystatin

**Dose and Administration** - usual Adult and Adolescent dose

Nystatin vaginal cream - *Intravaginal*, insert 1-2 applicatorfuls at night for at least 14 nights.

Nystatin vaginal pessary - *Intravaginally*, insert 1-2 pessaries at night for at least 14 nights.

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

**Oxytocin**

*Injection, 10units/ml in 0.5 and 1ml ampoules, 1unit/ml, 5units/ml in 1ml*

**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.

**Side effects:** - fast or irregular heartbeat, nausea or vomiting

**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.

**Dose and Administration** - usual Adult dose

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** - at room temperature, protect from freezing.

#### **Oxytocin + Ergometrine Maleate**

*Injection, 5 units + 500mcg in each ml*

See notes under ergometrine maleate

**Dose:** *by intramuscular injection*, 1ml; *by intravenous injection*, no longer recommended



**Ergometrine maleate**

*Tablet, 0.25mg, 0.5mg*

*Injection, 0.25 mg/ml, 0.5mg/ml in 1ml ampoule*

**Indications:** - for the prevention and treatment of postpartum and postabortion hemorrhage.

**Cautions:** - cardiovascular diseases, renal and hepatic function impairment, sepsis, or hypersensitivity.

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

**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.

**Contraindications:** coronary artery disease, eclampsia or preeclampsia, or pregnancy.

**Dose and Administration:** *Orally, intramuscularly, or intravenously.* It should not be administered prior to delivery of the placenta. Intravenous route should be used only for emergencies or cases of excessive uterine bleeding. Intravenous injection should be diluted and administered slowly.

Adults: *I.M. or I.V.*, 0.25mg repeated in 2—4 hours if necessary, up to five doses. Usually followed by, *Oral*, 0.25 – 0.5mg every 6—12 hours daily for 2 days or until the danger of uterine hemorrhage has passed.

**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.

**Methylergometrine Maleate**

*Tablet, 0.12mg*

*Injection, 0.2mg/ml*

**Indications:** - prevention and treatment of postpartum or postabortal uterine bleeding due to uterine atony or subinvolution. Its use is not recommended prior to delivery of the placenta since placental entrapment may occur. It is also used to lessen expulsion of uterine contents in cases of incomplete abortion.

It is not indicated for induction or augmentation of labor, to induce abortion, or in cases of threatened spontaneous abortion because of its propensity to produce non-physiologic, tetanic contractions and its long duration of action.



**Cautions:** - hepatic and renal function impairment, hypocalcaemia, mitral valve stenosis, venoatrial shunts and in those patients allergic to methylergometrine or ergot alkaloids.

**Drug interactions:** - general anaesthetic especially halothane, bromocriptine, other ergot alkaloids, nicotine, smoking tobacco, nitroglycerine, vasoconstrictors and vasopressors.

**Side effects** - nausea, vomiting, abdominal pain, diarrhoea, uterine cramping dizziness, sweating, tinnitus (ringing in the ears)

**Contraindications:** - pregnancy, labour and delivery, unstable anginal pectoris, recent myocardial infarction, history of cerebrovascular accident, history of transient ischemic attack, cardiovascular disease, coronary artery disease, eclampsia or preeclampsia, (history of) severe hypertension, occlusive peripheral vascular disease, severe raynaud's phenomenon.

**Dose and administration -**

Usual Adult and Adolescent dose - uterine stimulant - *Oral*, 0.2 to 0.4mg two or four times a day until the danger of uterine atony and hemorrhage has passed.

*IV, or IM* - 0.2mg repeated in two or four hours if necessary, up to five doses.

**Storage:** - at room temperature in a tight container (tablets), protect from light and from freezing.



## 10. BLOOD PRODUCTS AND DRUGS AFFECTING THE BLOOD

### 10.1. Hemostatic Agents.

#### Phytomenadione (vitamin K<sub>1</sub>)

*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.

Adults: *I.M. or S.C.*, 2.5 – 10mg (up to 25mg), may be repeated after 6-8 hours if necessary. Child: Infants - *IM or S.C.*, 1-2 mg; Children - *IM or S.C.*, 5-10mg.

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

### 10.2. 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 overload 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 B<sub>12</sub> (hydroxycobalamin) or folate or both. The clinical features of folate deficient megaloblastic anaemia are similar to those of vitamin B<sub>12</sub> 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**<sup>•</sup>*Tablet**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:** acetoxyhydroxamic acid, dimercaprol, etidronate (avoid using iron supplements with in 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 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 –

Adults: 300mg once daily.

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

Treatment –

Adults:

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

Children:

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 1year – 60mg every 8 hours daily.

**Storage:** -at room temperature, in a tight container. Protect from light and freezing.

- 
- Any Ferrous salt containing elemental Iron of accepted therapeutic value



**Ferrous salt + Folic Acid\****Tablet**Capsule***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, *by mouth*, Adult the equivalent of about 100mg elemental iron with 350 - 400 micrograms folic acid daily throughout pregnancy.

**10.3. Blood substitutes and Plasma Expanders**

Dextrans (Dextran 70 and Dextran 40) are macromolecular substances which are metabolized slowly; they may be used at the outset to expand and maintain blood volume in shock arising from conditions such as burns or septicemia. Plasma substitutes may be used as an immediate short - term measure to treat haemorrhage until blood is available.

They are rarely needed when shock is due to sodium and water depletion because, in these circumstances, the shock responds to water and electrolyte repletion. Plasma substitutes should not be used to maintain plasma volume in conditions such as burns or peritonitis where there is loss of plasma protein, water and electrolytes over periods of several days or weeks. In these situations, plasma or plasma protein fractions containing large amounts of albumin should be given.

Dextran 40 intravenous infusion is used in an attempt to improve peripheral blood flow in ischaemic disease of the limbs. Dextran 40 and 70 have also been used in the prophylaxis of thromboembolism but are now rarely used for this purpose.

Dextrans may interfere with blood group cross-matching or biochemical measurements and these should be carried out before infusion is begun.

**Cautions:** plasma substitutes should be used with caution in patients with cardiac disease or renal impairment; urine output should be monitored. Care should be taken to avoid haematocrit concentration from falling below 25 - 30% and the patient should be monitored for hypersensitivity reactions.

**Side effects:** Hypersensitivity reactions may occur including, rarely, severe anaphylactoid reaction. Transient increase in bleeding time may occur.

- Any Ferrous salt containing elemental Iron of accepted therapeutic value



**Dextran (Mw 40, 000)**

*Solution, 10% w/v in 5% Dextrose; 500ml*

**Indications:** - conditions associated with peripheral local slowing of the blood flow; prophylaxis of post surgical thromboembolic disease

**Cautions:** -see notes above; can interfere with some laboratory tests (see also above); correct dehydration beforehand, give adequate fluids during therapy and, where possible, monitor central venous pressure; pregnancy.

**Side effects:** -see notes above

**Dose and Administrations:**

*By intravenous infusion*, initially 500 - 1000 ml; further doses are given according to the patient's condition (see notes above).



## 11. DRUGS FOR CORRECTING WATER, ELECTROLYTE AND ACID - BASE DISTURBANCES

### 11.1.Oral

#### Potassium chloride

*Tablet, 500mg, 600mg, 750mg, and 1gm*

**Indications:** -for treatment of potassium depletion

**Cautions:** - in elderly, mild to moderate renal impairment (close monitoring required), intestinal stricture, history of peptic ulcer; see also interactions.

**Drug interactions:** - special hazard if given with drugs liable to raise plasma potassium concentration such as potassium-sparing diuretics, angiotension converting enzyme inhibitors, or cyclosporins.

**Side effects:** - nausea, vomiting (severe symptoms may indicate obstruction), oesophageal or small bowel ulceration.

**Contraindications:** - severe renal impairment, plasma potassium concentrations above 5 m mol/liter.

**Dose and Administration:** Adult - for prevention of hypokalaemia-*oral*, 2-4gm daily by mouth in patients taking normal diet. Smaller doses must be used if there is renal insufficiency (common in the elderly) otherwise there is danger of hyperkalaemia.

**Storage:** - at room temperature.

#### Oral Rehydration Salts (ORS)

*Powder –*

*Sodium Chloride-----3.5g/litre*

*Trisodium Citrate Dihydrate-----2.9g/litre*

*Potassium Chloride-----1.5g/litre*

*Glucose-----20.0g/litre*

**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:** caution in rehydrating severely malnourished children (Kwashiorkor and marasmus).

**Side effects:** None.

**Contraindications:** patients in shock.

**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 diarrhoea –

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 breastfed, 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. If the powder is white, even if it is hard, the ORS has deteriorated and it should not be used.

### 11.2 Parenteral

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.

#### Calcium gluconate or levulinate

*Injection, 10% in 10ml ampoule*

**Indications:** - in the treatment of hypocalcaemia in conditions that require a rapid increase in serum calcium - ion concentration, such as neonatal hypocalcaemia tetany; tetany due to parathyroid deficiency.



It is also indicated to decrease or reverse the cardiac depressant effect of hyperkalemia on electrocardiographic (ECG) function, and as an aid in the treatment of CNS depression due to over dosage of magnesium sulfate.

**Cautions:** - cardiac function impairment, ventricular fibrillation during cardiac resuscitation, renal function impairment, diarrhoea.

**Drug interactions** - calcitonin, verapamil, calcium and magnesium containing medications, digitalis glycoside, magnesium sulfate, milk and milk products, phenytoin, oral tetracyclines, vitamin D.

**Contraindications** - digitalis toxicity, primary or secondary hypercalcemia, hypercalciuria, calcium renal calculi, sarcoidosis.

**Side effects** - hypotension (dizziness), flushing and/or sensation of warmth or heat, irregular heartbeat; nausea or vomiting, skin redness, rash, pain, or burning at injection site, sweating, tingling sensation.

**Dose and Administration** -

Adult:

Antihypocalcemic or Electrolyte replenisher - *IV*, 970mg (94.7mg of calcium ion), administered slowly at a rate not to exceed 5ml (47.5mg of calcium ion) a minute. The dosage may be repeated, if necessary, until tetany is controlled.

Antihyperkalemic - *IV*, 1 to 2 grams (94.7 to 189 mg of calcium ion), administered slowly at a rate not to exceed 5ml a minute, the dosage being titrated and adjusted by constant monitoring of ECG changes during administration.

Antihpermagnesemic - *IV*, 1 to 2gms, administered at a rate not to exceed 5ml a minute.

Child - Antihypocalcemic - *IV*, 200-500mg (19.5-48.8mg of calcium ion) as a single dose, administered slowly at a rate not to exceed 5ml (47.5mg of calcium ion) a minute, repeated if necessary until tetany is controlled.

**Storage** - at room temperature, protect from freezing.

### **Dextrose**

*Injection, 5% in 500ml, 1000ml; 10% in 500ml, 1000ml; 40% in 20ml, 50%*

**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-

Adults and children: 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.*

Adults and Older Children: 100ml/kg of body weight within 4 hours, immediately until radial pulse is easily felt.

Infants: 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.

### **Potassium chloride**

*Injection, 150mg/ml in 10ml ampoule*

**Indications:** - treatment of potassium depletion or hypokalaemia, with or without metabolic alkalosis, in chronic digitalis intoxication, and in patients with hypokalaemia familiar periodic paralysis; see also oral potassium supplements, section 11.1.

**Cautions:** -for intravenous infusion the concentration of solution should not usually exceed 3.2g (43mmol)/litre; specialist advice and ECG monitoring in difficult cases.

**Drug-interactions:** - potassium sparing diuretics, angiotension converting enzyme inhibitors cyclosporins, digitalis glycoside, parenteral calcium salts, laxatives.

**Side effects** - rapid infusion toxic to heart; see section 11.1

**Contraindications** - hyperkalemia

**Dose and Administration** - *IV infusion*



Note: - Injectable potassium chloride products, in strengths of 1.5mEq and 2mEq per ml must be diluted prior to IV administration. Direct patient injection of potassium concentrate may be instantaneously fatal. However, injectable potassium chloride products in strengths of 0.1 and 0.4mEq per ml are intended for use with a calibrated infusion device and do not require dilution.

Adult: Antihypokalemic or electrolyte replenisher - *IV infusion*, the dose and rate of infusion to be determined by the individual requirements of each patient, up to 400mEq of potassium a day (usually not more than 3mEq per kg of body weight). The response of the patient, as determined by the measurement of serum potassium concentration and the electrocardiogram following the initial 40 to 60mEq infusion, should indicate the subsequent infusion rate required.

Child: Antihypokalemic or Electrolyte replenisher - *IV infusion*, up to 3mEq of potassium per kg of body weight or 40mEq per square meter of body surface area a day. Volume of administered fluids must be adjusted to body size.

**Storage:** at room temperature, protect from freezing.

### **Ringer's injection**

*Injectable solution, each 100ml contains*

*Na<sup>+</sup> 147mEq + K<sup>+</sup> 4mEq + Ca<sup>++</sup> 45mEq + Cl<sup>-</sup> 155.5mEq in 300ml, 100ml*

### **Sodium chloride**

*Injection, 235mg/ml in 20ml ampoule; 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:** - see section 11.1

**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); see also section 11.1

### **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

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### **11.3. Enteral Nutrition**

#### **Calcium Caseinate**

#### **Soya - based non milk preparation**



## 12.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 dose 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 B<sub>12</sub> is associated with megaloblastic anaemia. Folic acid should not be used in undiagnosed megaloblastic anaemia unless Vitamin B<sub>12</sub> 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 D<sub>2</sub>) and colecalciferol (Vitamin D<sub>3</sub>). 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 D<sub>3</sub>) 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 D<sub>3</sub> in their skin. Dark skin with a high melanin content must be exposed to daylight longer than light skin in order to obtain the same synthesis of vitamin D<sub>3</sub>. 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 (see sec. 10.1)

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### 12.1. 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.

**Calciferol (Ergocalciferol/Vitamin D<sub>2</sub>)**

*Tablet (strong), 1.25 mg (50,000units)*

*Oral solution, 20,000-units/ ml, 400,000 units/ml*

*Injection, 300,000-units/ml in 2 ml ampoule*

**Indications:** –used in the treatment of chronic hypocalcemia, hypophosphatemia, rickets and osteodystrophy associated with various medical conditions including chronic renal failure, familial hypophosphatemia, and hypoparathyroidism (post surgical or idiopathic or pseudohypoparathyroidism); for prevention and treatment of vitamin D deficiency states; and to treat anticonvulsant induced rickets & osteomalacia

Note: Ergocalciferol may not be the preferred agent in the treatment of familial hypophosphatemia or hypoparathyroidism because the large doses needed are associated with a risk of overdose and hypercalcemia, and ergocalciferol not usually preferred in patients with renal failure since these patients have impaired ability to synthesize calcitriol from colecalciferol and ergocalciferol.

**Cautions:** – ergocalciferol should be administered with extreme caution, if at all, to patients with impaired renal function and with extreme caution in patients with heart disease, renal stones, or arteriosclerosis; large doses of VitaminD analogs should not be administered to nursing women; take care to ensure correct dose in infants and pregnant

**Drug interactions:** – antacids (magnesium containing), in high doses of calcium containing preparations & diuretics (thiazide), vitamin D analogs.

**Side effects:** symptoms of over dosage include anorexia, lassitude, nausea and vomiting, diarrhoea, weight loss, polyuria, sweating, headache,



thirst, vertigo, and raised concentrations of calcium and phosphate in plasma and urine.

**Contraindications:** – hypercalcemia, hypervitaminosis D, Renal osteodystrophy with hyperphosphatemia, metastatic calcification, hypersensitivity to effects of Vitamin D.

**Dose and Administrations:**

Ergocalciferol injection

Usual adult and adolescent dose:

Deficiency (prophylaxis or treatment)-

*Intravenous infusion*, as part of total parenteral nutrition solutions, the specific amount determined by individual patient need.

Malabsorption – *Intramuscular*, 10,000 units per day

Usual pediatric dose: see usual adult and adolescent dose

Ergocalciferol oral solution

Usual adult and adolescent dose:

Deficiency (prophylaxis)-

*Oral*, amount based on normal daily-recommended intakes:

Person	Mcg	units
Adolescent and adult	5-10	200 – 400
Pregnant and breast feeding females	10	400

Deficiency treatment

Treatment dose is individualized by prescriber based on severity or deficiency

Vitamin D – resistant rickets – *Oral*, 12,000 to 500,000 units per day

Vitamin D – dependent rickets- *Oral* 10,000 to 60,000 units per day (up to 500,000 units/day)

Osteomalacia due to prolonged use of anticonvulsants- *Oral* 1000 to 4000 units per day

Familial hypo phosphatemia – *Oral*, 50,000 to 100,000 units per day

Hypoparathyroidism - *Oral*, 50,000 to 150,000 units per day

Usual pediatric dose:

Deficiency (prophylaxis)-

Oral amount based on normal daily-recommended intakes.

Persons	Mcg	Units
Infants & Children		
Birth to 3 years of age	7.5 - 10	300 - 400
4 to 10 years of age	10	400

Deficiency (treatment) -

Treatment dose is individualized by prescriber based on severity of deficiency

Vitamin D-dependent rickets - *Oral*, 3000 to 10,000 units per day (up to 50,000 units/day).



Osteomalacia due to prolonged use of anticonvulsants - *Oral*, 1000 units per day

Hypoparathyroidism- *Oral*, 50,000 to 200,000 units per day.

Ergocalciferol tablets

Usual adult and adolescent dose: see Ergocalciferol oral solution

Usual pediatric dose: see Ergocalciferol oral solution

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

### **Cholecalciferol (Vitamin D3)**

*Capsule, 250mcg*

*Injection (oily), 300,000 IU/ml*

Indications, Cautions, Side effects, Drug interactions, Dose and Administration; See notes under ergocalciferol.

### **Folic Acid**

*Tablet, 200 mcg, 1 mg, 5 mg*

*Injection, 5 mg/ml in 1 ml ampoule*

**Indications:** -for prevention and treatment of folic acid deficiency states, including megaloblastic anemia and in anemias of nutritional origin, pregnancy, infancy, or childhood; folic acid is being used in the diagnosis of folate deficiency

**Cautions:** - administer with extreme caution to patients with undiagnosed anemia. It should never be given alone for pernicious anaemia and other vitamin B<sub>12</sub> deficiency states.

**Drug interactions:** - phenytoin, chloramphenicol

**Side effects:** - allergic reaction, specifically; bronchospasm; erythema; fever; general malaise; skin rash; or itching.

**Contraindications:** - folic acid injection that contains benzyl alcohol as a preservative should not be used in new born and immature infants

**Dose and Administrations:** -

Folic acid Injection:

Usual adult and adolescent dose:

Deficiency (prophylaxis) -

*Intravenous infusion*, as part of total parenteral nutrition solutions, the specific amount determined by individual patients need.

Deficiency (treatment) -

*Intramuscular, intravenous, or deep subcutaneous:* 250 mcg (0.25 mg) to 1-mg a day until a hematologic response occurs.

Diagnostic aid (folate deficiency) -

*Intramuscular*, 100 to 200 mcg (0.1 to 0.2 mg) a day for ten days plus low dietary folic acid and Vitamin B<sub>12</sub>.

Usual pediatric dose: See usual adult and adolescent dose.

Folic acid Tablets:



Deficiency (prophylaxis)-

*Oral*, amount based on normal daily-recommended intakes:

Persons	Mcg
Adolescent and Adult males	150 – 400
Adolescent and adult females	150 – 400
Pregnant females	400 - 800
Breast – feeding females	260 – 800
Birth to 3 years of age	25
4 to 6 years of age	75 – 400
7 to 10 years of age	100 – 400

Diagnostic aid (folate deficiency) –

*Oral*, 100 to 200 mcg (0.1 to 0.2 mg) a day for ten days plus low dietary folic acid and vitamin B<sub>12</sub>.

Deficiency (treatment)

Treatment dose is individualized by prescriber based on severity of deficiency.

**Storage:** –at room temperature in a well-closed 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; see also section 10.1

**Cautions, Drug interactions, Side effect;** see section 10.1 under phytomenadione

**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.

Adults - 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.

Children - Nutritional supplement (vitamin), prothrombogenic or Antidote (to drug - induced hypoprothrombinemia), Treatment of hypoprothrombinemia.

Infants - *IM or SC*, 1-2 mg.

Children - *IM or SC*, 5-10mg.

**Storage:** at room temperature, protect from light and freezing.



**Pyridoxine Hydrochloride (Vitamin B<sub>6</sub>)***Tablet, 40mg, 100mg, 300mg.**Injection, 50mg/ml in 2ml ampoule, 150mg/ml*

**Indications:** - for prevention and treatment of pyridoxine deficiency states that may occur as a result of inadequate nutrition or intestinal malabsorption.

It is also used as antidote in cyclosporin poisoning and to terminate seizures and prevent neuropathy associated with isoniazid poisoning.

**Cautions:** - sensitive to pyridoxine.

**Drug interactions** - levodopa, cycloserine, isoniazid, penicillamines, hydralazine.

**Side effects:** - sensory neuropathy in prolonged use

**Dose and Administration:**

Usual Adult dose -

Deficiency states - *oral*, 20-50mg up to 3 times daily isoniazid neuropathy, prophylaxis 10mg daily, therapeutic - 50mg three times daily.

Idiopathic sideroblastic anaemia - *oral*, 100-400mg daily in divided doses.

Nutritional supplement - Dietary supplement - *oral*, 10-20mg per day for three weeks followed by 2 to 5mg per day (in a multivitamin preparation) for several weeks.

**Drug Induced deficiency** -

Prevention - *oral*, 10-50mg per day for penicillamine or 100-300mg per day for cycloserine, hydralazine, or isoniazid.

Treatment - *oral*, 50 to 100mg per day as needed to prevent relapse; *IM or IV*, 50 to 200mg per day for three weeks, followed by 25 to 100mg per day as needed.

Usual child dose-

Dietary supplement - *oral*, 2.5 to 10mg per day for three weeks, followed by 2 to 5mg per day (in a multivitamin preparation) for several weeks.

**Storage** - at room temperature, protect from light and from freezing.

**Thiamine Hydrochloride (Vitamin B<sub>1</sub>)***Tablet, 5mg, 10mg, 100mg, 300mg**Injection, 50mg/ml in 2ml ampoule*

**Indications:** - for prevention and treatment of thiamine deficiency states that may occur as a result of inadequate nutrition or intestinal malabsorption.

It is used for temporary metabolic correction of genetic enzyme deficiency diseases such as subacute necrotizing encephalomyelopathy (SNE, Leigh's disease), maple syrup urine disease (branched-chain



aminoacidopathy), and lactic acidosis associated with pyruvate carboxylase deficiency and hyperalaninemia.

**Cautions:** - patients sensitive to thiamine and in those with Wernicke's encephalopathy.

**Side effects:** - anaphylactic reaction (coughing, difficulty in swallowing; hives; itching of the skin, swelling of face, lips or eyelids, or wheezing or difficulty in breathing).

**Dose and Administration:-**

Usual Adult dose

Nutritional supplement (Vitamin)

**Beriberi** (initial in mild or maintenance following severe): *oral*, 5 to 10mg three times a day

(in a multivitamin preparation).

**Beriberi** (critical illness): *IM or slow IV*, 5-100mg three times a day followed by

maintenance oral administration.

**Treatment of deficiency:** *oral*, 1-10mg three times a day until improvement occurs, followed by recommended dietary allowance.

Usual child dose

Nutritional supplement (Vitamin)

**Beriberi** (mild): Infants - *oral*, 10mg per day.

**Beriberi** (critical illness): *IM or slow IV*, 10-25mg per day.

**Treatment of deficiency:** *oral*, 10 to 50mg per day in divided doses.

Dietary supplement:

Infants - *oral*, 300 to 500mcg (0.3-0.5mg) per day.

Children - *oral*, 500mcg (0.5mg) to 1mg per day.

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

Usual adult and adolescent dose:

**Deficiency** - *oral*, 30,000 RE (100,000 units) 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 to 15,000 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.

Usual child dose:

**Deficiency**

- Infants less than 1 year - *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.



**12.2. Vitamins, Combinations****Vitamin A + D**

Capsule, 4,000 IU + 400IU; see notes above

**12.3. Vitamin B complex preparations<sup>†</sup>****12.4. Multivitamin preparations<sup>†</sup>****12.5. Multivitamin with minerals and/or extracts<sup>†</sup>**

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<sup>†</sup> Any combination proven to be therapeutically effective can be used



## 13.ANTIHISTAMINES AND ANTIALLERGICS

### 13.1. 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. Histamine H<sub>1</sub> receptors are responsible for vasodilatation, increased capillary permeability, flare and itch reactions in the skin, and to some extent for contractions of smooth muscle in the bronchi and gastro-intestinal tract.

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. They should not be used to control transfusion reactions caused by ABO incompatibility.

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; antihistamines such as cyproheptadine may be of value in the prophylaxis of migraine, particularly in children.

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 in coordination, 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. Extrapyramidal symptoms may develop with phenothiazine derivatives and have been reported with some other antihistamines.

Older antihistamines possess antimuscarinic properties and may 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 1 year of age to children under 2 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.

### **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; injections may cause transient hypotension or CNS stimulation and may be irritant.

**Dose and Administration:**

*By mouth*, 4mg every 4-6 hours, max. 24mg daily; child under 1 year not recommended.

1-2 years 1mg twice daily; 2-5 years 1mg every 4-6 hours, max. 6mg daily; 6-12 years 2mg every 4-6 hours, max. 12mg daily.



*By subcutaneous or intramuscular injection, 10-20mg, repeated if required; max. 40mg in 24 hours.*

*By intravenous injection over 1 minutes, 10-20mg.*

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

### **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:** -

Usual adult and adolescent -

*Oral, 5-12.5mg three times a day before meals and at bed time, or 25mg 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.*

Usual child dose (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.

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### **13.2. Drugs 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. An intravenous corticosteroid e.g. hydrocortisone (as sodium succinate) in a dose of 100 - 300 mg is of secondary value in the initial management of anaphylactic shock because the onset of action is delayed for several hours, but should be given to prevent further deterioration in severely affected patients.

### **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

*Intramuscular or subcutaneous injection* use 1:1000 epinephrine injection.

*Slow intravenous 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.



**Hydrocortisone**

*Injection (sodium succinate), 50 mg/ml in 2 ml ampoule*

**Indications:** - used for life-threatening shock only after less toxic therapies have proven ineffective.

**Cautions:** - pregnancy and in children; in patients with hypothyroidism or cirrhosis, psychosis, hypertension, congestive heart failure, diverticulitis, HIV, herpes simplex, oral herpetic lesions, renal function impairment or disease, tuberculosis, diabetes mellitus.

**Drug interactions:** - alcohol, acetaminophen, non-steroidal anti-inflammatory drugs, parenteral amphoterecin B, atropine, oral antidiabetic agents or insulin, digitalis glycoside, diuretics, isoniazid.

**Contraindications:** - known hypersensitivity to any of corticosteroids, recent surgery, osteoporosis, scleroderma, Cushing's syndrome.

**Side effects:** - immunosuppression, muscle pain or weakness, delayed wound healing, edema, hypertension, cataract, diabetes mellitus, nausea, vomiting, anorexia, headache, vertigo, insomnia, restlessness, acne, impaired wound healing, increased sweating, hirsutism.

**Dose and Administration:**

Adult dose - for life threatening shock *IV*-massive dose 50mg/kg initially and repeated in 4 hours and/or every 24 hours if needed, or 0.5-2g *IV* initially and repeated at 2 to 6 hours intervals as required.

**Storage:** - at room temperature.



## 14. OPHTHALMIC AGENTS

### 14.1. Anti-infectives, Ophthalmic

#### 14.1.1 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 influenzae*. 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. Chloramphenicol eye drops are well tolerated and the recommendation that chloramphenicol eye drops should be avoided because of an increased risk of aplastic anaemia is not well founded.

#### **Chloramphenicol**

*Eye ointment, 1 %, 5 %*

*Solution (eye drop), 0.4 %, 0.5 %, 1 %, 5 %*

**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 & 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.

#### **Oxytetracycline Hydrochloride**

*Eye ointment, 0.5*

**Indications:** -oxytetracycline (in combination with polymyxin B sulphate) is used topically in the treatment of superficial infections of the eye caused by susceptible bacteria.

**Cautions:** - sensitive to tetracyclines.

**Side effects:** - burning, stinging, increased lachrymation, foreign body sensation.



**Dose and Administration**

Usual Adult dose - *topical, in the lower conjunctival sac of the infected eye*, a thin amount of ophthalmic ointment every 2-12 hours daily.

**Storage:** - at room temperature in a collapsible ophthalmic ointment tube, protect from freezing.

**Silver Nitrate**

*Solution (eye drop), 1 %*

**Indications:** -prophylaxis of neonatal conjunctivitis (*Ophthalmia neonatorum*) due to *Neisseria gonorrhoea*, if tetracycline not available.

**Cautions:** -avoid use of old, concentrated drugs; wipe excess drops from skin near the eye to prevent staining.

**Side effects:** - skin and mucous membrane irritation, mild conjunctivitis; repeated use may cause skin discoloration, corneal cauterization and blindness.

**Dose and Administration**

Prophylaxis of neonatal conjunctivitis, *by instillation into the eye*, Newborn at birth after cleansing eyes with sterile gauze, 2 drops into each eye.

**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.

**Dose and Administration:** - *Topical*, to the conjunctiva.

**Purulent Conjunctivitis** –Adults and Children: Apply, a thin strip (approximately 1cm) of ointment onto the infected eye every 6 hours daily for 5 days.

**Trachoma** –Adults and Children: 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:** -at room temperature.



**15.EAR, NOSE, AND THROAT PREPARATIONS****15.1.Nasal and Oropharyngeal, preparations**

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 a rebound congestion (rhinitis medicamentosa) on withdrawal, due to a secondary vasodilatation with a subsequent temporary increase in nasal congestion. Ephedrine nasal (not available at health center level) drop is the safest sympathomimetic preparation and can give relief for several hours. The more potent sympathomimetic drugs Xylometazoline, and oxymetazoline are more likely to cause a rebound effect. 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 on sale to the public at health center level are Amyl-metacresol + Dichlorobenzyl Alcohol and Dequalinium Chloride.

The most common cause of a sore throat is a viral infection which does not benefit from anti-infective treatment. Fungal mouth infections such as candida albicans which are sometimes associated with the use of broad - spectrum antibiotics or of cytotoxics; withdrawing the causative drug may lead to rapid resolution. Otherwise, an antifungal drug may be effective. Of the antifungal drugs used for mouth infections, miconazole and nystatin is not absorbed from the gastro-intestinal tract and is used by local application in the mouth. Miconazole occupies an intermediate position since it is used by local application in the mouth but is also absorbed to the extent that potential interactions need to be considered.

**Amyl-Meta-cresol + Dichlorobenzyl Alcohol**

*Lozenges, 0.6 mg + 1.2 mg*

See notes above



**Dequalinium chloride***Lozenge, 0.25 ml*

See notes above

**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.

Adults and Children: every 8 – 12 hours daily for 3 years.

**Storage:** -at room temperature, in tight containers.**Hexetidine<sup>☞</sup>***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** - use 15ml undiluted 2-3 times daily.**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.**Miconazole***Oral Gel, 25 mg/ml***Indications:** – oral fungal infections**Cautions:** – pregnancy, avoid in porphyria**Side effects:** - mild gastrointestinal disturbances reported

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<sup>☞</sup> Any mouth wash and antiseptic preparations are also acceptable



**Drug interactions:** – anticoagulants, antidiabetics (sulphonylureas), phenytoin, cisapride, and cyclosporin.

**Dose and Administration**

Place 5 – 10 ml in the mouth after food and retain near lesions 4 times daily; child under 2 years 2.5 ml twice daily, 2 – 6 years 5 ml twice daily, over 6 years 5 ml 4 times daily

\* Localized lesions smear small amounts of gel on affected area with clean finger

**Storage:** –at room temperature protected from light

**Nystatin**

*Pastilles, 100,000 units*

*Suspension, 100,000 units/ml*

**Indications:** – oral and perioral fungal infections

**Side effects:** – nausea, vomiting, and diarrhoea, oral irritation and sensitization reported

**Contraindications** –hypersensitivity to the drug or any ingredient in the respective formulation.

**Dose and Administration:** -

100,000 units 4 time daily after food. Usually for 7 days (continued for 48 hours after lesions have resolved). Nystatin 100,000 units up to four times daily may be given to neonates.

*Note:* Immuno suppressed patients may require higher doses (e.g 500,000 units 4 times daily). The formulation should be kept in contact with the affected area for as long as possible and patients should avoid taking food or drink earlier than one hour after a dose.

**Storage:** – nystatin deteriorates on exposure to heat, light, moisture, or air. Nystatin oral suspension should be stored in tight, light resistant containers at room temperature; freezing of the oral suspension should be avoided.

**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.

**Side effects:** - idiosyncratic mucosal irritation and hypersensitivity reactions, may interfere with thyroid function tests and with tests for occult blood.

**Dose and Administration** - Mouth wash or gargle.



Adults and children 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.

**Xylometazoline Hydrochloride**

*Solution (Nasal drop), 0.05 %, 0.1 %*

**Indications:** -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)

**Side effects:** -local irritation, nausea, headache; after excessive use tolerance with diminished effect rebound congestion; cardiovascular effects also reported.

**Dose and Administration**

Adult, *instil* 2 - 3 drops of 0.1 % solution into each nostril 2 - 3 times daily when required; maximum duration 7 days; not recommended for children under 12 years.

Child, over 3 months *instil* 1 - 2 drops of 0.05 % solution into each nostril 1 - 2 times daily when required (not recommended for infants under 3 months of age, doctor's advice only under 2 years); maximum duration 7 days.

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**15.2. Otic Agents**

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.

A solution of acetic acid 2 % acts as an antifungal and antibacterial in the external ear canal. It may be used to treat mild otitis externa but in severe cases an anti-inflammatory preparation with or without an anti-infective drug is required. Solutions containing an anti-infective and a corticosteroid are used for treating cases where infection is present with inflammation and eczema.

Otitis media. Otitis media or inflammation of the middle ear can be acute or chronic, serous (with effusion; secretory) 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.

**Acetic Acid**

*Solution (ear drop), 2 %*

See notes above

**Chloramphenicol**

*Solution (ear drop), 1 %, 2 %, 5 %*

**Indications:** –used in the treatment of bacterial infection in otitis externa.

**Cautions:** – over growth with non-susceptible organisms. Avoid prolonged use

**Side effects:** – high incidence of sensitivity reactions to vehicle, optic and peripheral neuritis.

**Drug interactions:** – alfentanil, chlorpropamide, phenytoin, tolbutamide, rifampicin, warfarin, vitamin B<sub>12</sub>, folic acid

**Contraindications:** – hypersensitive to the drug or any ingredients in the formulations; perforated tympanic membrane. Mothers receiving otic chloramphenicol should not breast-feed their infants.

**Dose and Administration:**

Chloramphenicol 5 % in propylene glycol; apply 2 – 3 drops into the ear 2 – 3 times daily

**Storage:** – Store below 30°C in a tight container protected from freezing

**Clotrimazole**

*Solution (ear drop), 1 %*

**Indications:** - fungal infection in otitis externa.

**Side effects:** - occasional local irritation or sensitivity

**Dose and Administration:**

Ear, apply 2 - 3 times daily continuing for at least 14 days after disappearance of infection.

**Hydrogen peroxide**

*Solution, 3 %*

Hydrogen peroxide is an oxidizing agent with antiseptic, disinfectant, and deodorant properties. It is used in dilute aqueous solution for cleansing wounds.

**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.



## 16.DERMATOLOGIC AGENTS

### 16.1.Anti-infective, Topical

#### Antifungals

Ringworm. 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 topical application of antifungal may reduce the risk of transmission.

Most other local ringworm infections can be treated adequately with topical antifungal preparations. Benzoic acid and Gentian violet solution are inexpensive and effective fungistatic compounds for the treatment of ringworm infections. Minor skin lesions due to ringworm can be cleared with repeated applications of compound benzoic acid ointment (Whitfield ointment), which combines the fungistatic action of benzoic acid with the keratolytic action of salicylic acid. However, the most effective topical treatment for dermatophyte infections is a cream containing an imidazole such as clotrimazole, ketoconazole and miconazole, which are effective for long established lesions but is more expensive than compound benzoic acid ointment.

Candidiasis. Candida can infect the oral cavity, the vagina or the skin. The most severe infections of candida are now seen in patients with HIV infection. Candidal skin infections may be treated with topical imidazole antifungals, clotrimazole, ketoconazole, miconazole.

Pityriasis versicolor. Pityriasis (tinea) versicolor is caused by a commensal yeast. It may be treated topically with a course of selenium sulphide repeated after one month. Topical imidazole antifungals and topical terbinafine are alternatives but large quantities may be required. If topical therapy fails or if the infection is widespread, pityriasis versicolor is treated systemically with an azole antifungal. Relapse is common, especially in immunocompromised patients.

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.

### **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.

Skin infections such as erysipelas and cellulitis systemic antibacterial treatment is more appropriate because the infection is too deeply seated for adequate penetration of topical preparations.

An ointment containing 2 % mupirocin, which is active against Gram-positive bacteria, is of value, particularly in impetigo.

Mupirocin is not related to any other antibacterial in use; it is effective for skin infections, particularly those due Gram-positive organisms but it is not indicated for pseudomonal infection. Although staphylococcus aureus strains with low-level resistance to mupirocin are emerging, it is generally useful in infections resistant to other antibacterials. To avoid the development of resistance mupirocin should not be used for longer than 10 days and its use in hospital should be avoided if possible.

Topical use of preparations containing antimicrobials which are widely used systemically should be avoided. These include penicillins, sulfonamides, streptomycin and gentamicin which should be reserved for the systemic treatment of infections because of the possibility of including sensitivity and favouring the emergence of resistant organisms.

### **Scabies and Pediculicides**

Permethrine are used for Scabies (*sarcoptes scabiei*). Aqueous preparations are preferable to alcoholic lotion, which are not recommended owing to irritation of excoriated skin and the genitalia. Older preparations include benzyl benzoate, which is an irritant and should be avoided in children; it is less effective than Permethrine.

The itch of scabies persists for some weeks after the infestation has been eliminated and antipruritic treatment may be required.

### **Benzoic Acid + Salicylic Acid (White field's Ointment)**

*Ointment, 6 % + 3 %, 12 % + 6 %*

**Indications:** - fungal infections of the skin.

**Cautions:** it should not be applied to broken or inflamed skin.

**Side effects:** skin irritation and dryness may occur.



**Dose and Administration:** *Topical*, to the skin for several weeks until the infected stratum is shed. Prolonged use should be avoided and irritation of the skin occurs.

Apply sparingly to the affected area every 8-12 hours daily.

**Storage:** at room temperature, in a tight container.

### **Benzyl Benzoate**

*Lotion, 25 %, 20.556*

**Indications:** - in the treatment of scabies; head, body and public lice.

**Cautions:** - avoid contact with face, eye mucous membranes and urethral meatus. Do not apply to inflamed skin or weeping surfaces.

**Side effects:** slight local irritation, transient burning sensation, occasionally rashes. Frequent use causes contact dermatitis.

### **Dose and Administration:**

Scabies, Adult, apply over whole body, repeat without bathing on the following day, then wash off after further 24 hours

Pediculosis, Adult, apply to affected area and wash off 24 hours later; further applications possibly needed after 7 and 14 days.

**Storage:** -at room temperature, in airtight, light resistant containers. Protect from heat.

### **Clotrimazole**

*Cream 1 %*

*Solution 1 %*

**Indications:** -topical clotrimazole is indicated in the treatment of cutaneous candidiasis (moniliasis) caused by *Candida albicans*.

It is also indicated for treatment of *tinea corporis* (ring worm of the body), *tinea cruris* (ringworm of the groin, jock itch), and *tinea pedis* (ringworm of the foot; athlete's foot).

It is also used in the treatment of *tinea versicolor* (*pityriasis versicolor*, 'sun fungus'), and in the treatment of paronychia, *tinea barbae*, and *tinea capitis*.

**Cautions:** - sensitive to clotrimazole

**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.



**Gamabenzene Hexachloride (Lindane)**

*Cream, 1 %*

**Indications:** for 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.

**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.

**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*

*Shampoo, 2 %*

**Indications:** – fungal skin infections.

**Cautions:** – patients should be advised to avoid contact of ketoconazole shampoo with the eyes since irritation may occur. Ketoconazole 2 % cream or shampoo should be used with caution in nursing women, during pregnancy and pediatrics.

**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

Usual adult and adolescent dose: *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

Usual adult and adolescent dose:

**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.

Usual pediatric dose: Safety and efficacy have not been established.

**Storage:** – at room temperature. Protect from freezing.

**Miconazole Nitrate**

*Cream, 2 %*

*Lotion, 2 %*

*Tincture, 2 %*

**Indications:** fungal skin infections

**Cautions, Side effects:** see notes above

**Dose and Administration:**

Apply twice daily continuing for 10 days after lesions have healed; nail infections, apply 1 – 2 times daily.

**Storage:** - at room temperature in a tight container

**Mupirocin**

*Ointment, 2%*

**Indications:** bacterial skin infection (see also notes above)

**Cautions:** - renal impairment; may sting

**Dose and Administration**

Skin infection; apply up to 3 times daily for up to 10 days



Note: - contains macrogol and manufacturer advises caution in renal impairment

**Storage:** at room temperature

### **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.

It is also indicated in skin grafting when bacterial contamination may cause graft rejection or donor site infection, especially in hospitals with a history of resistant bacteria.

**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:**

Usual adult and adolescent dose:

Burns or Skin infections – *Topical*, directly to lesion or place on gauze depending on the usual dressing technique

Usual pediatric dose: Safety and efficacy have not been established

**Storage:** –at room temperature in a well-closed container. Protect from freezing.

### **Permethrine**

*Cream 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**

Scabies and body lice; apply cream over whole body, and wash off after 8 – 12 hours.

**Storage:** - store between 15 and 25°C. Protect from freezing

Note: - for external use only.

### **Salicylic Acid**

*Ointment, 2 %, 5 %, 10 %*

**Indications:** treatment of acne vulgaris, seborrheic dermatitis, psoriasis, and common wart (excluding on the face).

**Cautions:** avoid contact with eyes, mouth, and mucous membranes; avoid application to large areas.

**Side effects:** stinging, local irritation, and salicylism may occur when large areas are treated particularly in children



**Contraindications:** broken or inflamed skin; children under 2 years

**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.

### Selenium Sulphide

*Suspension, 2.5 %*

**Indications:** seborrheic dermatitis

**Cautions:** - do not apply to damaged skin (risk of systemic toxicity); avoid contact with eyes; do not use within 48 hours of applying any type of hair coloring or permanent waving preparation.

**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).

**Contraindications:** - Children under 5 years.

#### **Dose and Administration**

Seborrheic dermatitis, massage 5 – 10 mg of suspension into wet hair and leave for 2 – 3 minutes before rinsing thoroughly; repeat twice weekly for 2 weeks, then once weekly for 2 weeks, and then 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.

### 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 Children (>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

### **Tetracycline**

*Ointment, 3 %*

**Indications:** – bacterial skin infections

**Cautions:** – sensitivity to tetracyclines; over growth with non-susceptible organisms; stains clothing

**Side effects:** – rarely local hypersensitivity reaction

**Dose and Administration:**

Usual adult and adolescent dose:

Antibacterial (topical)- *Topical*, to the skin, one or two times a day.

Usual Pediatric dose: see usual adult and adolescent dose.

**Storage:** – store at room temperature in a well-closed container. Protect from freezing.

### **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 with in 10 days or becomes worse during self medication with tolnaftate, treatment should be discontinued and the patient should consult a physician or pediatricist. 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 of athlete's foot (tinea pedis), jock itch (tinea cruris), and other skin infections caused by dermatophytic fungi (ring worm)

**Dosage and Administration -**

Athlete's foot ringworm - *topically*, twice daily after cleansing the affected area, for 4 weeks.

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.

### 16.2. Anti-Inflammatories, Topical

Topical corticosteroids often produces dramatic suppression of skin diseases, such as eczema, infantile eczema, atopic dermatitis, dermatitis herpetiformis, contact dermatitis, seborrhoeic dermatitis, neurodermatitis, some forms of psoriasis, and intertrigo, in which inflammation is a prominent feature. However, the disease may return or be exacerbated when corticosteroids are withdrawn.

Application of the corticosteroids to the skin has lead to loss of skin collagen, subcutaneous atrophy local hypo pigmentation of deeply pigmented skins. Topical corticosteroids should not be applied with an occlusive dressing to large areas of the body because of the risk of systemic absorption. Also they should not be used for the treatment of rosacea and should not be used indiscriminately for pruritus. Corticosteroids should not be applied to ulcers of the leg and long term topical use is best avoided, especially in children. Patients should be advised that topical corticosteroids should be applied sparingly in thin layers, by smoothing gently into the skin preferably after a bath and that no benefit is gained from more frequent than twice daily application or by vigorous rubbing

#### Hydrocortisone Acetate

*Cream 1%*

*Ointment 1%*

**Indications:** - symptomatic relief of inflammation and/or pruritus associated with acute and chronic adrenocorticoid - responsive disorders.

**Cautions:** - pregnancy and breast-feeding i.e. avoid extensive use during pregnancy and topical adrenocorticoids should not be applied to the breasts prior to nursing. Caution is also required in children and elderly patients. Caution is also taken in patients with infection at treatment site, intolerance to hydrocortisone, pre-existing atrophy.

**Contraindications:** - untreated bacterial, fungal or viral skin lesions.



**Side effects:** - contact dermatitis (burning and itching of skin, apparent chronic therapeutic failure), folliculitis, furunculosis, pustules, pyoderma, or vesiculation (painful, red or itchy, pus containing blisters in hair follicles), hyperaesthesia (increased skin sensitivity). Burning, dryness, irritation, itching, or redness of skin, mild and transient increased redness or scaling of skin lesions, minor and transient skin rash.

**Dose and Administration:**

Usual Adult dose - *topical*, to the skin, as a 0.1 - 1% cream or 0.5 - 2.5% ointment one to four times a day.

Children 2 years of age and older - *topical*, to the skin, as 0.5% cream one to four times a day or as a 1% ointment one or two times a day.

Note:- Advise patient not to use it in or around the eye.

**Storage:-** at room temperature in a well closed container, protect from freezing.

### 16.3. Anti-infective/Anti-inflammatory Combinations

Clioquinol is a halogenated hydroxyquinoline with antibacterial and antifungal activity and is used in creams and ointments, usually containing 3%, in the treatment of skin infections. It is applied together with a corticosteroid in inflammatory skin conditions complicated by bacteria or fungal infections.

Combination of Clioquinol and a mild corticosteroid (such as hydrocortisone 1 %) may be of value in the treatment of eczematous intertrigo and in the first few days only of a severely inflamed patch of ringworm. Such combinations should only be used under supervision because of the risk that signs of resistant infection may be suppressed.

#### Clioquinol + Hydrocortisone

*Cream, 3 % + 0.5 or 1 %*

*Ointment, 3% + 0.5% or 1%*

**Indications:** - see notes above, and under hydrocortisone

**Cautions:** - see notes above and under section. 16.2

**Dose and Administration:** - *Topical*, Apply thinly 1 – 2 times daily

### 16.4. 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 containing Glutaraldehyde and combination of salicylic acid, lactic acid and polidocanol are available at health center level. They are suitable for the removal of warts on hands and feet.



**Glutaraldehyde***Solution. 10 %***Indications:** - warts, particularly planar warts (see also notes above)**Cautions:** protect surrounding skin, not for application to face, mucosa, or anogenital areas.**Side effects:** – rashes, skin irritation (discontinue if severe), stains skin brown.**Dose and Administrations:** -Apply twice daily.**Storage:** store at a temperature not exceeding 15°C.**Salicylic Acid + Lactic Acid + Polidocanol***Tincture, 2 g + 0.5 g + 0.2g in each 10 g*

See notes above.

**16.5. Drugs 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 in sunscreens. Ichthammol is usually used in chronic lichenified forms of eczema or to control pruritus.

**Ichthammol***Ointment, 10 %***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 %***Zinc oxide + Talc***Paste, 15 % + 25 %***16.6. 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 %*

**Indications:** mild pruritus

**Dose and Administrations:** - *Topically*. Apply liberally 3 – 4 time daily

**Calamine + Zinc Oxide**

*Cream, 4 % + 3 %*

*Lotion, 15 % + 5 %*

**Indications:** – mild pruritus

**Dose and Administrations:** - *Topically*, Apply liberally 3 – 4 times daily

**Crotamiton**

*Lotion, 10 %*

**Indications:** – crotamiton is used for the topical treatment of scabies & 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.

**Side effects:** –slight local irritation, allergic skin sensitivity may occur with prolonged use

**Contraindications:** –history of sensitivity or allergy to the drug and in those who exhibit a primary irritation response to topically applied medications. Acute exudative dermatoses

**Dose and Administration:**

-Crotamiton, in the form of a 10 % lotion is applied topically. The drug should not be administered orally

-A thin layer of the 10 % lotion should be applied uniformly and massaged gently into all skin surfaces from the neck to the toes. A second coat of the lotion should be applied after 24 hours.

In adults, 30 g of the lotion for one application; a proportionately smaller amount is used in children. Treatment may be repeated after 7 – 10 days if mites appear or new lesions develop. The patient should bath 48 hours after the last application to remove the drug.



Note – Before applying crotamiton, advice the patient to bath with soap and water, taking cares to scrub and remove scaling or crusted detritus, then towel dry.

**Storage:** – It should be stored in tight, light resistant containers at a room temperature.

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### 16.7.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 at health center level include Chlorhexidine; Potassium permanganate & 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.

#### 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.

#### 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.

#### 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** - 1 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 or those receiving lithium therapy, 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 dose- 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 dose - 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 seborrheic 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 dose - child under 2 years not recommended

## 16.8.Dermatologicals, Others

### **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.

### **Methylsalicylate<sup>☞</sup>**

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.

<sup>☞</sup> Any other rubefacient proven to be therapeutically effective can be used



**17.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.

Ipecac is used in large doses as an emetic for selected patients. Vomiting usually occurs within 30 minutes of administration by mouth of an emetic dose due to an irritant effect on the gastro-intestinal tract and a central action on the chemoreceptor trigger zone. Doses are usually followed by a copious drink of water or fruit juice; in young children this may be given before the dose. Many clinicians recommend that activated charcoal be administered after ipecac syrup. Activated charcoal will adsorb syrup of ipecac; therefore, if both measures are to be used, it is imperative to induce vomiting with ipecac before administering activated charcoal is given.

The "Universal antidote" (2 parts activated charcoal, 1 part magnesium oxide, and 1 part tannic acid) 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".

**Acetylcysteine**

*Injection, 200 mg/ml in 10 ml ampoule*

**Indications:** -antidote to Acetaminophen overdose, to protect against hepatotoxicity.

**Cautions:** -patients with history of asthma, conditions predisposing to gastrointestinal hemorrhage such as esophageal varices, peptic ulceration, and in patients sensitive to acetylcysteine.

**Side effects:** - drowsiness, fever, nausea, or vomiting, bronchospastic allergic reaction (troubled breathing, tightness in chest, wheezing), skin rash or hives.

**Dose and Administration:**

Adult and Children: - Antidote - *IV*, 300mg per kg of body weight administered over twenty and one-fourth hours, divided as follows:

Initial loading dose - 150mg per kg of body weight in up to 200ml of 5% dextrose injection, administered over fifteen minutes.

Second infusion- 50mg per kg of body weight in 500ml of 5% dextrose injection, administered over four hours.



Third infusion - 100mg per kg of body weight in 1000ml of 5% dextrose injection, administered over the next sixteen 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 1 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.

**Side effects:** - 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.

**Contraindications** - impending coma, severe inebriation, corrosive poisoning with alkali and strong acids, depressed gag reflex, impending shock states.

**Dose and Administration, orally-**

Usual Adult and adolescent dose: - emetic-*oral*, 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.

Usual child dose - Emetic

Children up to 1 year of age - *oral*, 5 to 10ml

Children 1-12 years of age - *oral*, 15ml, 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".



## 18. 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 (immunoserum) 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.

### **Anti-Rho (D) Immune Globulin**

*Injection, 2ml in vial*

**Indications:** - to prevent a rhesus (Rh) negative mother actively forming antibodies to fetal rhesus positive (Rh+) red blood cells that may pass into the maternal circulation during child birth, abortion, or certain other sensitizing events causing disease of the new born (erythroblastosis fetalis).



**Cautions:** - as for immunoglobuline in general; Rho (D) immune globulin should be used with caution in individuals with a history of prior allergic reactions to preparation containing human immune globulins. Caution also in those with thrombocytopenia or bleeding disorders.

**Side effects:** - as for immunoglobulin in general; pain tenderness, and discomfort at site of injection, slight temperature elevations, fever, myalgia, lethargy.

**Contraindications:** - Rho (D)- positive individuals, Rho (D) - negative individuals who have been previously sensitized to Rho (D) antigens, anaphylactic reaction to preparation containing human immune globulins.

**Dose and Administration**

After full-time delivery - *IM*, 500 units (100ug). A higher dose may be required depending on the amount of transplacental bleeding.

Termination of pregnancy - Rh-negative women having spontaneous or induced up to 13 weeks of gestation or more - *IM*, 250 units (50ug) of anti (D) Immunoglobulin.

Occurrence of risk of sensitization during pregnancy from threatened abortion, amniocentesis or external version - *IM* - 250-500 units (50-100ug) of anti Rho (d) immunoglobulin.

**Storage** - at a temperature between 2°C and 8°C.

**Haemophilus Influenza type B (Hib) vaccine**

*Injection, 0.5 ml*

**Indications:** - for active immunization against Haemophilus influenzae type b infections, one of the major causes of meningitis and other severe systems illnesses in young children.

**Side effects, Cautions, and Contraindications.** As for vaccines in general, see notes above; and Erythema multiforme has been reported rarely in children.

**Note:** - Different proprietary vaccines may be conjugated to differing proteins and therefore the same vaccine should be used for an immunization course; if a different vaccine needs to be employed the entire primary course should be repeated.

**Dose and Administrations**

*By deep subcutaneous or intramuscular injection* in doses of 0.5 ml; doses are given at 2, 3 and 4 months of age.

**Note:** - The vaccine may be administered at the same time as combined diphtheria, tetanus, and pertussis vaccines of the primary immunization schedule children aged under 13 months who have already commenced or completed their primary immunization schedule should receive three doses of Hib at intervals of one month. Children aged 13 to 48 months



should be given a single dose as they are at lower risk and the vaccine is effective after a single dose in this age group.

### **Human Antirabies Immunoglobulin**

*Injection, 150 IU/ml, in 2 ml*

**Indications:** - passive immunization either post-exposure or in suspected exposure to rabies in high-risk countries in unimagined individuals (in conjunction with rabies vaccine).

**Cautions, Side effects:** see notes above, as for immunoglobulin in general.

**Contraindications:** see notes above; avoid repeat doses after vaccine treatment initiated; intravenous administration.

Note: If schedule requires rabies vaccine and rabies immunoglobulin to be administered at the same time, they should be administered using separate syringes and separate sites.

### **Dose and Administration**

Immunization against rabies: Post-exposure (or suspected infiltration), Adult and Child 20 units/kg (half *by intramuscular injection* and half *by wound infiltration*)

**Storage:** - store at 2° to 8° c,

### **Rabies Vaccine**

*Injection, 100 ml in vial*

**Indications:** - for active immunization against rabies. They are given, with rabies immunoglobulin or antisera, for post exposure treatment to patient who have been bitten by rabid animals or animals suspected of being rabid. They are also used for pre-exposure prophylaxis against rabies in persons at high risk of exposure to rabies vaccine.

**Cautions:** - as for vaccines in general; see notes above.

Note: studies have shown that when this vaccines is injected into the gluteal region, there is a poor response. Concomitant administration of chloroquine may also affect the antibody response. Because of the potential consequences of inadequately treated rabies exposure and because there is no indication that fetal abnormalities have been associated with rabies vaccination, pregnancy is not considered a contraindication to post exposure prophylaxis. If there is substantial risk of exposure to rabies, pre-exposure prophylaxis may also be indicated during pregnancy.

**Side effects:** -as for vaccines in general, see notes above; and patients may experience pain, eurhythmic, and in duration at the injection site after the use of any type of rabies vaccine; nausea, headache, fever, malaise, or myalgia may also occur.

Neuroparalytic and hypersensitivity reactions have been associated with the vaccines derived from animal nerve tissues or duck embryos.



**Dose and Administration**

Prophylactic, *by deep subcutaneous or intramuscular injection* in the deltoid region, 1 ml on days 0, 7, and 28; also booster doses every 2 – 3 years to those at continued risk.

**Storage:** store at 2° to 8°c, not be allowed to freeze, and be protected from light. Under these conditions it may be expected to retain its potency for at least 2 years.

**Rabies Vaccine, Duck Embryo**

*Injection; 100 ml in vial*

See under Rabies vaccine

**Dose Administration**

Prophylactic, *by intramuscular injection* in the deltoid muscle or anterolateral thigh in small children, 1 ml on days 0,7 and 21 or 28; also booster doses every 2 - 5 years for those at continued risk.

Post exposure, *by intramuscular injection* in the deltoid muscle or anterolateral thigh in small children, 1ml.

**Storage:** store at 2° to 8° c.

**Rabies Antiserum, Equine**

*Injection, 200 units in 5ml*

**Indications:** -rabies antiserum, equine is used to provide passive immunization to Rabis in patients who have received bites from rabid animals or animals suspected of being rabid.

**Cautions:** - as for antisera in general; caution should be taken in allergic patients. The patient must be kept under observation after the administration of full doses of antisera and adrenaline injection kept in readiness for emergency use.

**Side effects:** -as for antisera in general; nephritis, myocarditis, polyarthritis, neuritis and ureitis.

**Dose and Administration** - usual dose 40 units per kg of body weight given at the same time, but at different sites, as the first dose of a Rabis vaccine. It has been recommended that 50% of the dose should be administered by *local infiltration* at the site of the wound and the remainder given by *IM injection* unless the wound involves mucous membranes when the entire dose should be given *intramuscularly*.

**Storage:** -between 2° and 8°c.

**Rabies (Human diploid cell) vaccine**

*Injection, 2.5IU/ml*

**Indications:** -rabies human diploid cell vaccine is used for active immunization against rabies. They are used as a part of post exposure



treatment, for the prevention of rabies in patients who have been bitten by rabid animals or animals suspected of being rabid.

**Cautions:** - as for vaccine in general; the vaccine should be administered with caution in patients with a history of allergic disorders or who have exhibited previous systemic allergic reaction to human diploid cell vaccine.

**Drug interactions:** - rabies immunoglobulin, antimalarial agents, corticosteroids immuno suppressive agents.

**Side effects:** - as for vaccine in general; pain, erythema and induration at injection site, pruritis, nausea, headache, fever.

**Dose and Administration** -

For post exposure therapy - deep *SC or IM* - 6 doses of human diploid cell vaccine, each of 1ml on days 0,3,7,14, 30 and 90

For pre-exposure prophylaxis against rabies - *IM or ID*, 2 doses of human diploid cell vaccine given 4 weeks apart with a third dose after 12 months, either 1ml may be given by deep *SC or IM injection* or 0.1ml *ID*. Booster doses should be given every 1 to 3 years depending upon the risk of exposure.

### Scorpion Venom Antisera (Scorpion Antivenom)

*Injection*

**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:** - in people who have been snake-bitten if they have a history of asthma, hay fever, urticaria, or other allergic manifestation.



Intradermally sensitivity testing should be performed before administration.

**Side effects:** - 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.

### **Measles Virus Vaccine, Live Attenuated**

*Injection, 0.5 ml*

**Indications:** - active immunization against measles.

**Side effects:** as for vaccines in general, see notes above, and fever and skin rashes may occur following the administration of measles vaccines. The fever generally starts 5 to 10 days after the injection, lasts for about 1 or 2 days, and has sometimes been accompanied by convulsions. Conjunctivitis, coryza, pharyngitis, and cough may also occur. More serious effects reported rarely after the use of the vaccine include encephalitis and thrombocytopenic purpura.

**Cautions:** see notes above; pregnancy

**Contraindications:** see notes above; hypersensitivity to any antibiotic present in vaccine - consult manufacturer's literature; hypersensitivity to egg.

#### **Dose and Administration**

Immunization of children against measles, *by intramuscular or deep subcutaneous injection*, infant at 9 months of age, 0.5 ml

Prophylaxis in susceptible children after exposure to measles, *by intramuscular or deep subcutaneous injection* within 72 hours of contact, child over 9 months of age 0.5 ml

**Storage:** store at 2° to 8° c and be protected from light.

### **Meningococcal polysaccharide vaccine**

*Injection, 0.5ml*

**Indications:** -for active immunization against *Neisseria meningitidis* infections which include meningitis and septicaemia.

Note: - Meningococcal vaccines are indicated in persons at risk, in epidemic or endemic areas, of meningococcal disease caused by the specific serotypes contained in the vaccine. It is given as an adjunct to chemoprophylaxis in close contacts of persons traveling to countries where the disease is endemic. Asplenic persons or those who have terminal complement component deficiencies are at higher than normal risk of acquiring meningococcal infection.



**Cautions:** - as for vaccines in general; Immunity to some meningococcal vaccines may be insufficient to confer adequate protection against infection in infants under 2 years of age.

**Side effects, Contraindications;** as for vaccines in general.

**Dose and Administration**

A single injection of 0.5ml given *subcutaneously or intramuscularly*.

**Storage:** - store both the freeze-dried and the reconstituted vaccine between 2 and 8°C. Protect from freezing.

**Tetanus Antitoxin, Equine**

*Injection, 1500 units, 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*.

**Tetanus Immune-Human Globulin**

*Injection, 3000 units*

**Indications:** - for passive immunization against tetanus.

Note: -The use of tetanus immunoglobulins is recommended as part of the management of tetanus-prone wounds in persons unimmunized or incompletely immunized against tetanus, in persons whose immunization history is unknown, and in persons who received the last dose of tetanus vaccine more than 10 years previously.

**Cautions:** - as for immunoglobulin in general; tetanus immunoglobulins should not be injected in to the same site or in the same syringe.

**Side effects, Contraindications;** see notes under general description above.

**Dose and Administration:** The usual dose of tetanus immunoglobulin is 250 units by *intramuscular injection* but if more than 24 hours have elapsed since the wound was sustained, if there is a risk of heavy contamination, or following burns 500 units should be given irrespective of the immunization history.



Tetanus immunoglobulin is also used in the treatment of tetanus, a recommended dose being 150 units per kg body-weight given *intramuscularly* in to different sites.

Note: The pediatric dose is the same as for adults. Alternatively, in children younger than 7 years of age, tetanus immunoglobulin can be given in doses of 4 units per kilogram of body weight.

**Storage:** -store between 2 and 8°C. Do not freeze.



## 19. MISCELLANEOUS

### Oxidized Cellulose

**Indications:** -Oxidized cellulose is an absorbable haemostatics, when applied to bleeding surface, it swells to form a gelatinous mass that is gradually absorbed by the tissues, usually within 2 to 7 days. Complete absorption of large amounts of such material may take 6 weeks or more.

**Caution:** - Oxidized cellulose should not be used as a surface dressing, except for immediate control of bleeding, as it inhibits epitheliasation. It should not be used for packing or implantation in bone surgery

**Drug interactions:** - silver nitrate or other escharotic chemicals should not be applied prior to use as cauterization might inhibit absorption of oxidized cellulose. It should not be impregnated with other haemostatic or antibiotics.

**Side effects:** - foreign body reaction, headache, burning, stinging, sneezing.

**Contraindications:** - use should be avoided in infected wounds.

**Dose and Administration** - the gauze, lint or knitted material should be laid on the bleeding surface or held firmly against the tissue until haemostasis is achieved. Removal of excess oxidized cellulose should then be considered.

### 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.

### KY Jelly (Hydroxyethyl cellulose)

**Indications:** -KY Jelly is used as a thickener and stabilizer in pharmaceutical manufacturing. It is present in lubricant preparations, some of which are used as artificial tears in ocular disorder or dry eye.

### 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.

### **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.

### **Formaldehyde Solution**

*Solution, 8%*

**Indications:** - It is 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:** -Halazone is 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 1hour, 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.

**Supportive hepatic preparations that contain Essential Phospholipids and Vitamins**



**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. ABBREVIATIONS**

ACE	Angiotensin-converting enzyme
ADR	Adverse drug reaction
AIDS	Acquired immunodeficiency syndrome
AV	atrioventricular
CNS	Central Nervous System
CNS	Central nervous system
CSF	Cerebrospinal fluid
DACA	Drug Administration and Control Authority
ECG	electrocardiogram
EEG	Electro-encephalogram
G6PD	Glucose 6-phosphate dehydrogenase
GFR	Glomerular filtration rate
HIV	Human immunodeficiency virus
HRT	Hormone replacement therapy
IU	International Units
Mcg	Microgram
MDI	Metered dose inhaler
MU	Million Units
NSAID	Non steroidal anti inflammatory drug



Sec.	Section
spp.	Species
SSRI	Selective serotonin reuptake inhibitor
USP	United state pharmacopeia
WHO	World health organization

### APPENDIX III. ROUTES OF ADMINISTRATION

Oral = By Mouth  
 I.M. = Intramuscular  
 I.V. = Intravenously  
 S.C = Subcutaneously  
 I.D. = Intradermally

### APPENDIX IV. 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 V.

#### Approximate Measures

1 teaspoonful = 5ml  
 1 dessertspoonful = 10ml  
 1 tablespoonful = 15ml



#### APPENDIX VI. 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 MG
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 (1G)
5.0	2,000,000	1250 (1.25G)
10.0	4,000,000	2500 (2.5G)

#### APPENDIX VII- 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



## GLOSSARY

**Analgesics** - drugs which relieve pain.

**Antiflatulants** - drugs which expel gases from the stomach or intestine.

**Antipyretics**- drugs 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** - drugs 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).

**Health Stations** - the smallest health units in the conventional health service structure and are usually staffed with one to three health assistants.

**A Standard Health center (HC)** with its five satellite Community health Post (CHPs), is the first level health care unit which provides a package of public Health and essential curative services on ambulatory bases to a population of about 25,000. It has a capacity of ten beds provides emergency services through clock for 24 hours. Equipped with relevant diagnostic and therapeutic facilities.

**Hematinic**- an agent that improves the quality of blood by increasing the number of erythrocytes and the hemoglobin concentration

**Hemostatic**- an agent that arrests the escape of blood

**Laxative**- a drug 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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**Adverse Drug Reaction Reporting Form**

Patient's Name: (Initials only) \_\_\_\_\_ Card N<sup>o</sup>: \_\_\_\_\_ Age: \_\_\_\_\_ Sex: \_\_\_\_\_ Weight: \_\_\_\_\_  
 Habit: \_\_\_\_\_ Address: \_\_\_\_\_  
 Adverse Drug Reaction Description (Including Laboratory test results): \_\_\_\_\_ Date of onset of Reaction: \_\_\_\_/\_\_\_\_/\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Reaction necessitated: Discontinuation of drug/s/  Yes  No  
 Prolonged Hospitalization  Yes  No

Information on Suspected Drug						
Drug Name (use Brand Name . if generic name are used Please indicate manufacturer and batch no. if applicable.)	Route	Dose	Frequency	Date Drug		Therapeutic Indication
				Started	Stopped	
				D M Y	D M Y	
Other Drugs Taken Including self-medication						

Reaction subside after D/C of Suspected Drug  Y  N  NA  
 Reaction reappear after Restart of Suspected Drug  Y  N  NA

Treatment of reaction: \_\_\_\_\_  
 \_\_\_\_\_

Outcome:  Died due to adverse reaction  Died, drug may be contributory  Died Unrelated to drug  
 Not yet recovered  Recovered with out sequelae  Recovered with sequelae  Unknown  
 Sequelae: \_\_\_\_\_

Additional information: (e.g. relevant history such as allergies, chronic disease, pregnancy etc.)  
 \_\_\_\_\_

Reported by: Name \_\_\_\_\_ Profession: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
 Name of health Institution: \_\_\_\_\_ Address: \_\_\_\_\_ Tele N<sup>o</sup>: \_\_\_\_\_



Continued

**For office use only**

Received On: \_\_\_\_\_ Registration N<sup>o</sup>: \_\_\_\_\_  
Key: D|M|Y Date |Month |Year; D/C Discontinue Treatment; Y Yes; N No; NA Not available

What to report

- All suspected reactions to drugs
- Unknown or unexpected ADRs
- Serious adverse drug reactions
- Unexpected therapeutic effects
- All suspected drug interactions

From \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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