NATIONAL ESSENTIAL MEDICINES FORMULARY

NEMF 2022

ESSENTIAL MEDICINES AND TECHNOLOGY DIVISION

DEPARTMENT OF MEDICAL SERVICES

MINISTRY OF HEALTH

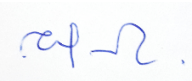
9th EDITION

FOREWORD

As documented in the National Drug Policy 2007 of the Kingdom of Bhutan under section 10.0, Rational Drug Use, sub-section 10.5, Essential Medicines and Technology Division (EMTD) is mandated to develop and review the National Essential Medicine Formulary (NEMF) based on National Essential Medicines List (NEML). This is the 9th edition of the formulary developed by EMTD.

With the format and information laid, the formulary defines its purpose to bring rationality to the use of medicines and prescription habits within the country. It has the valuable and necessary information about each medicine which will serve as a quick source of reference and information. The advancement in the modern health system is having such kind of informative resource and this formulary certainly finds to meet its purpose.

I urge all the health professionals to use this for your quick reference and may it help to enrich your knowledge. The Minster of Health is grateful and acknowledge World Health Organization for funding the revision and publication of this edition.



(Pemba Wangchuk)

Offtg. Secretary

Ministry of Health

PREFACE

The first edition of the NEMF was published in the year 1994. Since then, subsequent editions were brought out as per changes in the NEML. The current edition is based on newly added medicines in the NEML 2021. The lists in NEML are updated and reviewed in every two years by the National Medicine Committee (NMC) based on the priority health care needs of a population, disease prevalence and public health relevance, evidence of efficacy and safety and comparative cost-effectiveness.

In this edition, the medicines in NEMF, are arranged by adopting WHO Model List of Essential Medicines – 22nd List (2021). For each medicine, information on the indication, dose, side effects, cautions, contraindications, dose adjustment in hepatic and renal impairment, pregnancy category and breastfeeding, IV fluid compatibility, cautionary notes and special counselling are provided. Information under appendix including medicine interactions, protocol for malaria treatment, immunization schedule and emergency treatment of poisoning has also been updated.

Information on medicines is drawn from the medical and pharmaceutical literature, manufacturers' product literature, professional bodies, and review and evaluation of clinical literature with evidence from diverse sources. Further, the editors have adopted the World Health Organization (WHO) recommendation to replace the word "drug" with "medicine".

This Formulary is designed to provide quick access to basic and necessary important information regarding medicines listed in NEML and it may not always include all the information necessary for prescribing and dispensing. There is little or no information covered on medicines for very rare conditions. The NEMF should be interpreted in the light of professional knowledge and supplemented as necessary by specialized publications and by reference to the product literature.

Suggestions and constructive criticism regarding NEMF are welcomed from health professionals. You can write and send to:

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Special thanks are also due to the Chairperson and the members of National Medicine Committee (NMC) for the review and endorsing the formulary.

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GENERAL GUIDANCE ON PRESCRIBING

(Adapted from WHO model formulary 2008)

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

It is important to discuss treatment options carefully with the patient to ensure that the patient is content to take the medicine as prescribed. In particular, the patient should be helped to distinguish the adverse effects of prescribed medicines from the effects of the medical disorder. When the beneficial effects of the medicine are likely to be delayed, the patient should be advised of this.

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

1. Define the patient's problem

Whenever possible, making the right diagnosis is based on integrating many pieces of information: the complaint as described by the patient; a detailed history; physical examination; diagnostic tests and other investigations. This will help in rational prescribing, always bearing in mind that diseases are evolutionary processes.

2. Specify the therapeutic objective

Clinicians must clearly state their therapeutic objectives based on the pathophysiology underlying the clinical situation. Very often physicians must select more than one therapeutic goal for each patient.

3. Select the therapeutic strategies

The selected strategy should be agreed with the patient. The selected treatment can be non-pharmacological and/or pharmacological; it also needs to take into account the total cost of all therapeutic options.

a. Non-pharmacological treatment

It is very important to bear in mind that the patient does not always need a medicine for treatment of their condition. Very often, health problems can be resolved by a change in lifestyle or diet, use of physiotherapy or exercise, provision of adequate psychosocial support, and other non-pharmacological treatments; these have the same importance as prescription medicines, and instructions for such treatments must be written, explained, and monitored in the same way.

b. Pharmacological treatment

Selecting the correct group of medicines: Knowledge about the pathophysiology involved in the clinical situation of each patient and the pharmacodynamics of the chosen group of medicines, are the two fundamental principles for rational therapeutics.

Selecting the medicine from the chosen group: The selection process must consider benefit/risk/cost information. This step is based on evidence about maximal clinical benefits of the medicine for a given indication (efficacy) with the minimum production of adverse effects (safety). It must be remembered that each medicine has adverse effects and it is estimated that up to 10% of hospital admissions in industrialized countries are due to adverse effects. Not all medicine-induced injury can be prevented but much of it is caused by inappropriate selection of medicines. In cost comparisons between medicines, the cost of the total treatment and not only the unit cost of the medicine must be considered.

Verifying the suitability of the chosen pharmaceutical treatment for each patient: The prescriber must check whether the active substance chosen, its dosage form, standard dosage schedule, and standard duration of treatment are suitable for each patient. Medicine treatment should be individualized to the needs of each patient.

Prescription writing: As the prescription is the link between the prescriber, the dispenser, and the patient, it is vital to the successful management of the presenting medical condition. (*Refer to prescription writing*)

Giving information, instructions, and warnings: This step is important to ensure patient adherence and is covered in detail in a following section *(refer to adherence with medicine treatment)*.

Monitoring treatment: Evaluation of the follow-up and the outcome of treatment allows the stopping of it (if the patient's problem is solved) or its reformulation it when necessary. This step gives rise to important information about the effects of medicines, contributing to the building up of the body of knowledge of pharmacovigilance, which is needed to promote the rational use of medicines.

Variation in dose–response

Success in medicine treatment depends not only on the correct choice of medicine but on the correct dose regimen. Unfortunately, medicine treatment frequently fails because the dose is too small or produces adverse effects because it is too large. 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 medicines, 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 suggests that standard responses are the rule, but in reality, there is considerable variation in medicine response. There are many reasons for this variation, which include adherence, medicine formulation, body weight and age, composition, variation in medicine absorption, distribution, metabolism, and excretion, variation in pharmacodynamics, disease variables, and genetic and environmental variables.

Medicine formulation: Poorly formulated medicines may fail to disintegrate or to dissolve. Enteric-coated medicines have been known to pass through the gastrointestinal tract intact. In medicines with a narrow therapeutic to toxic ratio, changes in absorption can produce sudden changes in medicine concentration. For such medicines, 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 2- to 3-fold, while a patient with a large fat mass can store large excesses of highly lipid soluble medicines compared with a lean patient of the same weight.

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

Dose calculation in children: Children's doses may be calculated from adult doses by using age, body weight, or body surface area, or by a combination of these factors.

Body weight may be used to calculate doses expressed in mg/kg. Young children may require a higher dose per kilogram than adults because of their higher metabolic rates. Other problems need to be considered. For example, calculation by body weight in an overweight child may result in much higher doses being administered than necessary; in such cases, dose should be calculated from an ideal weight, related to height and age.

Body Surface Area (BSA) estimates are more accurate for calculation of pediatric doses than body weight because many physiological phenomena correlate better with body surface area. The average body surface area of a 70kg human is about $1.8m^2$. Thus, to calculate the dose for a child the following formula may be needed

Approximate dose for patient =

$$\frac{\text{Surface area of child } (m^2)}{1.8} \times \text{adult dose}$$

Where the dose for children is not readily available, prescribers should seek specialist advice before prescribing for a child.

Age	Weight		Height		Body surface area (m^2)
	Kg	Lb	Cm	Inch	
Newborn	3.5	7.7	50	20	0.23
1 months	4.2	9	55	22	0.26
3 months	5.6	12	59	23	0.32
6 months	7.7	17	67	26	0.4
1 year	10	22	76	30	0.47
3 years	15	33	94	37	0.62
5 years	18	40	108	42	0.73
7 years	23	51	120	47	0.88
12 years	39	86	148	58	1.25
Adult					
Male	68	150	173	68	1.8
Female	56	123	163	64	1.6

Physiological and pharmacokinetic variables: Medicine absorption rates may vary widely between individuals and in the same individual at different times and in different physiological states. Medicines taken after a meal are delivered to the small intestine much more slowly than in the fasting state, leading to much lower medicine concentrations. In pregnancy, gastric emptying is also delayed, while some medicines may increase or decrease gastric emptying and affect absorption of other medicines.

Medicine distribution: Medicine distribution varies widely: fat-soluble medicines are stored in adipose tissue, water-soluble medicines are distributed chiefly in the extracellular space, acidic medicines bind strongly to plasma albumin and basic medicines to muscle cells. Hence, variation in plasma albumin concentration, fat content or muscle mass may all contribute to dose variation. With very highly albumin-bound medicines like warfarin, a small change of albumin concentration can produce a big change in free medicine and a dramatic change in medicine effect.

Medicine metabolism and excretion: Medicine metabolism is affected by genetic, environmental, and disease-state factors. Medicine acetylation shows genetic polymorphism, whereby individuals fall clearly into either fast or slow acetylator types. Medicine oxidation, however, is polygenic, and although a small proportion of the population can be classified as very slow oxidizers of some medicines, for most medicines and most subjects there is a normal distribution of medicine metabolizing capacity.

Many medicines are eliminated by the kidneys without being metabolized. Renal disease or toxicity of other medicines on the kidney can therefore slow excretion of some medicines.

Pharmacodynamic variables: There is significant variation in receptor response to some medicines, especially central nervous system responses, for example pain and sedation. This can be because of genetic factors, tolerance, medicine interactions, and medicine dependence.

Disease variables: Both liver disease and kidney disease can have major effects on medicine response, chiefly through the effect on metabolism and elimination, respectively (increasing toxicity), but also through their effect on plasma albumin (increasing free medicine and thus toxicity). Heart failure can also affect metabolism of medicines with rapid hepatic clearance (for example lignocaine, propranolol). Respiratory disease and hypothyroidism can impair their oxidation.

Environmental variables: Many medicines and environmental toxins can induce the hepatic microsomal enzyme oxidizing system or cytochrome P450 oxygenases, leading to more rapid metabolism and elimination, and thus less effective treatment. Environmental pollutants, anesthetics, and other compounds such as pesticides can also induce metabolism. Diet and nutritional status also affect pharmacokinetics. For example, in infantile malnutrition and in malnourished elderly populations medicine 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 medicines, but in the presence of high circulating alcohol concentrations, medicine metabolism may be inhibited.

Adherence with the medicine treatment

It is often assumed that once the appropriate medicine 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.

Difficulties in compliance with medicine treatment occur regardless of age. Factors contributing to poor compliance with prescribed medicines include:

- Prescription not collected or not dispensed
- Purpose of medicine not clear
- Perceived lack of efficacy
- Real or perceived side effects
- Patients' perception of the risk and severity of adverse effects may differ from that of the prescriber
- Instruction for administration not clear
- Physical difficulty in taking medicines (e.g. with swallowing the medicines);
- Unattractive formulation (e.g. unpleasant taste) and
- Complicated regimen.

Recommendations

- Review the prescription to make sure it is correct.
- Spend time explaining the health problem and the reason for the medicine.
- Establish good rapport with the patient.
- Explore problems, for example, difficulty with reading the label or getting the prescription filled.
- Encourage patients to bring their medication to the clinic, so that tablet counts can be done to monitor compliance.
- Encourage patients to learn the names of their medicines and review their regimen with them. Write notes for them.
- Keep treatment regimens simple.
- Communicate with other health-care professionals to develop a team approach and to collaborate on helping and advising the patient.
- Involve the partner or another family member.
- Listen to the patient

Adverse effects and interactions

Adverse reactions to medicines: An adverse reaction to medicines may be defined as "any response to a medicine which is noxious, unintended and occurs at doses normally used for prophylaxis, diagnosis, or therapy. Adverse reactions are therefore unwanted or unintended effects of a medicine, which occur during its proper use. They differ from accidental or deliberate excessive dosage or administration.

Adverse reactions may be directly linked to the properties of the medicine in use, known as "A" type reactions. E.g. hypoglycemia caused by antidiabetic medicines. Adverse reactions may also be unrelated to the known pharmacology of the medicine, known as "B" type reactions e.g. anaphylaxis with penicillin.

Major factors predisposing to adverse effects are:

Extremes of age: The very young and very old are more susceptible to adverse reactions. For e.g. medicines commonly causing problems in elderly are hypnotics, diuretics, NSAIMs, antihypertensives, psychotropics and digoxin.

All children, and particularly neonates, differ from adults in their response to medicines. Some medicines are likely to cause problems in neonates (e.g. morphine), but are generally tolerated in children. Other medicines (e.g. valporic acid) are associated with increased risk of adverse reactions in children of all ages. Other medicines associated with

problems in children include chloramphenicol (grey baby syndrome), antiarrhythmics (worsening of arrhythmias), and acetylsalicylic acid (Reye's syndrome).

Inter current illness: Besides the condition being treated, if the patient is suffering from another disease such as liver, kidney or heart disease, special precautions may be necessary to prevent adverse reactions.

Medicine interactions (*appendix 1*): It is one of the commonest causes of adverse reactions to medicines. It may occur between medicines which compete for the same receptor or which act on the same physiological system. They may also occur indirectly when a medicine-induced disease or a change in fluid or electrolyte balance alters the response to another medicine. In addition, interactions may occur when one medicine alters the absorption, distribution or elimination of another medicine, such that the amount, which reaches the site of action, is increased or decreased.

Medicine-medicine interactions are some of the commonest causes of adverse effects. When two medicines 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 medicines concerned and may cause unexpected toxicity. As newer and more potent medicines become available, the number of serious medicine interactions is likely to increase. Remember that interactions which modify the effects of a medicine may involve non-prescription medicines, non-medicinal chemical agents, and social drugs such as alcohol, marijuana, tobacco, and traditional remedies, as well as certain types of food for example, grapefruit juice. The physiological changes in individual patients, caused by such factors as age and gender, also influence the predisposition to adverse reactions to medicines resulting from medicine interactions.

Note***: please report any adverse reactions to medicines by filling up the ADR reporting forms and sending it to the Pharmacy Department, JDWNRH or to the Drug Regulatory Authority. The forms may be downloaded from the website:*** www.dra.gov.bt

The effect of food on medicine absorption

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

Guidance on intravenous infusions

Medicines should only be added to infusion containers when constant plasma concentrations are needed or when the administration of a more concentrated solution would be harmful. In general, only one medicine should be added to any infusion container and the components should be compatible. Ready-prepared solutions should be used whenever possible. Medicines should not normally be added to blood products, mannitol, or sodium bicarbonate. Only specially formulated additives should be used with fat emulsions or amino-acid solutions.

Solutions should be thoroughly mixed by shaking and checked for absence of particulate matter before use.

Strict asepsis should be maintained throughout and in general the giving set should not be used for more than 24 hours (for medicine admixtures).

The infusion container should be labelled with the name and quantity of additives, and the date and time of addition (and the new expiry date or time). Such additional labelling should not interfere with information on the manufacturer's label that is still valid. When possible, containers should be retained for a period after use in case they are needed for investigation.

It is good practice to examine intravenous infusions from time to time while they are running. If cloudiness, crystallization, change of color, or any other sign of interaction or contamination is observed the infusion should be discontinued.

Method

When addition is required to be made extemporaneously, any product reconstitution instructions such as those relating to concentration, vehicle, mixing, and handling precautions should be strictly followed using an aseptic technique throughout. Once the product has been reconstituted, addition to the infusion fluid should be made immediately in order

to minimize microbial contamination and, with certain products, to prevent degradation or other formulation change, which may occur, e.g. reconstituted ampicillin injection degrades rapidly on standing, and also may form polymers which could cause sensitivity reactions. It is also important in certain instances that an infusion fluid of specific pH be used (e.g. furosemide injection requires dilution in infusions of pH greater than 5.5).

When medicine additions are made it is important to mix thoroughly; additions should not be made to an infusion container that has been connected to a giving set, as mixing is hampered. If the solutions are not thoroughly mixed, a concentrated layer of the additive may form owing to differences in density. Potassium chloride is particularly prone to this 'layering' effect when added without adequate mixing to infusions packed in non-rigid infusion containers; if such a mixture is administered it may have a serious effect on the heart.

A time limit between addition and completion of administration must be imposed for certain admixtures to guarantee satisfactory medicine potency and compatibility. For admixtures in which degradation occurs without the formation of toxic substances, an acceptable limit is the time taken for 10% decomposition of the medicine. When toxic substances are produced, stricter limits may be imposed. Because of the risk of microbial contamination, a maximum time limit of 24 hours.

Certain injections must be protected from light during continuous infusion to minimize oxidation, e.g. sodium nitroprusside. Dilution with a small volume of an appropriate vehicle and administration using a motorized infusion pump is advocated for preparations such as unfractionated heparin where strict control over administration is required. In this case, the appropriate dose may be dissolved in a convenient volume (e.g. 24-48 mL) of sodium chloride 0.9%.

Continuous infusion Medicines for continuous infusion must be diluted in a large volume infusion. Penicillins and cephalosporins are not usually given by continuous infusion because of stability problems and because adequate plasma and tissue concentrations are best obtained by intermittent infusion.

Intermittent infusion Medicines that are both compatible and clinically suitable may be given by intermittent infusion in a relatively small volume of infusion over a short period of time, e.g. 100mL in 30 minutes. The method is used if the product is incompatible or unstable over the period necessary for continuous infusion; the limited stability of ampicillin in large volume glucose or lactate infusions may be overcome in this way.

Intermittent infusion is also used if adequate plasma and tissue concentrations are not produced by continuous infusion as in the case of medicines such as gentamicin.

An in-line burette may be used for intermittent infusion techniques in order to achieve strict control over the time and rate of administration, especially for infants and children and in intensive care units. Intermittent infusion may also make use of the 'piggy-back' technique if no additions are made to the primary infusion. In this method the medicine is added to a small secondary container connected to a Y-type injection site on the primary infusion giving set; the secondary solution is usually infused within 30 minutes.

Addition via the drip tubing: Addition via the drip tubing is indicated for a number of cytotoxic in order to minimize extravasation. The preparation is added aseptically via the rubber septum of the injection site of a fast-running infusion. In general, medicine preparations intended for a bolus effect should be given directly into a separate vein where possible. Failing this, administration may be made via the drip tubing if the preparation is compatible with the infusion fluid when given in this manner.

The medicines compatibility with infusion fluids depends on the respective brands; therefore, refer the manufacturer's directions.

Prescription writing

A prescription is an instruction from a prescriber to a dispenser. The most important requirement is that the prescription be clear. It should be legible and indicate precisely what should be given. The prescription should be always:

- Dated
- Stated with the full name, address, age and gender of the patient

- Stated the name of the medicine in generics with strength, pharmaceutical form (e.g. tablet or capsule), route, dose and frequency, except for syrups and combination medicines. The strength of the medicine should be stated in standard units using abbreviations that are consistent with the Système International (SI). "Microgram" and "nanogram" should not, however, be abbreviated. In addition, 'units' should not be abbreviated. Avoid decimals whenever possible. If this is unavoidable, a zero should be written in front of the decimal point.
- Signed in ink by the prescriber along with their name and BHMC registration number. It is recommended that they use their seal if they have one.

Narcotics and controlled substances

The prescribing of a medicinal product that is liable to abuse requires special attention and is subjected to specific statutory requirements.

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.

CONVERSION TABLE

1 kg	= 1000 mg
1 mg	= 1000 mcg
1 mcg	= 0.000001 kg
1 litre	= 1000 ml or cc

1. ANAESTHETICS, PREOPERATIVE MEDICINES AND MEDICAL GASES

1.1 General anaesthetics and oxygen

1.1.1 Inhalational medicines

HALOTHANE

Inhalational, (250 mL) NRH/RR/DH

Therapeutic group General anaesthetic.
Indications and dose **Induction and maintenance of anaesthesia** by inhalation with or without nitrous oxide and oxygen, ADULT and CHILD 1-2%, gradually introduce halothane up to 2-4%. CHILD 1.5-2%; **Maintenance** ADULT and CHILD 0.5-2%.
Contraindications History of unexplained jaundice or pyrexia following previous exposure to halothane, family history of malignant hyperthermia, raised cerebrospinal fluid pressure and porphyria.
Cautions Previous exposure and reactions to halothane (at least 3 months between each exposure).
Side effects Hepatotoxicity (there is an increased risk with frequent exposure to halothane), arrhythmias, bradycardia, and respiratory depression.
Pregnancy category C
Breast-feeding Use with caution. Low levels anticipated in milk due to its properties but may persist for a prolonged period.

ISOFLURANE

Solution, (250 mL) NRH/RRH/DH

Therapeutic group General anaesthetic.
Indications and dose **Induction of anaesthesia (in oxygen or nitrous oxide-oxygen)** by inhalation, ADULT and CHILD 0.5-3%. **Maintenance of anaesthesia (in nitrous oxide-oxygen)** ADULT and CHILD 1-2.5% an additional 0.5-1 % may be required when given with oxygen alone. **Maintenance of anaesthesia in caesarean section (in nitrous oxide-oxygen)** ADULT: 0.5-0.75%, by inhalation.
Contraindications Susceptibility to malignant hyperthermia.
Cautions Can trigger malignant hyperthermia, raised intracranial pressure, and children under 2 years.
Side effects Breath-holding, cough, irritate mucous membrane and laryngospasm.
Pregnancy category C
Breast-feeding Can be resumed as soon as mother has recovered sufficiently from anaesthesia.

NITROUS OXIDE

Inhalation gas NRH/RRH/DH

Therapeutic group General anaesthetic and labour analgesia.
Indications and dose **Maintenance of anaesthesia in conjunction with other anaesthetic agents** ADULT and CHILD 50-66%, by inhalation with oxygen. **Analgesia** ADULT and CHILD Up to 50%, by inhalation with oxygen adjusted according to the patient's need.
Contraindications Closed collections of air or gas in any body space including intestinal obstruction, middle ear occlusion, eye surgery and in pneumothorax.
Cautions Pneumothorax, presence of intracranial air after head injury, and recent intraocular gas injection.
Side effects Depression of white cell formation, hypoxia, megaloblastic anaemia, and neurological toxic effects.
Breast-feeding Can be resumed as soon as mother has recovered sufficiently from anaesthesia.

OXYGEN

Inhalation gas NRH/RRH/DH/PHC

Therapeutic group Medical gas.

Indications and dose The concentration of inspired oxygen used has generally been determined by the condition being treated, but for acute therapy it is preferable to adjust the concentration in line with the patient's oxygen saturation. For most patients, the target oxygen saturation, measured by pulse oximetry, should be 94 to 98%. However, for patients with hypercapnia or at risk of hypercapnia, a lower target range of 88 to 92 % is recommended. **Critically ill patients including those with carbon monoxide poisoning** High concentration oxygen (reservoir mask at flow rate of 15 litres/minute). **Acute hypoxaemia due to conditions such as acute asthma, pneumonia, pulmonary embolism and postoperatively** *Oxygen saturation below 85%* Reservoir mask at flow rate of 10 to 15 litres/minute; *Oxygen saturation 85 % or higher* Nasal cannulae or simple face mask at flow rate of 2 to 10 litres/minute. **Chronic obstructive pulmonary disease or otherwise at risk of hypercapnia** *if oxygen saturation unknown* 28% at 4 litres/minute, or 24% at 2 to 4 litres/minute if there is a history of hypercapnia (via Venturi mask); *Oxygen saturation below 88%* Nasal cannulae at 2 to 6 litres/minute or simple face mask at 5 litres/minute.
Cautions Fire and explosion may be the risk, high oxygen concentrations in incubators have led to the development of retrolental fibroplasia leading to permanent blindness in premature infants.
Side effects Pulmonary toxicity usually results from prolonged or repeated exposure. Symptoms include cough, dyspnoea, and substernal discomfort, and there may also be a reduction in vital capacity; alveolar collapse (absorption atelectasis), pulmonary oedema, pneumonitis. CNS toxicity is at pressures above 2 atmospheres absolute; the risk is higher in wet conditions and with physical activity. Symptoms include nausea, mood changes, vertigo, twitching, convulsions, and loss of consciousness. Toxic effects on the eyes may also occur.

SEVOFLURANE

Solution (250 mL) NRH/RRH

Therapeutic group General anaesthetic inhalation.
Indications and dose **Induction of anaesthesia** (*with oxygen or nitrous oxide-oxygen*) ADULT and CHILD Initially 0.5-1%, then increased to up to 8%, increased gradually, according to response, to be administered using specifically calibrated vaporizer; NEONATE Initially 0.5-1%, then increased to up to 4%; **Maintenance** (*in oxygen or nitrous oxide-oxygen*) ADULT and CHILD 0.5-3%, adjusted according to response, to be administered using specifically calibrated vaporizer; NEONATE 0.5-2%, adjust according to response.
Contraindications Known or suspected sensitivity to sevoflurane or other halogenated inhalation anaesthetics. Known or suspected susceptibility to malignant hyperthermia.
Cautions Susceptibility to QT-interval prolongation. Dose-related hypotension and hemodynamic changes may occur.
Side effects Drowsiness, fever, hypotension, and hypothermia.
Renal impairment Use with caution.
Pregnancy category May depress neonatal respiration if used during delivery.
Breast-feeding Resume as soon as mother has recovered sufficiently from anaesthesia.

1.1.2 Injectable medicines

KETAMINE

Injection, 50 mg/mL (10 mL) NRH/RRH/DH

Therapeutic group General anaesthetic.
Indications and dose **Induction and maintenance of anaesthesia for short procedures** ADULT 6.5-13 mg/kg, IM OR 1-4.5 mg/kg IV administer over at least 60 seconds; CHILD 4-13 mg/kg, IM; CHILD (1 month-11 years) 1-2 mg/kg, IV given over at least 60 seconds; CHILD (12-17 years) 1-4.5 mg/kg, IV given over at least 60 seconds. **Diagnostic manoeuvres and procedures not involving intense pain** ADULT 4 mg/kg, IM; CHILD 1-2 mg/kg. **Induction and maintenance of anaesthesia for long procedures** ADULT 0.5-2 mg/kg, IV using an infusion solution containing 1 mg/mL; **Maintenance** 10-45 mcg/kg/minute; CHILD 0.5-2 mg/kg, IV followed by 10-45 mcg/kg/minute.
Contraindications Acute porphyria, eclampsia, head trauma, hypertension, pre-eclampsia, raised intracranial pressure, severe cardiac disease, and stroke.
Cautions Acute circulatory failure (shock), cardiovascular disease, dehydration, elderly, fixed cardiac output, hallucinations, head injury, hypertension, hypovolaemia, increased cerebrospinal fluid pressure, intracranial mass

lesions, nightmares, predisposition to seizures, psychotic disorders, raised intraocular pressure, respiratory tract infection, thyroid dysfunction.
Side effects Diplopia, hallucinations, hypertension, nausea, nightmares, nystagmus, rash, tachycardia, transient psychotic effects, vomiting, arrhythmias, bradycardia, hypotension, laryngospasm, respiratory depression.
Hepatic impairment Consider dose reduction.
Pregnancy category C
Breast-feeding Avoid for at least 12 hours after the last dose.
IV fluid compatibility Dextrose 5%, sodium chloride 0.9% and water for injection.
Note *Diazepam administered before, during or after anaesthetic reduces incidence of hallucinations.*

PROPOFOL

Injection, 10 mg/mL (10 mL) NRH/RRH/DH

Therapeutic group General anaesthetics (short acting)
Indications and dose **Induction of anaesthesia** ADULT (18-54 years) 1.5-2.5 mg/kg, IV administer at a rate of 20-40 mg/10 secs until response; ADULT (55 years and over) 1-1.5mg/kg administer at a rate of 20 mg/10 secs until response; CHILD (1 month-16 years) 2.5-4 mg/kg, IV**; Maintenance** ADULT 4-12 mg/kg/hour, IV and repeat the dose according to response; ELDERLY 3-6 mg/kg/hour, IV; CHILD (1 month-16 years) 9-15 mg/kg/hour, IV**. Sedation of ventilated patients in intensive care** ADULT 0.3-4 mg/kg/hour, IV; CHILD (16-17 years) 0.3-4 mg/kg/hour; CHILD (1 month-16 years) 1-2 mg/kg, IV. **Induction of sedation for surgical and diagnostic procedures** ADULT 0.5-1 mg/kg, IV administered over 1-5 minutes. **Maintenance of sedation for surgical and diagnostic procedures** ADULT 1.5-4.5 mg/kg/hour, IV.
Contraindications Porphyria and hypersensitivity, and children under 16 years receiving intensive care.
Cautions Acute circulatory failure (shock), cardiac impairment, cardiovascular disease, elderly, epilepsy, fixed cardiac output, hypotension, hypovolaemia, raised intracranial pressure, respiratory impairment.
Side effects Headache, hypotension, tachycardia, transient apnoea; phlebitis, thrombosis; anaphylaxis, arrhythmia, convulsions (onset can be delayed), delayed recovery from anaesthesia, euphoria.
Pregnancy category B
Breast-feeding Can be resumed as soon as the mother has recovered sufficiently from anaesthesia.
Hepatic impairment Use with caution.
Renal impairment Use with caution.
IV fluid compatibility Dextrose 5% and sodium chloride 0.9%.
Note *Propofol is not recommended for use in obstetrics including caesarean section; repeated dose can lead to prolonged recovery and should not be used for maintenance; it has no analgesic activity and supplementary analgesia may be required.*

THIOPENTAL SODIUM

Powder for injection, 1 g NRH/RRH/DH

Therapeutic group General anaesthetic.
Indications and dose **Induction of anaesthesia** ADULT 100-150 mg slow IV, administer over 10-15 seconds usually as a 2.5 % solution, followed by 100-150 mg after 0.5-1 minute; Debilitated patients or adults over 65 years may require a lower dose or increase administration time, alternatively initially up to 4 mg/kg (MAX. 500 mg/dose); CHILD Initially up to 4 mg/kg, slow IV and then 1 mg/kg, repeat if necessary (MAX. 7 mg/kg/dose). **Anaesthesia of short duration** ADULT 100-150 mg, slow IV, administer over 10-15 seconds usually as a 2.5% solution, followed by 100-150 mg after 0.5-1 minute; debilitated patients or adults over 65 years may require a lower dose or increased administration time, alternatively initially up to 4 mg/kg (MAX. 500 mg/dose). **Reduction of raised intracranial pressure if ventilation-controlled** ADULT 1.5-3 mg/kg, slow IV repeated if necessary. **Status epilepticus (only if other measures fail)** ADULT 75-125 mg, slow IV administered as a 2.5% solution.
Contraindications Acute porphyrias, myotonic dystrophy.

Cautions Acute circulatory failure (shock), avoid intra-arterial injection, cardiovascular disease, elderly, fixed cardiac output, hypovolaemia, reconstituted solution is highly alkaline (extravasation causes tissue necrosis and severe pain).
Overdose *Respiratory depression progresses through hypotension to circulatory collapse. Repeated dose can lead to prolonged recovery, therefore it should not be used for maintenance.*
Side effects Arrhythmias, cough, headache, hypersensitivity reactions, hypotension, laryngeal spasm, myocardial depression, rash, sneezing.
Hepatic impairment Use with caution, reduce dose.
Renal impairment Caution in severe impairment.
Pregnancy category C
Breast-feeding Can be resumed as soon as the mother has recovered sufficiently from anaesthesia.

1.2 Local anaesthetics

BUPIVACAINE

Injection, 0.5 % (20 mL) NRH/RRH/DH

Therapeutic group Local anaesthetic.
Indications and dose **Lumbar epidural block anaesthesia** ADULT and CHILD (>12 years) 75-150 mg, by regional administration. **Field block anaesthesia** ADULT and CHILD (>12 years) Up to 150 mg using a 2.5 mg/mL (0.25%) solution, by regional administration. **Thoracic epidural block anaesthesia** ADULT and CHILD (>12 years) 12.5-50 mg, by thoracic epidural. **Caudal epidural block anaesthesia** ADULT and CHILD (>12 years) 50-150 mg, by regional administration. **Major nerve block anaesthesia** ADULT 50-175 mg, by regional administration. **Intra-articular block anaesthesia** ADULT by intra-articular injection, up to 100 mg administered using a 2.5 mg/mL (0.25%) solution; when co-administered with bupivacaine by another route, MAX. 150 mg. **Thoracic epidural block anaesthesia** by continuous epidural infusion, ADULT 6.3-18.8 mg/hour administered using a 1.25mg/mL (0.125%) or 2.5 mg/mL (0.25%) solution; MAX. 400 mg per day. **Acute labour pain** by continuous epidural infusion, ADULT 6.25-12.5 mg/hour administered using a 1.25 mg/mL (0.125%) solution. MAX. 400 mg per day. **Lumbar epidural block anaesthesia** Initially by lumbar epidural, ADULT 15-37.5 mg, then 15-37.5 mg, repeat when required at intervals of at least 30 minutes using a 2.5 mg/mL (0.25%) solution, alternatively (by continuous epidural infusion) 12.5-18.8 mg/hour using a 1.25 mg/mL (0.125%) or 2.5 mg/mL (0.25%) solution; MAX. 400 mg per day. **Intrathecal anaesthesia** by intrathecal injection, ADULT 10-20 mg.
Contraindications Application to the middle ear (can cause ototoxicity), infected tissues, inflamed tissues, complete heart block, preparations containing preservatives should not be used for caudal, epidural, or spinal block, or for IV regional anaesthesia (Bier's block), damaged skin.
Cautions Cardiovascular disease, cerebral atheroma, debilitated patients (consider dose reduction), elderly (consider dose reduction), epilepsy, hypertension, hypotension, hypovolaemia, impaired cardiac conduction, impaired respiratory function, myasthenia gravis, myocardial depression may be more severe and more resistant to treatment, shock.
Side effects Arrhythmias, blurred vision, cardiac arrest, convulsions, dizziness, drowsiness, feeling of inebriation, headache, light-headedness, muscle twitching, myocardial depression, nausea, numbness of the tongue and perioral region, paraesthesia, peripheral vasodilatation, tremors, vomiting.
Hepatic impairment Use with caution in severe impairment.
Renal impairment Use with caution in severe impairment.
Pregnancy category C
Breast-feeding Amount too small to be harmful.
Note *To avoid excessive dosage in obese patients, dose may need to be calculated based on ideal body weight.*

EPHEDRINE

Injection, 3 mg/mL (10 mL) NRH/RRH/DH

Therapeutic group Local anaesthetic.
Indications and dose **Reversal of hypotension from spinal or epidural anaesthesia** ADULT 3-6 mg *IV* every 3-4 minutes (MAX. dose 9 mg), adjusted according to response, MAX. 30 mg per course; CHILD (1-11 years) 500-750

mcg/kg IV every 3-4 minutes, adjusted according to response, MAX. 30 mg per course; CHILD (12-17 years) 3-7.5 mg *IV* every 3-4 minutes (MAX. dose 9 mg), adjusted according to response, MAX. 30 mg per course.
Cautions Diabetes mellitus, elderly, hypertension, Hyperthyroidism, ischaemic heart disease, prostatic hypertrophy (risk of acute urinary retention), susceptibility to angle-closure glaucoma.
Side effects Anginal pain, anorexia. anxiety, arrhythmias, changes in blood-glucose concentration, confusion, difficulty in micturition, dizziness, dyspnoea, flushing, headache, hypersalivation, insomnia, nausea, psychoses, restlessness, sweating, tachycardia, tremor, urine retention, vasoconstriction with hypertension, vasodilation with hypotension and vomiting.
Renal impairment Use with caution.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.

LIGNOCAINE

Injection, 2% with preservative (30 mL) NRH/RRH/DH/PHC
Injection, 2% preservative free (50 mL) NRH/RRH
Injection, 2% + adrenaline 1 in 200,000 (30 mL) NRH/RRH/DH

Therapeutic group Local anaesthetic.
Indications and dose **Infiltration anaesthesia** *by local infiltration,* ADULT Dose to be given according to patient's weight and nature of procedure; MAX. 200 mg, MAX. dose 500 mg if given in solutions containing adrenaline; NEONATE Up to 3 mg/kg, dose may be repeated not more often than every 4 hours, 3 mg/kg equivalent to 0.3 mL/kg of 1% solution; CHILD (1 month-11 years) Up to 3 mg/kg, dose may be repeated not more often than every 4 hours, 3 mg/kg equivalent to 0.3 mL/kg of 1% solution; CHILD (12-17 years) MAX. per dose 200 mg, dose may be repeated not more often than every 4 hours. **Intravenous regional anaesthesia and nerve block** The following table is a guide to dosage for the more commonly used techniques in an average adult. The figures reflect the expected average dose range needed. The lowest dose required for adequate anaesthesia should be used. Individual variations in onset and duration occur. The duration may be prolonged with the adrenaline-containing solutions.

Type of block	Conc. (mg/mL)	Dose without/ with adrenaline		Onset (min)	Duration of effect (h)	
		mL	mg		Without adrenaline	With adrenaline
SURGICAL ANAESTHESIA						
Lumbar epidural administration[1]	20	15-25	300-500	15-20	1.5-2	*2-3*
Thoracic epidural administration[1]	20	10-15	200-300	10-20	1.5-2	*2-3*
Caudal epidural block[1]	10 20	20-30 15-25	200-300 300-500	15-30 15-30	1-1.5 1.5-2	*1-2* *2-3*
Intra-articular block	10	≤40	≤400	5-10	30-60 min after washout	
FIELD BLOCK (e.g., minor nerve blocks and infiltration)						
Infiltration	10	≤40	≤400	1-2	2-3	3-4
Digital block	10	1-5	10-15	2-5	1.5-2	NR
Intercostals (per nerve) [Maximal number of nerves blocked at same time should be ≤ 8]	10	2-5	20-50	3-5	1-2	3-4
Retrobulbar	20	4	80	1.5-2	1.5-2	*2-4*
Peribulbar	10	10-15	100-150	1.5-2	1.5-2	*2-4*
Pudendal (each side)	10	10	100	5-10	1.5-2	*2-3*

MAJOR NERVE BLOCK						
Paracervical (each side)	10	10	100	3-5	1-1.5	*2-2.5*
Brachial plexus:						
Axillary	10	40-50	400-500	15-30	1.5-2	*3-4*
Supraclavicular, interscalene and subclavian perivascular	10	30-40	300-400	15-30	1.5-2	*3-4*
Sciatic	20	15-20	300-400	15-30	2-3	*3-4*
3 in 1 (Femoral, obturator and lateral cutaneous)	10	30-40	300-400	15-30	1.5-2	*2-4*

1 Dose includes a test dose.

Dosage Recommendations in Children (1 - 12 years)

Type of block	Conc (mg/mL)	Volume (mL/kg)		Dose (mg/kg)		Onset (min)	Duration (h)	
		without adrenaline	with adrenaline	Without adrenaline	with adrenaline		Without adrenaline	With adrenaline
Caudal epidural	10	0.5	up to 0.7	5	up to 7	10-15	1-1.5	1.5-2

Consider both age and weight for calculation of dose.

Contraindications All grades of atrioventricular block, application to the middle ear (can cause ototoxicity), infected tissues, inflamed tissues, preparations containing preservatives should not be used for caudal, epidural, or spinal block, or for IV regional anaesthesia (Bier's block), severe myocardial depression, damaged skin, sino-atrial disorders, Children under 3 years of age (with adrenaline).
Cautions Acute porphyria (consider infusion with glucose for its anti-porphyrinogenic effects), children (consider dose reduction), congestive cardiac failure (consider lower dose), debilitated patients (consider dose reduction), elderly (consider dose reduction), epilepsy, hypovolaemia, impaired cardiac conduction, impaired respiratory function, myasthenia gravis, post cardiac surgery (consider lower dose) and shock.
Side effects Bradycardia (may lead to cardiac arrest), confusion, convulsions, Hypotension (may lead to cardiac arrest), respiratory depression and anaphylaxis.
Pregnancy category B

LIGNOCAINE

Gel, 2% (30 g) NRH/RRH/DH

Therapeutic group Local anaesthetic.
Indications and dose **Anaesthetic lubricant for oral or nasal endotracheal intubation** ADULT and CHILD (> 10 years) Apply 2% moderate amount to external surface of endotracheal tube shortly before use, not to exceed 600 mg/12 hrs; CHILD (<10 years) Not to exceed 4.5 mg/kg per 12 hr. **Urethral surface anaesthesia** ADULT (Female) Instil 2-5 mL gel (60-100 mg) into urethra, allow several minutes following instillation prior to performing urological procedure; ADULT (Male) Slowly instil 15 mL (300 mg lidocaine) into urethra or until patient experiences tension. Additional dose of not more than 15 mL (300 mg) can be instilled for adequate anaesthesia. A total dose of 30 mL (600 mg) is usually required to fill and dilate the male urethra; Prior to catheterization, smaller volumes of 5-10 mL (100-200 mg) are adequate for lubrication.
Contraindications Known or suspected hypersensitivity.
Cautions Absorption from inflamed or highly vascular surfaces may cause systemic effects.

LIGNOCAINE

Injection, 2% + adrenaline 1:80000 (1.8 mL) NRH/RRH/DH

Therapeutic group Local anaesthetic.
Indications and dose **Dental procedures** *by local infiltration,* ADULT 1.8 mL is generally sufficient; 3.6 mL in case of large interventions but do not exceed 5.4 mL. ADOLESCENTS (14-17 years) and ELDERLY usual dose 1.8 mL; Do not exceed 3.6 mL; CHILD (6-14 years) Usual dose 1.35 mL, do not exceed 2.7 mL. CHILD (3-6 years) 0.9-1.8 mL.
Contraindications Avoid if there is known or suspected hypersensitivity, spinal or epidural anaesthesia in patients on anticoagulant therapy and abnormal bleeding tendency, arterial hypertension, coronary disease and valvular cardiac disease**,** children under 3 years of age.
Cautions Lignocaine with adrenaline when used together with halothane.
Side effects Oedema, erythema at injection site, petechiae, skin irritation.

LIGNOCAINE + PRILOCAINE

Gel, 2.5% + 2.5% (5 g) NRH/RRH

Therapeutic group Local anaesthetic.
Indications and dose **Cannulation or Venipuncture** Apply 2.5 g over 20-25 cm of skin surface area, for at least 1 hour prior to procedure. **Split thickness skin graft harvesting** Apply 2 g per 10 cm^2 of skin and allow it to remain in contact with the skin for at least 2 hours. CHILD (Age 0-3 months or <5 kg) (intact skin) Apply a maximum of 1 g over no more than 10 cm^2 of skin; leave on for no longer than 1 hour. CHILD (Age 3 months to 12 months and >5 kg) Apply no more than a maximum 2 g total over no more than 20 cm^2 of skin; leave on for no longer than 4 hours; CHILD (Age 1-6 years and >10 kg) Apply no more than a maximum of 10 g total over no more than 100 cm^2 of skin; leave on for no longer than 4 hours; CHILD (Age 7-12 years and >20 kg) Apply no more than a maximum 20 g total over no more than 200 cm^2 of skin; leave on for no longer than 4 hours.
Side effects Erythema, itching, rash, burning, and urticaria.
Cautions Avoid use on open wounds or near the eyes.

LIGNOCAINE

Solution, 4% (30 mL) NRH/RRH/DH
Spray, 10% (80 mL) NRH

Therapeutic group Local anaesthetic.
Indications and dose **Solution** *by local infiltration,* **Bronchoscopy** 1-7.5 mL with suitable swab; **Biopsy in mouth** 3-4 mL with suitable spray or swab. ***Spray***, **Dental practice** 1-5 doses; **Procedure in pharynx, larynx and trachea**: up to 20 doses.
Cautions Absorption from inflamed or highly vascular surfaces may cause systemic effects.
Side effects Oedema, erythema at injection site, petechiae, skin irritation.

1.3 Preoperative medication and sedation for short-term procedures

ATROPINE SULPHATE

Injection, 0.6 mg/mL (1 mL) NRH/RRH/DH/PHC

Therapeutic group Preoperative and intraoperative medication.
Indications and dose **Premedication** by IV injection, ADULT 300-600 mcg, administer immediately before induction of anaesthesia; CHILD (12-17 years) 300-600 micrograms, administer immediately before induction of anaesthesia; By SC or IM injection, 300-600 micrograms, administer 30-60 minutes before induction of anaesthesia; CHILD (12-17 years) 300-600 micrograms, to be administer 30-60 minutes before induction of anaesthesia. **Intraoperative bradycardia** by IV injection, ADULT 300-600 micrograms, larger doses may be used in emergencies; CHILD (12-17 years) 300-600 micrograms, larger doses may be used in emergencies.
Contraindications Angle-closure glaucoma, myasthenia gravis, paralytic ileus, pyloric stenosis, prostatic enlargement.
Cautions Down syndrome, children, elderly, ulcerative colitis, diarrhoea, hyperthyroidism, heart failure, hypertension.

Side effects Dry mouth, flushing and dryness of skin, rash, difficulty in micturition, less commonly arrhythmias, tachycardia and palpitations, confusion (particularly in the elderly), heat prostration and convulsions, especially in febrile children.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.

GLYCOPYRROLATE

Injection, 200 mcg/mL (2 mL) NRH/RRH

Therapeutic group Preoperative medication and sedation for short-term procedure.
Indications and dose **Reduction of nasopharyngeal secretions** Preoperative by IM injection, ADULT 4 mcg/kg 30-60 minutes before procedure; CHILD (Age < 2 years) 4-9 mcg/kg 30-60 minutes before procedure; CHILD (>2 years) 4 mcg/kg 30-60 minutes before procedure; Intraoperative by IV injection, ADULT 100 mcg repeat at 2 to 3-minute intervals as needed; CHILD 4 mcg/kg not to exceed 100 mcg; Repeat at 2-to-3-minute intervals as needed. **Reversal of neuromuscular blockade** by IV injection, ADULT 200 mcg for each 1 mg of neostigmine or 5 mg of pyridostigmine; CHILD 5-15 mcg/kg with 25-70 mcg/kg of neostigmine or 0.1-0.3 mg/kg of pyridostigmine.
Contraindications Gastrointestinal obstruction, glaucoma, intestinal atony in elderly or debilitated patients, myasthenia gravis, obstructive uropathy, paralytic ileus, severe ulcerative colitis.
Cautions Hypertension, coronary heart disease, congestive heart failure, cardiac arrhythmia, elderly, hyperthyroidism, hepatic impairment.
Side effects Dry mouth, dry skin, anhidrosis, flushing, blurred vision, cycloplegia, photophobia, palpitation, xerophthalmia, constipation, urinary retention, angioedema, paradoxical bronchospasm, dysphonia.
Renal Impairment No dose adjustment required.
Hepatic impairment No dose adjustment required.
Pregnancy category B
Breast-feeding Excretion in breast milk unknown, use caution.
IV fluid compatibility Dextrose 5% in 0.45% sodium chloride, dextrose 5 %, dextrose 10%, compound sodium lactate and sodium chloride 0.9 % solutions.

MIDAZOLAM

Injection, 1 mg/mL (10 mL) NRH/RRH/DH

Therapeutic group Preoperative medication and sedation for short-term procedure.
Indications and dose **Conscious sedation for procedures** by slow IV injection, ADULT Initially 2-2.5 mg, administer 5-10 minutes before procedure at a rate of approximately 2 mg/minute, increase in the steps of 1 mg if required, usual total dose is 3.5-5 mg; MAX. 7.5 mg per course; ELDERLY Initially 0.5-1 mg, administer 5-10 minutes before procedure at a rate of approximately 2 mg/minute, increase in steps of 0.5-1 mg if required; MAX. 3.5 mg per course; CHILD (1 month-5 years) Initially 25-50 mcg/kg, administer over 2-3 minutes, 5-10 minutes before procedure, dose can be increased if necessary in small steps to MAX. 6 mg per course; CHILD (6-11 years) Initially 25-50 mcg/kg, administer over 2-3 minutes, 5-10 minutes before procedure, dose can be increased if necessary in small steps to MAX. 10 mg per course; CHILD (12-17 years) Initially 25-50 mcg/kg, administer over 2-3 minutes, 5-10 minutes before procedure, dose can be increased if necessary in small steps to MAX. 7.5 mg per course. **Sedative in combined anaesthesia** Initially by IV injection, ADULT 30-100 mcg/kg, repeat if necessary; Alternatively (by continuous IV infusion) 30-100 mcg/kg/hour; ELDERLY Lower doses needed. **Sedation of patient receiving intensive care** Initially by slow IV injection, ADULT Initially 30-300 mcg/kg in steps of 1-2.5 mg every 2 minutes, then 30-200 mcg/kg/hour, reduce dose or omit initial dose in hypovolaemia, vasoconstriction, or hypothermia; Lower doses may be adequate if opioid analgesic also used; CHILD (6 months-11 years) Initially 50-200 mcg/kg, administer over at least 3 minutes, followed by (by continuous IV infusion) 30-120 mcg/kg/hour, adjust according to response, initial dose may not be required and lower maintenance doses needed if opioid analgesics also used; Reduce dose or omit initial dose in hypovolaemia, vasoconstriction or hypothermia; CHILD (12-17 years) Initially 30-300 mcg/kg in steps of 1-2.5 mg every 2 minutes, followed by 30-200 mcg/kg/hour, adjust according to response, initial dose may not be required and lower maintenance doses needed if opioid analgesics also used; reduce dose or omit initial dose in hypovolaemia, vasoconstriction, or

hypothermia; *By continuous IV infusion* NEONATE (up to 32 weeks corrected gestational age) 60 mcg/kg/hour for 24 hours, then reduce to 30 mcg/kg/hour, adjust according to response for maximum treatment duration of 4 days; NEONATE (32 weeks corrected gestational age and above) 60 mcg/kg/hour, adjust according to response for maximum treatment duration of 4 days; CHILD (1-5 months) 60 mcg/kg/hour, adjust according to response.
Contraindications CNS depression, compromised airway, severe respiratory depression.
Cautions Cardiac disease, children (particularly if cardiovascular impairment), concentration in children under 15 kg not to exceed 1 mg/mL, debilitated patients, hypothermia, hypovolaemia, neonates, risk of airways obstruction and hypoventilation in children under 6 months, vasoconstriction.
Side effects Amnesia, anaphylaxis, ataxia, blood disorders, bronchospasm, cardiac arrest, confusion, convulsions (more common in neonates), depression of consciousness, dizziness, drowsiness, dry mouth, dysarthria, euphoria, fatigue, gastro-intestinal disturbances, hallucinations, headache, heart rate changes, hiccups, hypotension, incontinence, increased appetite, injection-site reactions. involuntary movements, jaundice, laryngospasm, muscle weakness, paradoxical aggression, paradoxical excitement, respiratory arrest (particularly with high doses or on rapid injection), respiratory depression (may be severe with sedative and perioperative use), respiratory depression (particularly with high doses or on rapid injection), restlessness (with sedative and perioperative use); salivation changes, severe disinhibition (with sedative and perioperative use), skin reactions, thrombosis, urinary retention, vertigo, visual disturbances.
Hepatic impairment Use with caution particularly.
Renal impairment Use with caution in chronic renal failure.
Pregnancy category D
Breast-feeding Excreted in milk, avoid breast-feeding for 24 hours after administration.
Counselling The dangers of taking alcohol should be emphasised.

MORPHINE

Injection, 15 mg/mL (1 mL) NRH/RRH/DH

Therapeutic group Preoperative medication and sedation for short-term procedure.
Indications and dose **Preoperative medication** ADULT: 10 mg SubQ or IM inj. 60 to 90 minutes before surgery; CHILD, *by subcutaneous injection*, (neonates): 100 mcg/kg every 6 hours; CHILD (1 to 6 months): 100 to 200 mcg/kg every 6 hours; CHILD (6 months to 2 years): 100 to 200 mcg/kg every 4 hours; CHILD (2 to 12 years): 200 mcg/kg every 4 hours; CHILD (12 to 18 years): 2.5 to 10 mg every 4 hours; CHILD, *by intravenous injection over at least 5 minutes*, (neonates): 50 mcg/kg every 6 hours; CHILD (1 to 6 months): 100 mcg/kg every 6 hours; CHILD (6 months to 12 years): 100 mcg/kg every 4 hours; CHILD (12 to 18 years): 5 mg every 4 hours.
For details, refer to page no. 21

1.4 Medical gases

NITROUS OXIDE

Inhalation gas NRH/RRH/DH

Therapeutic group General anaesthetic. *For details, refer to page no. 8.*

OXYGEN

Inhalation gas NRH/RH/DH/PHC

Therapeutic group Medical gas. *For details, refer to page no. 8.*

2. MEDICINES FOR PAIN AND PALLIATIVE CARE

2.1 Non-opioids & Nonsteroidal Anti-inflammatory Medicines (NSAIMs)

ASPIRIN

Tablet, (soluble) 300 mg NRH/RRH/DH

Therapeutic group Non-steroidal Anti-inflammatory Medicines (NSAIMs).
Indications and dose **Osteoarthritis and rheumatoid arthritis** 300 mg PO three to four times daily, MAX. 4 g daily; *Not recommended in children below 16 years.*
Contraindications Hypersensitivity to aspirin or other NSAIMs, use other than as an antiplatelet in children and adolescents under 16 years (Reye's syndrome), active peptic ulceration, haemophilia, other bleeding disorders.
Cautions Asthma, uncontrolled hypertension, pregnancy, breastfeeding.
Side effects Bronchospasm, gastrointestinal haemorrhage, vomiting, upset stomach, heartburn, drowsiness, or headache.
Counselling To be taken after or with meals.

DICLOFENAC SODIUM

Injection, 25 mg/mL (3 mL) NRH/RRH/DH/PHC

Therapeutic group Non-steroidal Anti-inflammatory Medicines (NSAIMs).
Indications and dose **Acute exacerbations of pain and postoperative pain** by deep IM injection, ADULT 75 mg once daily for maximum 2 days, administer into the gluteal muscle. **Acute exacerbations of pain and postoperative pain (severe cases)** by deep IM injection, ADULT 75 mg twice daily for maximum 2 days, administered into the gluteal muscle. **Ureteric colic** by deep IM injection, ADULT 75 mg, then 75 mg after 30 minutes if required. **Acute postoperative pain (in supervised settings)** by IV injection, ADULT 75 mg every 4-6 hours if required for maximum 2 days; MAX. 150 mg per day. **Prevention of postoperative pain** by IV injection, ADULT 25-50 mg, give after surgery; further doses given after 4-6 hours if necessary; MAX.150 mg in 24 hours for 2 days.
Contraindications Patients with a history of hypersensitivity to aspirin or any other NSAID-which includes those in whom attacks of asthma, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other NSAID, history of asthma, confirmed or suspected cerebrovascular bleeding and haemorrhagic diathesis, active GI bleeding and ulceration, cerebrovascular disease, ischaemic heart disease, mild to severe heart failure, peripheral arterial disease.
Cautions Allergic disorders, cardiac impairment (NSAIDs may impair renal function), coagulation defects, connective-tissue disorders, Crohn's disease (may be exacerbated), elderly (risk of serious side-effects and fatalities), history of cardiac failure, hypertension, left ventricular dysfunction, oedema, risk factors for cardiovascular events, ulcerative colitis (may be exacerbated).
Side effects Alveolitis, aseptic meningitis (patients with connective-tissue disorders such as systemic lupus erythematosus may be especially susceptible), hepatic damage, interstitial fibrosis associated with NSAIDs can lead to renal failure, pancreatitis, papillary necrosis associated with NSAIDs can lead to renal failure, pulmonary eosinophilia, Stevens-Johnson syndrome, toxic epidermal necrolysis, visual disturbances, injection site reactions.
Hepatic impairment Use with caution; Avoid in severe liver disease.
Renal impairment Avoid if possible or use with caution; the lowest effective dose should be used for the shortest possible duration. Avoid IV use if serum creatinine is greater than 160 micromol/litre. Not recommended in moderate or severe renal impairment.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.

IBUPROFEN

Tablet, 400 mg NRH/RRH/DH/PHC

Therapeutic group Non-steroidal Anti-inflammatory Medicines (NSAIMs).
Indications and dose **Pain and inflammation in rheumatic disease and other musculoskeletal disorders, Mild to moderate pain including dysmenorrhoea, Postoperative analgesia**, **and Migraine and Dental pain** ADULT Initially 400 mg PO, 3 times a day; increase if necessary up to 600 mg 4 times a day; **Maintenance** 400 mg 3 times a day. **Mild to moderate pain, Pain and inflammation of soft tissue injuries and Pyrexia with discomfort** CHILD (3-5 months) 50 mg PO, 3 times a day; CHILD (6-11 months) 50 mg PO, 3-4 times a day; CHILD (1-3 years) 100 mg PO, 3 times a day; CHILD (4-6 years) 150 mg PO, 3 times a day; CHILD (7-9 years) 200 mg PO, 3 times a day; CHILD (10-11 years) 300 mg PO, 3 times a day; CHILD (12-17 years) Initially 300-400 mg PO, 3-4 times a day; increased if necessary up to 600 mg 4 times a day; maintenance 200–400 mg 3 times a day.

For CHILD, maximum daily dose to be given in 3-4 divided doses; for 3 months-6 years, maximum 30 mg/kg per day and for 7-9 years, maximum 2.4 g per day.
Contraindications Active GI bleeding and ulceration, history of GI bleeding and perforation related to previous NSAID therapy, history of recurrent GI haemorrhage and ulceration (two or more distinct episodes), established ischaemic heart disease, peripheral arterial disease, cerebrovascular disease, congestive heart failure and uncontrolled hypertension.
Cautions Cardiac impairment; cerebrovascular disease, coagulation defects, connective-tissue disorders, Crohn's disease, heart failure, ischaemic heart disease, peripheral arterial disease, risk factors for cardiovascular events, risk factors for cardiovascular events, ulcerative colitis, uncontrolled hypertension.
Side effects Dizziness, epigastric pain, heartburn, constipation, nausea, rash, tinnitus, oedema, headache, vomiting.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.
Counselling Take after/with food or water to avoid GI effects.

INDOMETHACIN

Capsule, 25 mg NRH/RRH/DH

Therapeutic group Non-steroidal Anti-inflammatory Medicines (NSAIMs).
Indications and dose **Ankylosing spondylitis; Osteoarthritis and Rheumatoid arthritis** ADULT and CHILD (> 15 years) Initial, 25 mg PO, 2 to 3 times daily; increase daily dosage by 25 to 50 mg at weekly intervals if necessary, until satisfactory pain control to total daily dosage of 150 to 200 mg, MAX. 100 mg/dose or 200 mg/day; For patients with persistent night pain or morning stiffness, 100 mg of the total daily dose may be administered at bedtime. **Acute gout** ADULT and CHILD (> 15 years) Initial, 50 mg PO 3 times daily until pain is tolerable; rapidly taper based on pain response to discontinuation. **Acute shoulder pain** ADULT and CHILD (> 15 years) 75 to 150 mg PO, 3 to 4 divided doses for 7 to 14 days.
Contraindications Active GI bleeding and ulceration, history of GI bleeding and perforation related to previous NSAID therapy, history of recurrent GI haemorrhage and ulceration (two or more distinct episodes), established ischaemic heart disease, peripheral arterial disease, cerebrovascular disease, congestive heart failure and uncontrolled hypertension.
Cautions Cardiac impairment; cerebrovascular disease, coagulation defects, connective-tissue disorders, Crohn's disease, heart failure, ischaemic heart disease, peripheral arterial disease, risk factors for cardiovascular events, risk factors for cardiovascular events, ulcerative colitis, uncontrolled hypertension.
Side effects Dizziness, epigastric pain, heartburn, constipation, nausea, rash, tinnitus, oedema, headache, vomiting.
Hepatic impairment Use with caution, avoid in severe liver disease.
Renal impairment Avoid in severe impairment. The lowest effective dose should be used for the shortest possible duration.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.
Counselling Take with/after food.

MEFENAMIC ACID

Tablet or Capsule, 250 mg NRH/RRH/DH

Therapeutic group Nonsteroidal anti-inflammatory medicines (NSAIMs).
Indications and dose **Acute pain in dysmenorrhoea and menorrhagia** ADULT 500 mg PO, 3 times a day; CHILD (12-17 years) 500 mg PO, 3 times a day.
Contraindications Active GI bleeding and ulceration, history of GI bleeding and perforation related to previous NSAIMs therapy, history of recurrent GI haemorrhage and ulceration (two or more distinct episodes), inflammatory bowel disease, severe heart failure.
Cautions Acute porphyrias, allergic disorders, cardiac impairment, cerebrovascular disease, coagulation defects, connective tissue disorders, Crohn's disease, elderly, epilepsy, heart failure, ischaemic heart disease, peripheral arterial disease, ulcerative colitis, uncontrolled hypertension.

Side effects Diarrhoea, rashes, stomatitis, fatigue, and paraesthesia.
Hepatic impairment Use with caution, there is an increased risk of GI bleeding and fluid retention. Avoid in severe liver disease.
Renal impairment Avoid in severe impairment. Use the lowest effective dose for the shortest possible duration.
Pregnancy category C
Breast-feeding Amount too small to be harmful.
Counselling Take with or after food.

PARACETAMOL

Injection, 150 mg/mL (2 mL)	NRH/RRH/DH
Suppository, 250 mg	NRH/RRH/DH
Syrup, 125 mg/5 mL (60 mL)	NRH/RRH/DH/PHC
Tablet, 500 mg	NRH/RRH/DH/PHC

Therapeutic group Non-steroidal Anti-inflammatory Medicines (NSAIMs).
Indications and dose **Mild to moderate pain and pyrexia** ADULT 0.5-1 g, PO every 4-6 hours; MAX. 4 g per day; ADULT (body weight 10-50 kg) 15 mg/kg by IV injection, every 4-6 hours, dose to be administered over 15 minutes; MAX. 60 mg/kg per day; ADULT (body weight 50 kg and above) 1 g by IV injection, every 4-6 hours, dose to be administered over 15 minutes; MAX. 4 g per day; ADULT: 0.5-1 g By rectum, every 4-6 hours; MAX. 4 g per day. **Mild to moderate pain in patients with risk factors for hepatotoxicity** ADULT (body weight 50 kg and above) 1 g by IV infusion, every 4-6 hours, dose to be administered over 15 minutes; MAX. 3 g per day. **Pain and Pyrexia with discomfort** NEONATE (28 - 32 weeks) corrected gestational age 20 mg/kg PO for 1 dose, then 10-15 mg/kg every 8-12 hours as required, maximum daily dose to be given in divided doses; MAX. 30 mg/kg per day; NEONATE (32 weeks corrected gestational age and above) 20 mg/kg for 1 dose, then 10-15 mg/kg every 6-8 hours as required, maximum daily dose to be given in divided doses; MAX. 60 mg/kg per day; CHILD (3-5 months) 60 mg every 4-6 hours; max. 4 doses per day; CHILD (6 months-1 year) 120 mg every 4-6 hours; MAX. 4 doses per day; CHILD (2-3 years) 180 mg every 4-6 hours; MAX. 4 doses per day; CHILD (4-5 years) 240 mg every 4-6 hours, MAX. 4 doses per day; CHILD (6-7 years) 240-250mg every 4-6 hours, MAX. 4 doses per day; CHILD (8-9 years) 360-375 mg every 4-6 hours, MAX. 4 doses per day; CHILD (10-11 years): 480-500 mg every 4-6 hours, MAX. 4 doses per day; CHILD (12-15 years) 480-750 mg every 4-6 hours, MAX. 4 doses per day; CHILD (16-17 years) 0.5-1 g every 4-6 hours, MAX. 4 doses per day; By rectum, CHILD (3-11 months) 60-125 mg every 4-6 hours as required, MAX. 4 doses per day; CHILD (1-4 years) 125-250 mg every 4-6 hours as required; MAX. 4 doses per day; CHILD (Child 5-11 years) 250-500mg every 4-6 hours as required, MAX. 4 doses per day; CHILD (12-17 years) 500mg every 4-6 hours. **Post-immunisation pyrexia in infants** CHILD (2 months) 60 mg for 1 dose PO, then 60 mg after 4-6 hours if required.
Contraindications Severe hepatic failure.
Cautions Alcohol dependence; before administering, check when paracetamol last administered and cumulative paracetamol dose over the previous 24 hours. Chronic alcoholism, chronic dehydration, chronic malnutrition hepatocellular insufficiency.
Side effects Acute generalised exanthematous pustulosis, malaise, skin reactions, Stevens-Johnson syndrome, toxic epidermal necrolysis; *With IV use*: flushing, tachycardia.
Overdose Single ingestion of more than 150mg/kg in less than one hour or children who have ingested more than 10-15 g in single ingestion in less than one hour may result in severe liver damage, hypoglycemia and acute renal tubular necrosis.
Hepatic impairment Dose-related toxicity, avoid large doses.
Renal impairment Increase infusion dose interval to every 6 hours in severe renal impairment (CrCl ≤ 30 mL/min).
Pregnancy category B
Breast-feeding Amount too small to be harmful.

PIROXICAM

Tablet, 20 mg	NRH/RRH

Therapeutic group Non-opioid analgesic, Nonsteroidal Inflammatory Medicine (NSAIMs).

Indications and doses **Rheumatoid arthritis and osteoarthritis** ADULT 20 mg once a day. **Ankylosing spondylitis** ADULT 10-20 mg/day in 1 to 2 divided doses. **Juvenile idiopathic arthritis** CHILD 0.2 - 0.4 mg/kg per day, MAX. dose 20 mg once daily.
Contraindications Asthma, urticaria, or allergic type reaction to aspirin or NSAIMs. Active or history of gastro-intestinal bleeding. Coronary artery bypass surgery (CABG). Third trimester pregnancy.
Cautions History of gastro-intestinal disorders, ischemic heart disease, risk of cardiovascular events, coagulation defects, connective tissue disorder, uncontrolled hypertension, cerebrovascular disease, hyperkalaemia.
Side effects Skin rash, oedema, blurring of vision, dizziness, drowsiness, constipation, vomiting, nausea, headache, abdominal pain, bronchospasm, anorexia, eosinophilia, fatigue, anaemia, hyponatremia, leukopenia, thrombocytopenia, abnormal renal function, tinnitus, hyperkalaemia, hyponatremia, increased liver function test, heart failure, myocardial infarction.
Hepatic impairment Use with caution, with low dose as possible. In advanced liver disease or hepatotoxicity during treatment, discontinue the use of piroxicam.
Renal impairment If eGFR 30 - 60 mL/min, temporarily discontinue to avoid acute kidney injury. If eGFR <30 mL/min, avoid.
Pregnancy category C
Breast-feeding Use with caution, amount too small to be harmful. However, if the infant has platelet dysfunction, thrombocytopenia, or a ductal-dependent cardiac lesion maternal use of piroxicam should be avoided.
Counselling Take with/after food. Advise patients to immediately report if they develop signs of congestive heart failure, myocardial infarction, cardiovascular events or stroke, GI irritation. Avoid use in third trimester pregnancy, renal and hepatic failure. Instruct patients to report symptoms of skin rashes.

2.2 Opioid analgesics

CODEINE PHOSPHATE

Tablet, 15 mg NRH/RRH/DH

Therapeutic group Opioid analgesic.
Indications **Acute diarrhoea** ADULT 30 mg PO 3-4 times a day, usual dose 15-60 mg 3-4 times a day; CHILD (12-17 years) 30 mg 3-4 times a day, usual dose 15-60 mg 3-4 times a day. **Mild to moderate pain** ADULT 30-60 mg every 4 hours if required; MAX. 240 mg per day. **Short-term treatment of acute moderate pain** CHILD (12-17 years) 30-60 mg every 6 hours if required for maximum 3 days; MAX. 240 mg per day. **Dry or painful cough** ADULT: 15-30 mg 3-4 times a day.
Contraindications Acute ulcerative colitis, antibiotic associated colitis, children under 12, children under 18 years who undergo the removal of tonsils or adenoids, conditions where abdominal distension develops, conditions where inhibition of peristalsis, known ultra-rapid codeine metabolizers, breast-feeding.
Cautions Cardiac arrhythmias, gallstones.
Side effects Abdominal pain, anorexia, antidiuretic effect, hypothermia, malaise, muscle fasciculation, pancreatitis, seizures.
Renal impairment Avoid use or reduce dose.
Pregnancy category C
Breast-feeding Avoid.
Note Tolerance and dependence may occur with prolonged use; In terminal care, this should not inhibit treatment, but simultaneous administration of laxative medicines may be required; chronic diarrhoea should be investigated before any attempt to suppress it with codeine phosphate. Should not drive or operate machinery.

FENTANYL CITRATE

Injection, 50 mcg/mL (2 mL) NRH/RRH/DH
Patch, 50 mcg/hr (72 hours) NRH/RRH

Therapeutic group Opioid analgesic.

Indications and dose **Chronic intractable pain** by transdermal application ADULT Initially 50 -100 mcg/hour every 72 hours. **Spontaneous respiration for Analgesia and enhancement of anaesthesia during operation** by slow IV injection, ADULT Initially 50-100 mcg (MAX. dose 200 mcg), then 25-50 mcg as required; By IV infusion, ADULT 3-4.8 mcg/kg/hour, adjust according to response; CHILD (1 month-11 years) Initially 1-3 mcg/kg, then 1 mcg/kg as required, administer over at least 30 seconds; CHILD (12-17 years) Initially 50-100 mcg (MAX. dose 200 mcg), then 25-50 mcg as required, administered over at least 30 seconds. **Assisted ventilation for Analgesia and enhancement of anaesthesia during operation** by slow IV injection, ADULT Initially 300-3500 mcg, then 100-200 mcg as required; By IV infusion, Initially 10 mcg/kg, given over 10 minutes, then 6 mcg/kg/hour, adjust according to response, may require up to 180 mcg/kg/hour during cardiac surgery; NEONATE Initially 1-5 mcg/kg, then 1-3 mcg/kg administer over at least 30 seconds; CHILD (1 month-11 years) Initially 1-5 mcg/kg, then 1-3 mcg/kg administer over at least 30 seconds; CHILD (12-17 years) Initially 1-5 mcg/kg, then 50-200 mcg administer over at least 30 seconds. **Assisted ventilation for analgesia and respiratory depression in intensive care** By slow IV injection, ADULT Initially 300-3500 mcg, then 100-200 mcg as required; By IV infusion, ADULT Initially 10 mcg/kg, administer over 10 minutes, then 6 mcg/kg/hour, adjust according to response, may require up to 180 mcg/kg/hour during cardiac surgery; NEONATE Initially 1-5 mcg/kg, then (by IV infusion) 1.5 mcg/kg/hour, adjust according to response; CHILD Initially 1-5 mcg/kg, then (by IV infusion) 1-6 mcg/kg/hour, adjust according to response.
Contraindications Known or suspected GI obstruction, significant respiratory depression, acute or severe bronchial asthma.
Cautions Cerebral tumour, impaired consciousness; *With transdermal patch:* not suitable for acute pain or in those patients whose analgesic requirements are changing rapidly; *With intravenous*: repeated intra-operative doses should be given with care.
Side effects Abdominal pain, asthenia, anorexia, anxiety, appetite changes, application-site reactions, diarrhoea, dyspepsia, dyspnoea, gastroesophageal reflux disease, hypertension, myoclonus, paraesthesia, pharyngitis, rhinitis, stomatitis, tremor, vasodilation, myoclonic movements, laryngospasm, asystole, insomnia.
Renal impairment Avoid use or reduce dose.
Pregnancy category C
Breast-feeding Excreted in breast milk, avoid.
Note *For patches, apply to dry, non-irritated, non-irradiated and non-hairy skin on torso or upper arm. Remove after 72 hours and siting replacement patch on a different area (avoid using the same area for several days). Patches should be removed immediately in case of breathing difficulties, marked drowsiness, confusion, dizziness, or impaired speech, and seek prompt medical attention.*

MORPHINE

Injection, 15 mg/mL (1 mL)	NRH/RRH/DH
Tablet, 10 mg	NRH/RRH/DH
Tablet (ER), 15 mg	NRH/RRH

Therapeutic group Opioid analgesic.
Indications and dose **Acute pain** by SC or IM injection, ADULT Initially 10 mg every 4 hours, adjust according to response; Use dose for elderly in frail patients; ELDERLY Initially 5 mg every 4 hours, adjust according to response; By slow IV injection, ADULT Initially 5 mg every 4 hours, adjust according to response; reduce dose in frail and elderly patients. **Pain** by SC injection, CHILD (1-5 months) Initially 100-200 mcg/kg every 6 hours; CHILD (6 months-1 year) Initially 100-200 mcg/kg every 4 hours; CHILD (2-11 years) Initially 200 mcg/kg every 4 hours; CHILD (12-17 years) Initially 2.5-10 mg every 4 hours; all SC doses should be adjusted according to the response; By IV injection, CHILD (1-5 months) Initially 100 mcg/kg administer over at least 5 minutes, followed by 10-30 mcg/kg/hour adjust according to response; CHILD (6 months-11 years) Initially 100 mcg/kg administer over at least 5 minutes, followed by 20-30 mcg/kg/hour adjust according to response; CHILD (12–17 years) Initially 5 mg administered over at least 5 minutes, followed by 20-30 mcg/kg/hour adjust according to response; By oral administration, CHILD (1 year) Initially 200-300 mcg/kg every 4 hours adjust according to response; CHILD (2-11 years) Initially 200-300 mcg/kg every 4 hours (MAX. dose 10 mg) adjust according to response; CHILD (12-17 years) Initially 5-10 mg every 4 hours adjusted according to response. **Chronic pain** by oral administration, or SC or IM injection, ADULT Initially 5-10 mg every 4 hours, adjust

according to response. **Pain management in palliative care (starting dose for opioid-naive patients)** by oral administration using ER tablet, ADULT 20-30 mg daily in divided doses; **Pain management in palliative care (starting dose for patients being switched from a regular weak opioid)** by oral administration using ER tablet, ADULT 40-60 mg daily in divided doses; **Pain in palliative care (following initial titration)** by oral administration using ER tablet, Usual dose 100 mg every 12 hours, up to 600 mg every 12 hours. **Dyspnoea at rest in palliative care** by oral administration, ADULT Initially 5 mg every 4 hours to be given in carefully titrated doses. **Premedication** by SC or IM injection, ADULT Up to 10 mg 60-90 minutes before operation. **Myocardial infarction** by slow IV injection, ADULT 5-10 mg followed by 5-10 mg if required, administer at a rate of 1-2 mg/minute, use dose for elderly in frail patients; ELDERLY 2.5-5 mg followed by 2.5-5 mg if required, administer at a rate of 1-2 mg/minute. **Acute pulmonary oedema** by slow IV injection, ADULT 5-10 mg, administer at a rate of 2 mg/minute, use dose for elderly in frail patients; ELDERLY: 2.5-5 mg, administer at a rate of 2 mg/minute. **Persistent cyanosis in congenital heart disease when blood glucose less than 3 mmol/litre (following glucose)** by IV or IM injection, CHILD: 100 mcg/kg.
Note *Subcutaneous injection not suitable for oedematous patients.*
Contraindications Acute abdomen, delayed gastric emptying, heart failure secondary to chronic lung disease, pheochromocytoma.
Cautions Cardiac arrhythmias, pancreatitis severe corpulmonale.
Side effects Abdominal pain, agitation, amenorrhoea, anorexia, asthenia, bronchospasm, delirium, disorientation, dyspepsia, hypertension, hypothermia, inhibition of cough reflex, malaise, muscle fasciculation, myoclonus, nystagmus, paraesthesia, paralytic ileus, raised intracranial pressure, restlessness, rhabdomyolysis, seizures, syncope, taste disturbance.
Renal impairment Avoid use or reduce dose.
Pregnancy category C
Breast-feeding Therapeutic doses unlikely to affect infants.
IV fluid compatibility Dextrose 5%, dextrose 10% and sodium chloride 0.9%.

PETHIDINE

Injection, 50 mg/mL (1 mL) NRH/RRH/DH/PHC

Therapeutic group Opioid analgesic.
Indications and dose **Acute pain** by SC or IM injection, ADULT 25-100 mg, then 25-100 mg after 4 hours, for debilitated patients use elderly dose; ELDERLY Initially 25 mg, then 25-100 mg after 4 hours; By slow IV injection, ADULT 25-50 mg, then 25-50 mg after 4 hours, for debilitated patients use elderly dose; ELDERLY Initially 25 mg, then 25-50 mg after 4 hours. **Obstetric analgesia** by SC or IM injection, ADULT 50-100 mg, then 50-100 mg after 1-3 hours if required; MAX. 400 mg per day. **Premedication** by IM injection, ADULT 25-100 mg, 1 hour before operation, for debilitated patients use elderly dose; ELDERLY 25 mg, 1 hour before operation. **Postoperative pain** by SC or IM injection, ADULT 25-100 mg every 2-3 hours if required, for debilitated patients use elderly dose; ELDERLY Initially 25 mg every 2-3 hours if required.
Contraindications Pheochromocytoma.
Cautions Accumulation of metabolites may result in neurotoxicity, cardiac arrhythmias; not suitable for severe continuing pain, severe cor pulmonale.
Side effects Hypothermia, restlessness, tremor.
Pregnancy category B
Breast-feeding Excreted in milk but not known to be harmful.
Renal impairment Avoid use or reduce dose.

TRAMADOL HYDROCHLORIDE

Injection, 50 mg/mL (1 mL) NRH/RRH/DH

Therapeutic group Opioid analgesic.
Indications and dose **Moderate to severe pain** by IM or IV infusion, ADULT 50-100 mg every 4-6 hours, IV injection to be given over 2-3 minutes; CHILD (12-17 years) 50-100 mg every 4-6 hours, IV injection to be given over 2-3 minutes. **Postoperative pain** by IV injection, ADULT Initially 100 mg, then 50mg every 10-20 minutes, if required up

to total maximum 250 mg (including initial dose) in first hour, then 50-100mg every 4-6 hours, given over 2-3 minutes; MAX. 600 mg per day; CHILD (12-17 years) Initially 100 mg, then 50 mg every 10-20 minutes if required up to total maximum 250 mg (including initial dose) in first hour, then 50-100 mg every 4-6 hours, given over 2-3 minutes; MAX. 600 mg per day.
Contraindications Children younger than 12 years, postoperative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy, significant respiratory depression, acute or severe bronchial asthma, in unmonitored settings or without resuscitative equipment, known or suspected gastrointestinal obstruction, including paralytic ileus, hypersensitivity to opioids, concurrent use of MAOIs or use within the last 14 days.
Cautions Excessive bronchial secretions, history of epilepsy-use tramadol only if compelling reasons, impaired consciousness, not suitable as a substitute in opioid-dependent patients, not suitable in some types of general anaesthesia, susceptibility to seizures-use tramadol only if compelling reasons.
Side effects Flushing, pruritus, constipation, nausea, vomiting, xerostomia, dizziness, headache, insomnia, somnolence.
Hepatic impairment Caution in severe impairment.
Renal impairment Avoid use or reduce dose.
Pregnancy category C
Breast-feeding Avoid.

2.3 Medicines used in neuropathic pain

AMITRIPTYLINE

Tablet, 25 mg NRH/RRH/DH

Therapeutic group Medicines used for neuropathic pain.
Indications and dose neuropathic pain 12.5-25 mg daily at bedtime; MAX. 100 mg daily. *For details, refer to page no. 145.*

CARBAMAZEPINE

Tablet, 200 mg NRH/RRH/DH

Therapeutic group Medicines used for neuropathic pain.
Indications and dose **Trigeminal neuralgia** ADULT Initially 100 mg PO, Q24H to Q12H, increased gradually according to response, increased if necessary up to 1.6 g daily in 3 to 4 divided doses. *For detail, refer to page no. 30.*

GABAPENTIN

Tablet 300 mg NRH/RRH/DH

Therapeutic group Medicines used for neuropathic pain.
Indications and dose **Fibromyalgia** ADULT: Initial, 300 mg orally once daily at bedtime; titrate over 6 weeks to a maximum of 2400 mg/day, given as 600 mg twice daily and 1200 mg at bedtime. **Neuropathy due to diabetes mellitus** ADULT: 1200 to 3600 mg/day orally in 3 divided doses. **Postherpetic neuralgia** ADULT: 300 mg orally on day 1, increase to 300 mg twice a day on day 2 and to 300 mg 3 times a day on day 3; may increase up to 1800 mg/day (divided into 3 doses). **Postoperative pain (Acute), pre-emptive therapy** ADULT: 300 to 1200 mg orally as 1 dose administered 1 to 2 hours prior to surgery. **Trigeminal neuralgia** ADULT: up to 3600 mg orally per day has been used.
Cautions History of psychosis, renal impairment, elderly, pregnancy and breastfeeding, diabetes mellitus, avoid abrupt withdrawal.
Counselling Take consistently at the same time of the day; continue until advised to stop.

3. ANTIALLERGICS AND MEDICINES USED IN ANAPHYLAXIS

ADRENALINE

Injection, 1 mg/mL (1 mL) NRH/RRH/DH/PHC

Therapeutic group Antiallergics and medicines used in anaphylaxis.
Indications and dose **Anaphylaxis**, By *IM injection,* as given below:

Age	Volume
< 1 - year	0.05 mL
2 years	0.2 mL
3 - 4 years	0.3 mL
5 years	0.4 mL
6 - 12 years	0.5 mL
ADULT	0.5 - 1.0 mL

Doses may be repeated every 10 minutes, according to blood pressure and pulse, until improvement occurs (may be repeated several times). **Asthma** *by IM injection,* ADULT 0.1-0.5 mg, IM, Q15-20 minute intervals as required; CHILD 0.01 mg/kg, SC, Q4H if required to a maximum of 0.5 mg. **Cardiac arrest** ADULT 0.1-0.5 mcg/kg/min, IV; CHILD 0.1-1 mcg/kg/min, IV and titrate to response.
Cautions Hyperthyroidism, diabetes mellitus, heart disease, hypertension, arrhythmias, cerebrovascular disease, angle-closure glaucoma, second stage of labour, elderly patients.
Side effects Anxiety, tremor, tachycardia, arrhythmias, headache, cold extremities, hypertension (risk of cerebral haemorrhage) and pulmonary oedema (on excessive dosage or extreme sensitivity), nausea, vomiting, sweating, weakness, dizziness, hyperglycaemia.
Over dosage Sudden extreme hypertension may lead to cerebral haemorrhage, reversal by vasodilatation with isosorbide dinitrate may be attempted.
Renal impairment Use with caution in severe impairment.
Pregnancy category C
Breast-feeding Excretion in breast milk unknown: Use with caution.
IV fluid compatibility Dextrose 5%, dextrose 10%, compound sodium lactate solution, sodium chloride 0.9% and dextrose 5% in sodium chloride 0.45%.

CETIRIZINE

Tablet, 10 mg — NRH/RRH/DH/PHC

Therapeutic group Antiallergic and medicine used in anaphylaxis.
Indications and dose **Symptomatic relief of allergy such as hay fever, urticaria** ADULT and CHILD (over 12 years) 10 mg PO, Q24H; CHILD (6-11 years) 5 mg, PO Q12H; CHILD (2-5 years) 2.5 mg, PO, Q12H.
Contraindications Acute porphyrias.
Cautions Epilepsy.
Side effects Blurred vision, dry mouth, GI disturbances, headache, psychomotor impairment, urinary retention.
Pregnancy category B
Breast-feeding Excreted in breast milk, avoid.
Counselling May cause drowsiness, do not drive or operate machinery and avoid alcohol.

DEXAMETHASONE

Injection, 4 mg/mL (2 mL) — NRH/RRH/DH
Tablet, 4 mg — NRH/RRH

Therapeutic group Antiallergic and medicine used in anaphylaxis.
Indications and dose **Allergic conditions and inflammation** ADULT 1-4 mg PO, Q12H to Q8H daily; CHILD 0.5-2 mg/kg PO, Q12H to Q8H daily. **Cerebral oedema** ADULT 10 mg *IV stat*, then 4 mg *IM*, Q6H until clinical improvement; **Shock** ADULT 20 mg IV, then 3 mg/kg/day by continuous IV infusion. **Multiple Sclerosis** ADULT 30 mg/day PO x 1 week, followed by 4-12 mg/day x 1 month.
Contraindicated Systemic fungal infections; cerebral malaria; administration of live vaccines.
Cautions Prolonged use of steroids increases susceptibility to infections and severity of infections.
Side effects Hypertension, cataract, raised intraocular pressure, corneal oedema, depression, euphoria, cardiomyopathy, hyperglycaemia.

Pregnancy category C
Breast-feeding Excreted in breast milk, avoid.
IV fluid compatibility Dextrose 5% and sodium chloride 0.9%.

HYDROCORTISONE SODIUM SUCCINATE

Injection, 100 mg/mL (2 mL) NRH/RRH/DH

Therapeutic group Antiallergic and medicine used in anaphylaxis.
Indications and dose **Acute hypersensitivity reactions such as angioedema of the upper respiratory tract and anaphylaxis (adjunct to adrenaline)** ADULT 100-300 mg, *IV injection*. **Acute hypersensitivity reactions and Angioedema** CHILD (1-5 months) Initially 25 mg *IM or IV injection,* Q8H, adjusted according to response; CHILD (1-5 months) Initially 25 mg *IM or IV injection,* Q8H, adjusted according to response; CHILD (6 months-5 years) Initially 50 mg *IM or IV injection,* Q8H adjusted according to response; CHILD (6-11 years) Initially 100 mg IM or Iv injection, Q8H, adjusted according to response; CHILD (12-17 years) Initially 200 mg *IM or IV injection,* Q8H adjusted according to response. *For details, refer to page no. 69*

PREDNISOLONE

Tablet, 5 mg and 20 mg NRH/RRH/DH

Therapeutic group Antiallergic and medicine used in anaphylaxis.
Indications and dose **Suppression of inflammatory and allergic disorders, Inflammatory bowel disease, Asthma, Immuno-suppression, Rheumatic disease and Nephrotic syndrome** ADULT 10-20 mg PO, Q24H daily, may increase to 1 mg/kg (up to 60 mg daily in severe disease), preferably taken in the morning after breakfast; ***Maintenance*** 2.5-15 mg PO, Q24H; CHILD: 1-2 mg/kg *PO* (max 60 mg). **Multiple sclerosis** ADULT 200 mg PO, Q24H x 1 week, then 80 mg Q24H alternate days x 1 month. **Acute exacerbation of COPD** ADULT 30-40 mg *PO,* Q24H x 7-14 days.
Contraindications Systemic fungal infections, varicella, superficial herpes simplex keratitis, administration of live or attenuated virus vaccines.
Cautions Cirrhosis, diabetes, ocular herpes simplex, hypertension, thyroid disease, seizure disorders, hypothyroidism, myasthenia gravis, hepatic impairment, peptic ulcer disease, osteoporosis, ulcerative colitis, untreated systemic infections, renal insufficiency, pregnancy.
Side effects Acne, adrenal suppression, delayed wound healing, diabetes mellitus, GI perforation, glucose intolerance, hepatomegaly, insomnia, menstrual irregularity, myopathy, osteoporosis, peptic ulcer.
Hepatic impairment Use with caution.
Renal impairment Use with caution; fluid retention may occur.
Pregnancy category C
Breast-feeding Excreted in breast milk, use with caution.
Counselling To be taken after or with meals.
Note *In acute asthma, tail off steroids within 7-10 days to avoid adrenal suppression*.

PROMETHAZINE

Injection, 25 mg/mL (2 mL) NRH/RRH/DH/PHC
Tablet, 10 mg NRH/RRH/DH/PHC

Therapeutic group Antiallergic (sedating antihistamines).
Indications and dose **Allergic conditions** ADULT 10-20 mg PO, Q12H to Q8H; 25-50 mg, deep IM (MAX. per dose 100 mg); CHILD 1 mg/kg/day PO, in divided doses; CHILD (2-4 years) 5 mg PO, Q12H, alternately 5-15 mg PO, Q24H at night; CHILD (5-9 years) 5-10 mg PO, Q12H, alternatively 10-25 mg PO, Q24H at night; CHILD (10-17 years): 10-20 mg PO, Q12H-Q8H, alternatively 25 mg PO, Q24H at night, increased if necessary to 25 mg Q12H. **Nausea and vomiting, and motion sickness** ADULT 20-25 mg PO at bedtime on night before travel and repeat following morning if necessary; CHILD (2-4 years) 5mg PO at bedtime on night before travel, repeat following morning if necessary; CHILD (5-9 years) 10 mg PO at bedtime on night before travel, repeat following morning if necessary; CHILD (10-17 years) 20-25 mg PO at bedtime on night before travel, repeat following morning if necessary. **Emergency treatment**

of anaphylactic reactions ADULT 25-50 mg (as solution of 2.5 mg/mL in water for injections), IV injections (max. 100 mg/course).
Contraindications Children less than 2 years of age, subcutaneous, coma, treatment of lower respiratory tract symptoms including asthma.
Caution Asthma, epilepsy, prostatic hypertrophy, pyloroduodenal obstruction, severe coronary artery disease, susceptibility to angle-closure glaucoma, urinary retention.
Side effects Sedation, dizziness and other CNS symptoms are common at the start of treatment, but tolerance usually develops, GI irritation and anticholinergic effects are occasionally seen.
Pregnancy category C
Breast-feeding Excreted in breast milk, not recommended.
Counselling May cause drowsiness, do not drive or operate machinery and avoid alcohol.

4. ANTIDOTES AND OTHER SUBSTANCES USED IN POISONINGS

4.1 Non-Specific

CHARCOAL

Activated powder, 450 g NRH/RRH/DH/PHC

Therapeutic group Non-specific antidote.
Indications and dose **Reduction of absorption of poisons in the GI system** ADULT 50 g PO; CHILD (1-2 years) 25-50 g PO; INFANT: 1 g/kg (approx. 5 mL/kg). **Active elimination of poisons** ADULT: Initially 50 g PO, then 50 g Q4H, reduced if not tolerated to 25 g PO, Q2H; CHILD (1 month-11 years) 1 g/kg PO, Q4H (MAX. per dose 50 g), dose may be reduced and the frequency increased if not tolerated; CHILD (12-17 years) Initially 50 g PO, then 50 g PO, Q4H, reduced if not tolerated to 25 g PO, Q2H.
Contraindications Poisoning by corrosive substances (strong acid or alkali), concurrent administration with specific oral antidotes or oral emetics, not for poisoning with petroleum distillates, corrosive substances, alcohols, clofenotane (dicophane, DDT), Malathion, and metal salts including iron and lithium salts, intestinal obstruction.
Cautions Comatose and drowsy patients (risk of aspiration), reduced gastrointestinal motility (risk of obstruction).
Side effects Constipation, black stool.
Administration Aqueous slurry of charcoal should be made by suspending in a glass of water and administered; following administration of charcoal (after about 2 hours) a cathartic should be administered to enhance removal of poison charcoal complex promptly and to prevent enhanced toxicity; catharsis should occur within 4 to 8 hours after the use of activated charcoal.

4.2 Specific

ACETYLCYSTEINE

Injection, 200 mg/mL (2 mL) NRH/RRH/DH

Therapeutic group Specific antidote (paracetamol poisoning).
Indications and dose **Paracetamol poisoning** ADULT (body weight 40 kg and above) 150 mg/kg *IV infusion* over 1 H, dose to be administered in 200 mL dextrose 5% (D5%), then 50 mg/kg over 4 hours in 500 mL D5%, then 100 mg/kg over 16 hours, in 1 L D5%; CHILD (body weight 40 kg and above) 150 mg/kg IV infusion over 1 hour, in 200 mL D5%, then 50 mg/kg over 4 hours in 500 mL D5%, then 100 mg/kg over 16 hours, in 1 L D5%; CHILD (body weight 20-39 kg) Initially 150 mg/kg IV infusion over 1 hour in 100 mL D5%, followed by 50 mg/kg over 4 hours, in 250 mL D5%, then 100 mg/kg over 16 hours, 500 mL D5%; CHILD (body weight up to 20 kg) Initially 150 mg/kg IV infusion over 1 hour in 3 mL/kg D5%, followed by 50 mg/kg over 4 hours in 7 mL/kg D5%, then 100 mg/kg over 16 hours in 14 mL/kg D5%.
Contraindications Severe tachycardia, cardiovascular disease (IHD).
Cautions Asthma, atopy, may slightly increase INR, may slightly increase prothrombin time.
Side effects Hypersensitivity-like reactions, rashes, slight increase in INR and prothrombin time.
Pregnancy category C
Breast-feeding Excreted in milk unknown, use with caution.

ANTI-SNAKE VENOM SERUM

Powder for injection (10 g) NRH/RRH/DH/PHC

Therapeutic group Specific (Antitoxin).
Indications and dose **Treatment of bite from viper, cobra and krait** **Treatment of bite from viper, cobra and krait** Dried anti-snake venom serum power is reconstituted usually with 10 mL of sterile water for injection. Two methods of administration are recommended: **Intravenous "push" injection** Reconstituted antivenom is given by slow intravenous injection (not more than 2 mL/minute) OR **Intravenous infusion** Reconstituted antivenom is diluted in approximately 5-10 mL of isotonic fluid per kg body weight (i.e. 250-500 mL of isotonic saline or 5% dextrose in the case of an adult patient) and is infused at a constant rate over a period of about one hour.
Contraindications Bite by non-poisonous snake, or when puncture marks are not seen, hypersensitive to horse or sheep serum.
Cautions History of previous serum injections (including anti-tetanus, anti-diphtheria); history of allergy, asthma or eczema.
Side effects Local flare or general anaphylactic reaction may be seen after the test dose or during the full dose. Pallor, sweating, nausea, vomiting, urticaria and hypotension are the features of anaphylaxis. Adrenaline 1mL, by IM injection should be given immediately and 0.5mL after 10 minutes if required.

ATROPINE SULPHATE

Injection, 0.6 mg/mL (1 mL) NRH/RRH/DH/PHC

Therapeutic group Specific antidote.
Indications and dose **Treatment of poisoning by organophosphorus insecticide or nerve agent (in combination with pralidoxime chloride)** ADULT 2 mg IV injection, Q5-10 minutes until the skin becomes flushed and dry, the pupils dilate, and bradycardia is abolished, frequency of administration dependent on the severity of poisoning; CHILD 20 mcg/kg IV injection, Q5-10 minutes (MAX. per dose 2 mg) until the skin becomes flushed and dry, the pupils dilate, and bradycardia is abolished, frequency of administration dependent on the severity of poisoning.
Contraindications Angle-closure glaucoma, myasthenia gravis, paralytic ileus, pyloric stenosis; prostatic enlargement.
Cautions Down syndrome, children, the elderly, ulcerative colitis, diarrhoea, hyperthyroidism, heart failure, or hypertension.
Side effects Dry mouth, flushing and dryness of skin, rash, difficulty in micturition, less commonly arrhythmias, tachycardia and palpitations, confusion (particularly in the elderly), heat prostration and convulsions, especially in febrile children.
Pregnancy category C
Breast-feeding Small amount excreted in milk, use with caution.

CALCIUM GLUCONATE

Injection, 10% (10 mL) NRH/RRH/DH

Therapeutic group Specific antidote.
Indications and dose **Magnesium intoxication or cardiac arrest in the presence of hyperkalemia or hypocalcemia** ADULT 500-800 mg/dose (MAX. 3 g/dose); INFANT and CHILD 60-100 mg/kg/dose (MAX. 3 g/dose). **Maintenance electrolyte requirements for TPN** ADULT 1.7-3.4 g/1000 kcal/24 hours.
Not for IM or SC administration. *For IV administration only, administer slowly (.1.5 mL calcium gluconate 10% per minute) through a small needle into a large vein to avoid too rapid increase in serum calcium and extravasation.*
IV fluid compatibility Stable in dextrose 5% in compound sodium lactate, dextrose 5% in sodium chloride 0.9%, dextrose 5%, dextrose 10%, dextrose 25%, compound sodium lactate, sodium chloride 0.9%. *For detail, refer to page no. 156*

FLUMAZENIL

Injection, 0.1 mg/mL (5 mL) NRH/RRH/DH

Therapeutic group Specific antidote.

Indications and dose **Reversal of sedative effects of benzodiazepines in anaesthesia and clinical procedures** ADULT 0.2 mg IV injection administered over 15 seconds, then 0.1 mg Q1 minute if required; Usual dose 0.3-0.6 mg; max. 1 mg per course. **Reversal of sedative effects of benzodiazepines in intensive care** ADULT 0.3mg IV injection administered over 15 seconds, then 0.1 mg Q1 minute if required; MAX. 2 mg per course. **Reversal of sedative effects of benzodiazepines in intensive care (if drowsiness recurs after initial dose)** ADULT 0.1-0.4 mg/hour IV infusion, adjusted according to response.
Contraindications Life-threatening condition (e.g., raised intracranial pressure, status epilepticus) controlled by benzodiazepines.
Cautions Avoid rapid injection following major surgery, avoid rapid injection in high-risk or anxious patients, benzodiazepine dependence, elderly, ensure neuromuscular blockade cleared before giving, history of panic disorders, prolonged benzodiazepine therapy for epilepsy.
Side effects Nausea, vomiting, anxiety, fear, palpitation, agitation, chills, convulsions, dizziness, flushing, sensory disturbance, sweating, tachycardia, transient hypertension.
Hepatic impairment Carefully titrate dose.
Pregnancy C
Breast-feeding Excretion in milk unknown, use with caution.
IV fluid compatibility Dextrose 5% and sodium chloride 0.9%.

FOLINIC ACID (Leucovorin calcium)

Injection, 10 mg/mL (5 mL) NRH

Therapeutic group Specific antidote (Chemotherapy rescue agent).
Indications and dose **Methotrexate overdose** 1:1 ratio for leucovorin to inadvertent methotrexate overdose, within 1 hour. **High-dose methotrexate-rescue dose** 10 mg/m² IV Q6H starting 24 hours after methotrexate, then may switch to IM Q6H and continue until methotrexate level has fallen below 0.05 micromolar.
Contraindications Vitamin B12 deficiency anaemia and pernicious anaemia.
Side effect Diarrhoea, nausea, vomiting, stomatitis, thrombocytosis.
Pregnancy category C
Breast-feeding Not known whether distributed in breast milk, use with caution.
IV fluid compatibility Sodium chloride 0.9%, compound sodium lactate, water for injection and dextrose 5% solution.
Note *Do not mix leucovorin injection with 5-FU because precipitation will occur.*

LIPID EMULSION

Injection, 20% (250 mL) NRH/RRH

Therapeutic Group Specific antidote (severe local anaesthetic-induced cardiovascular toxicity).
Indications and dose ADULT 1.5 mL/kg IV bolus over 2 to 3 minutes; Repeat bolus for persistent asystole or pulseless electrical activity. **Maintenance** Continuous IV infusion of 0.25 mL/kg/min; if response is achieved after 3 minutes, adjust infusion rate to 0.025 mL/kg/min; increase to 0.25 mL/kg/min if necessary; Continue infusion until hemodynamic stability is achieved or until a total dose of 8 to 10 mL/kg is reached.
Note Strict adherence to proper infusion rates, dosing and monitoring are necessary in premature infants. Infusion rate should not exceed 1g fat/kg in four hours. Monitor serum triglyceride levels.
Contraindications Severe allergies to eggs and legumes, hyperlipidaemia, lipoid nephrosis, acute pancreatitis associated with hyperlipidemia, severe haemorrhagic disorders.
Cautions Anaemia, bleeding disorders, patients susceptible to fat embolism, pancreatitis and respiratory disease, premature infants.
Side effects Bradycardia, haemorrhage, hyperglycaemia, apnoea, agitation, vomiting, hypertriglyceridemia.
Hepatic impairment Use with caution in patients with severe hepatic impairment.
Pregnancy category C

NALOXONE

Injection, 0.4 mg/mL (1 mL) NRH/RRH/DH

Therapeutic group Specific antidote (opioid overdose).
Indications and dose **Overdose with opioids** by IV or IM or SC injection, ADULT Initially 0.4 mg, then 0.8 mg for up to 2 doses at 1 minute intervals; if no response, then increase to 2 mg for 1 dose if still no response (4 mg dose may be required in seriously poisoned patients); further doses may be required if respiratory function deteriorates; CHILD (1 month-11 years) Initially 0.1 mg/kg (Max. per dose 2 mg), if no response, repeat at intervals of 1 minute to a total MAX. 2 mg; further doses may be required if respiratory function deteriorates; CHILD (12-17 years) Initially 0.4 mg, then 0.8 mg for up to 2 doses at 1 minute intervals if no response to preceding dose, then increase to 2 mg for 1 dose if still no response (4mg dose may be required in seriously poisoned patients). **Reversal of postoperative respiratory depression** ADULT Initially 0.1-0.2 mg IV injection; if response inadequate, give subsequent doses, 0.1 mg Q2 minutes; CHILD (12-17 years) Initially 0.1-0.2 mg IV injection, if response inadequate, give subsequent doses, 0.1mg Q2 minutes; CHILD (1 month-11 years) 0.1 mg/kg IV injection, repeated Q2-3 minutes if required.
Cautions Cardiovascular disease or those receiving cardiotoxic medicines (serious adverse cardiovascular effects reported); maternal physical dependence on opioids (may precipitate withdrawal in new-born), pain, physical dependence on opioids (precipitated withdrawal).
Side effects Cardiac arrest (in children), dizziness, dyspnoea (in children), headache, hypertension, hyperventilation (in children), hypotension, nausea, pulmonary oedema (in children), tachycardia, ventricular fibrillation (in children), vomiting.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.
IV fluid compatibility Dextrose 5% and sodium chloride 0.9%.
Note *This medicine is short acting, and repeated injections may be required.*

PHYTOMENADIONE (Vit K)

Injection, 10 mg/mL (1 mL) NRH/RRH/DH/PHC

Therapeutic group Specific antidote (Anticoagulant antagonists).
Indications and dose **Major bleeding in patients on warfarin** ADULT 5 mg slow IV infusion, STAT**; INR > 8.0 with minor bleeding in patients on warfarin** 1-3 mg slow IV infusion, dose may be repeated if INR still too high after 24 hours; **INR > 8.0 with no bleeding in patients on warfarin** 1-5 mg PO (IV preparation to be used orally), repeat dose if INR still too high after 24 hours; **INR 5.0-8.0 with minor bleeding in patients on warfarin** 1-3 mg PO.
**Stop warfarin treatment and restart if INR level falls below 5.*
Cautions Any risk factors for haemorrhage, elderly**,** rapid IV injection can lead to fatal collapse.
Side effects Cyanosis, flushing, hypotension, scleroderma-like lesions.
Pregnancy category C
Breast-feeding Excreted in milk; Use with caution.
Note *Phytomenadione does not neutralise heparin, use protamine sulphate instead. Store at room temperature away from light and moisture*.

PRALIDOXIME

Injection, 25 mg/mL (20 mL) NRH/RRH/DH

Therapeutic group Specific antidote.
Indications and dose **Adjunct to atropine in the treatment of organophosphorus poisoning or nerve agent** ADULT Initially 30 mg/kg IV infusion, to be given over 20 minutes, followed by 8 mg/kg/hour; max. 12 g per day; CHILD Initially 30 mg/kg IV infusion, to be given over 20 minutes, followed by 8 mg/kg/hour; max. 12 g per day.
Contraindications Poisoning due to carbamates and to organophosphorus compounds without anticholinesterase activity.
Cautions Myasthenia gravis.

Side effects Drowsiness, dizziness, disturbances of vision, nausea, tachycardia, headache, hyperventilation, and muscular weakness.
Renal impairment Use with caution.
Pregnancy category C
IV fluid compatibility Sodium chloride 0.9%.

PROTAMINE SULPHATE

Injection, 10 mg/mL (5 mL) NRH/RRH

Therapeutic group Specific antidote.
Indications and dose **Overdose with IV injection of unfractionated heparin** ADULT administer at a rate not exceeding 5 mg/minute IV injection, 1 mg neutralises 80-100 units of heparin when given within 15 minutes; if longer than 15 minute since heparin, less protamine required (consult product literature for details) as heparin rapidly excreted; MAX. 50 mg; **Overdose with IV infusion of unfractionated heparin** ADULT 25-50 mg IV injection, to be administered once heparin infusion stopped at a rate not exceeding 5mg/minute; **Overdose with SC injection of unfractionated heparin** ADULT Initially 25-50 mg IV injection, to be administered at a rate not exceeding 5mg/minute, 1mg neutralises 100 units of heparin, then (by IV infusion), any remaining dose to be administered over 8-16 hours; MAX. 50 mg per course; **Overdose with subcutaneous injection of low molecular weight heparin** ADULT administer by intermittent IV injection at a rate not exceeding 5 mg/minute; 1 mg neutralises approx. 100 units of low molecular weight heparin (consult product literature of low molecular weight heparin for details); MAX. 50 mg.
Contraindications Hypersensitivity to fish.
Cautions Excessive doses can have an anticoagulant effect, increased risk of allergic reaction to protamine (includes previous treatment with protamine or protamine insulin, allergy to fish, men who are infertile or who have had a vasectomy and who may have antibodies to protamine), rapid administration, repeated doses.
Side effects Anaphylaxis, angioedema, back pain, bradycardia, dyspnoea, flushing, hypertension, hypotension, lassitude, nausea, pulmonary oedema, rebound bleeding, vomiting.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.
Note *The long half-life of low molecular weight heparins should be taken into consideration when determining the dose of protamine; the effects of low molecular weight heparins can persist for up to 24 hours after administration; protamine does not neutralise oral anticoagulants.*

5. ANTICONVULSANTS/ANTIEPILEPTICS

CARBAMAZEPINE

Tablet, 200 mg NRH/RRH/DH

Therapeutic group Antiepileptic.
Indications and dose **Focal and secondary generalised tonic-clonic seizures and Primary generalised tonic-clonic seizures** ADULT Initially 100-200 mg PO, Q24H to Q12H, increase in steps of 100-200 mg every 2 weeks; increase if necessary up to 1.6-2 g daily in divided doses; CHILD (1 month-11 years) Initially 5 mg/kg/day PO, Q24H or Q12H, then increased in steps of 2.5-5 mg/kg every 3-7 days as required; increase if necessary up to 20 mg/kg/day given in 2 to 3 divided doses. **Trigeminal neuralgia** ADULT Initially 100 mg PO, Q24H to Q12H, increase gradually according to response, increased if necessary up to 1.6 g daily in 3 to 4 divided doses. **Prophylaxis of bipolar disorder unresponsive to lithium** ADULT Initially 400 mg daily in divided doses, increase until symptoms are controlled up to a maximum 1.6 g/day given 3 to 4 divided doses.
Contraindications Acute porphyria, AV conduction abnormalities, history of bone marrow depression.
Cautions Cardiac disease, history of haematological reactions, absence and myoclonic seizures, skin reactions, susceptibility to angle-closure glaucoma.
Side effects Allergic skin reactions, aplastic anaemia, ataxia, blood disorders, blurring of vision, dermatitis, dizziness, drowsiness, dry mouth, eosinophilia, fatigue, haemolytic anaemia, headache, hyponatraemia, leukopenia, nausea, oedema, thrombocytopenia, unsteadiness, urticaria, vomiting.

Hepatic impairment Use caution; Metabolism impaired in advanced liver disease.
Renal Impairment Use with caution, If GFR < 10 mL/min, administer 75% of dose and monitor.
Pregnancy category D
Breast-feeding Excreted in breast milk, avoid.
Counselling Patients or their family members should be taught how to recognise the signs of blood, liver, or skin disorders; and advised to seek immediate medical attention if symptoms such as fever, rash, mouth ulcers, bruising, or bleeding develop.

CLOBAZAM

Tablet, 5 mg NRH/RRH

Therapeutic group Antiepileptic (benzodiazepines).
Indications and dose **Lennox-Gastaut syndrome, Adjunct** ADULT (≥30 kg) and CHILD (≥2 years and ≥30 kg) Initial, 10 mg PO daily (2 divided doses); Titrate to 20 mg daily (2 divided doses) on day 7 and to 40 mg daily (2 divided doses) on day 14; ADULT (≤ 30 kg) and CHILD (≥ 2 years and ≤ 30 kg) Initial, 5 mg once daily; Titrate to 10 mg daily (2 divided doses) on day 7 and to 20 mg daily (2 divided doses) on day 14.
Contraindications History of hypersensitivity to the medicine or ingredients.
Cautions Abuse, misuse, and addiction, do not exceed the usual recommended dosing frequency, if a substance use disorder is suspected, patient evaluation and early treatment. Concomitant therapy with benzodiazepines or CNS depressants should not be denied access to medication-assisted treatment medicines (e.g., buprenorphine), if concomitant use is necessary, careful management and monitoring recommended. Avoid or minimise concomitant use of CNS depressants and other substances associated with abuse, misuse, and addiction (e.g., opioid analgesics, stimulants).
Side effects Constipation, drooling, ataxia, dysarthria, insomnia, lethargy, sedation, somnolence, aggressive behaviour, fever, Stevens-Johnson syndrome and toxic epidermal necrolysis.
Hepatic impairment Mild-to-moderate (Child-Pugh 5-9): starting dose should be 5 mg/day and titrated according to weight, but to half the typical adult dose; additional titration to the maximum dose (20 mg/day or 40 mg/day), depending on the weight group) may be started on day 21. Not recommended in severe hepatic impairment.
Renal impairment No dose adjustment required in mild or moderate CKD. Data not available in severe CKD.
Pregnancy category X
Breast-feeding Excreted in breast milk, avoid.
Counselling Advise the risks and symptoms of benzodiazepine abuse, misuse, and addiction and to report such symptoms. Immediately report a dermatologic reaction. Avoid activities requiring mental alertness or coordination medicine may cause drowsiness. Advise female patients that the medicine decreases the effectiveness of hormonal contraceptives and to use additional non-hormonal methods of contraception during therapy and for 28 days after the last dose. Advise patients against sudden discontinuation of medicines as this may increase seizure frequency. Avoid alcohol and other CNS depressants.

CLONAZEPAM

Tablet, 0.5 mg NRH/RRH

Therapeutic group Antiepileptic (benzodiazepines).
Indications and dose **All forms of epilepsy, myoclonus and status epilepticus** ADULT 1 mg (0.5 mg in elderly) PO, initially at night for 4 nights, increase according to response over 2-4 weeks to usual maintenance dose of 4-8 mg usually at night in 3-4 divided doses; CHILD (up to 1 year) Initially 0.25 mg PO, increase as above to usual maintenance dose of 0.5-1 mg; CHILD (1-5 years) Initially 0.25 mg PO increased as above to 1-3 mg; CHILD (5-12 years) Initially 0.5 mg increased as above to 3-6 mg.
Contraindications Coma, current alcohol and drug abuse, respiratory depression.
Caution Acute porphyrias, airways obstruction, brain damage, cerebellar ataxia, depression, spinal ataxia, suicidal ideation.

Side effects Drowsiness, fatigue and light-headedness, persisting until next day; confusion and ataxia in the elderly; salivary hypersecretion in infants; tolerance, amnesia, muscle weakness; hypotension and apnoea.
Hepatic impairment Start with smaller initial doses or reduced doses. Can precipitate coma, avoid in severe impairment.
Renal impairment Start with small doses in severe impairment.
Pregnancy category D
Breast-feeding Excreted in breast milk, avoid.
Counselling Do not drive or operate machineries during initiation of therapy; May enhance effects of alcohol.

DIAZEPAM

Injection, 5 mg/mL (2 mL) NRH/RRH/DH/PHC

Therapeutic group Antiepileptic.
Indications and dose **Status epilepticus and Febrile convulsions** by IV injection, ADULT and CHILD (12 years and above) 10 mg IV injection, then 10 mg after 10 minutes if required administered at a rate of 1mL/min; CHILD (1 month-11 years) 300-400 mcg/kg (MAX. 10 mg/dose) IV injection, then 300-400 mcg/kg after 10 minutes if required administered over 3-5 minutes.
Contraindications Respiratory depression, severe hepatic impairment, chronic psychosis.
Cautions Muscle weakness, reduce dose in elderly. avoid prolonged use and abrupt withdrawal.
Side effects Drowsiness and light-headedness, persisting until next day, confusion and ataxia in the elderly, tolerance, amnesia, muscle weakness; hypotension and apnoea.
Hepatic impairment Avoid in severe impairment.
Renal impairment Start with small doses in severe impairment.
Pregnancy category D
Breastfeeding Excreted in milk, avoid.

GABAPENTIN

Tablet/Capsule, 300 mg NRH/RRH/DH

Therapeutic group Antiepileptic.
Indications and dose **Monotherapy and adjunctive treatment of partial seizures with or without secondary generalisation** ADULT and CHILD (12 years and above) 300 mg by mouth on day 1 of treatment, 300 mg twice daily on day 2, and 300 mg thrice daily on the day 3; thereafter the dose may be increased in increments of 300 mg daily every 2-3 days until effective antiepileptic control is achieved (MAX. 4.8 g/day); CHILD (6 to 11 years) 10 mg/kg once daily on the day 1 of treatment, 10 mg/kg twice daily on the day 2, and then 10 mg/kg thrice daily on day 3 (max. 70 mg/kg/day). **Neuropathic pain** ADULT 300mg on the day 1, 300 mg twice daily on the day 2, and 300 mg thrice daily on the day 3; thereafter the dose may be increased in increments of 300 mg daily in every 2-3 days adjusted according to response (MAX. 3.6 g/day).
Cautions Diabetes mellitus, elderly, history of psychotic illness, mixed seizures.
Side Effects Abdominal pain, abnormal reflexes, abnormal thoughts, acne, amnesia, anorexia, anxiety, arthralgia, ataxia, confusion, constipation, convulsions, cough, depression, diarrhoea, dizziness, drowsiness, dry mouth, dyspnea, fever, flatulence, flu syndrome, gingivitis, headache, hypertension, impotence, increased appetite, insomnia, leucopenia, malaise, movement disorders, myalgia, nausea, nervousness, nystagmus, oedema, paraesthesia, pharyngitis, pruritus, rash, rhinitis, speech disorder, tremor, twitching, vasodilatation, vertigo, visual disturbances, vomiting, weight gain.
Renal impairment Reduce dose to 0.6–1.8 g daily in 3 divided doses if GFR 50–80 mL/min. Reduce dose to 300–900mg daily in 3 divided doses if GFR 30–50 mL/min. Reduce dose to 300mg on alternate days (up to max. 600mg daily) in 3 divided doses if GFR 15–30 mL/min. Reduce dose to 300mg on alternate days (up to max.300mg daily) in 3 divided doses if GFR < 15 mL/min.
Pregnancy category C
Breast-feeding Excreted in breast milk, use with caution.
Counselling *Do not drive or operate machinery. Do not drink alcohol.*

LAMOTRIGINE

Tablet, 50 mg NRH/RRH

Therapeutic group Antiepileptic.
Indications and dose **Treatment of partial seizures, and primary and secondarily generalised tonic-clonic seizures; seizures associated with Lennox-Gastaut syndrome Monotherapy** ADULT and CHILD (12 years and above) Initially 25 mg *PO,* Q24H x 14 days, then increase to 50 mg *PO,* Q24H x 14 days, and then increase by max of 50-100 mg, Q24 x H7-14 days; up to 500 mg, Q12H. **Adjunctive therapy with valproate** ADULT and CHILD (over 12 years): Initially 25 mg *PO,* alternate Q24H x 14 days, then 25 mg *PO,* Q24H x 14 days, thereafter increase by max of 25-50 mg, Q24H x 7-14 days; usual maintenance dose, 100-200 mg daily in 1-2 divided doses; CHILD (2-11 years): Initially 0.15 mg/kg *PO,* Q24H x 14 days, then 0.3 mg/kg Q24H x 14 days, thereafter increased by maximum of 0.3 mg/kg, Q24H x 7-14 days; usual maintenance 1-5 mg/kg, Q24H to Q12H (max. 200 mg/day). **Adjunctive therapy without valproate** ADULT and CHILD (12 years and above): Initially 50 mg *PO,* Q24H x 14 days, then 50 mg *PO,* Q12H x 14 days, thereafter increase by max. of 100 mg, Q24H x 7-14 days; usual maintenance 200-400 mg, Q12H (up to 700 mg daily); CHILD (2-11 years): Initially 0.3 mg/kg *PO,*Q12H x 14 days, then 0.6 mg/kg, Q12H x 14 days, thereafter increased by maximum of 1.2 mg/kg, Q24H x 7-14 days; usual maintenance 5-15 mg/kg, Q12H (max. 400 mg/day.
Cautions Myoclonic seizures, Parkinson's disease.
Side effects Blurred vision, aggression, agitation, arthralgia, ataxia, back pain, diarrhoea, diplopia, dizziness, drowsiness, dry mouth, headache, insomnia, nausea, nystagmus, rash, tremor, vomiting; serious skin reactions including Stevens Johnson syndrome and toxic epidermal necrolysis (rarely with fatalities) have been reported in children.
Hepatic impairment Halve dose in moderate impairment, quarter dose in severe impairment.
Renal impairment Consider reducing maintenance dose in significant impairment, caution in renal failure.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.

LEVETIRACETAM

Tablet, 500 mg NRH/RRH

Therapeutic group Antiepileptic.
Indications and dose **Monotherapy for partial seizures with or without secondary generalisation** ADULT and CHILD (over 16 years): Initially 250 mg *PO,* Q12H, increasing according to response to 500 mg, Q12H after 2 weeks; max. 3 g/day; CHILD (4-15 years or body weight over 50 kg): Initially 10 mg/kg *PO,* Q12H (max. 30 mg/kg/dose, Q12H). **Adjunctive therapy in partial seizure, myoclonic seizure, and general tonic-clonic seizure** ADULT and CHILD (over 12 years & body weight > 50 kg): 250 mg *PO,* Q12H, adjusted in steps of 500 mg, Q12H x Q 2-4 weeks (max. 3 g/day); CHILD (12-18 years and body weight < 50 kg): Initially 10 mg/kg *PO,* Q12H, adjusted in steps of 10 mg/kg, Q12H x Q 2 weeks; max. 30 mg/kg twice daily.
Side effects Abdominal pain, aggression, anorexia, anxiety, ataxia, convulsion, cough, depression, diarrhoea, dizziness, drowsiness, dyspepsia, headache, insomnia, irritability, malaise, naso-pharyngitis, nausea, rash, tremor, vertigo, vomiting.
Hepatic impairment No adjustment required.
Renal impairment Reduce dose if GFR rate > 80 mL/minute.
Pregnancy category C
Breast-feeding Excreted in breast milk, avoid.
Counseling Do not drive or operate machinery. This medicine is to be taken whole after meals preferably.

LORAZEPAM

Tablet, 1 mg NRH

Therapeutic group Antiepileptic.

Indications and dose **Seizure** (*Adjunct in intractable partial complex seizures*) ADULT: 1 mg PO twice daily increasing twice weekly until seizures decreased or toxicity occurred; CHILD (*Treatment of serial seizures*): 1 to 4 mg sublingually; onset generally observed within 15 minutes (5 to 60 minutes).
Contraindications Chronic psychosis, CNS depression, compromised airway, hyperkinesis, obsessional states, phobic states, respiratory depression.
Cautions Muscle weakness, organic brain changes, personality disorder.
Side effects Amnesia, ataxia (especially in elderly), confusion (especially in the elderly), dependence, drowsiness the next day, lightheadedness the next day, muscle weakness, paradoxical increase in aggression.
Hepatic impairment May precipitate coma. Avoid in severe impairment.
Renal impairment Start with small doses in severe impairment.
Pregnancy category D
Breastfeeding Excreted in breast milk, avoid.
Counselling drowsiness may affect performance of skilled tasks, avoid driving or operating machinery.

MAGNESIUM SULPHATE

Injection, 50% (2 mL) NRH/RRH/DH

Therapeutic group Antiepileptic.
Indications and dose **Treatment of seizures and prevention of recurrent seizures in eclampsia,** *by IV injection*, initially 4 g over 5-15 minutes followed either *by IV infusion,* 1 g/hour for at least 24 hours after the last seizure or delivery (whichever occurs later). **Prevention of seizures in pre-eclampsia,** *by IV injection*, initially 4 g over 5-15 minutes followed by *IV infusion,* 1 g/hour for 24 hours*;* if seizure occurs, give an additional dose *by IV injection* of 2 g. **Mild hypomagnesaemia,** deep IM injection, 1 g every 6 hourly for 4 doses. **Severe hypomagnesaemia,** by IV infusion, 5 g IV over 3 hours.
Note *for IV injection, concentration of magnesium sulphate should not exceed 20% (dilute 1 part of magnesium sulphate injection, 50%, with at least 1.5 parts of water for injections); for IM injection, mix magnesium sulphate injection, 50%, with 1 mL of lignocaine injection 2%. Monitor renal function, blood pressure, respiratory rate and deep tendon reflex.*
Contraindications myocardial damage, heart block, diabetic coma, hypermagnesemia, hypercalcemia.
Cautions digitalized patients, myasthenia gravis and other neuromuscular diseases.
Side effects respiratory depression, oliguria, neuromuscular depression and muscle weakness.
Renal impairment Do not exceed 20 g in 48 hours, increased risk of toxicity.
Pregnancy category A or C
Breast-feeding Compatible, infant risk is minimal.

MIDAZOLAM

Injection, 1 mg/mL (10 mL) NRH/RRH/DH

Therapeutic group Antiepileptic.
Indications and dose **Status epilepticus** ADULT: 10 mg IM in the mid-outer thigh (vastus lateralis muscle). **Refractory status epilepticus** ADULT: 0.2 mg/kg IV (via slow bolus injection) followed by 0.75 to 10 mcg/kg/min maintenance infusion (off-label dosage) OR 0.2 mg/kg IM (off-label dosage); CHILD: 0.2 mg/kg IV bolus followed by a continuous IV infusion starting at 2 mcg/kg/min and increasing at 5-minute intervals until seizure control (MAX, 10 mcg/kg/min); continue infusion for at least 6 hours after seizure control, then gradually taper over 12 to 24 hours; increase infusion rate for seizure recurrence. *For detail, refer page no. 15.*

PHENOBARBITAL

Injection, 200 mg/mL (1 mL) NRH/RRH/DH
Tablet, 30 mg NRH/RRH/DH/PHC

Therapeutic group Antiepileptic.
Indications and doses **All forms of epilepsy except absence seizures** ADULT: 60-180 mg *PO* at night; CHILD: 5-8 mg/kg *PO,* Q24H; **Control of acute seizures** 200 mg *IM injection*, Q6H if necessary; CHILD: 15 mg/kg STAT; **Status**

epilepticus ADULT: 10 mg/kg *IV injection* at a rate of not more than 100 mg/min; max 1 g; CHILD (1 month-11 years): Initially 20 mg/kg *slow IV injection* administered at a rate no faster than 1 mg/kg/min, then 2.5-5 mg/kg, Q24H to Q12H; CHILD (12-17 years) Initially 20 mg/kg (max. per dose 1 g) *slow IV injection* administered at a rate no faster than 1 mg/kg/minute, then 30 mg Q12H.
For IV injection, dilute injection 1 in 10 with water for injection.
Contraindications Porphyria.
Cautions Elderly, debilitated, children, impaired renal (avoid large doses) and hepatic function (may precipitate coma), respiratory depression, pregnancy and breastfeeding, avoid sudden withdrawal.
Side effects Drowsiness, lethargy, depression, ataxia and allergic skin reactions; paradoxical excitement, restlessness and confusion in the elderly and hyperkinesia in children, megaloblastic anaemia.
Hepatic impairment May precipitate coma, avoid in severe impairment.
Renal impairment Use with caution.
Pregnancy category D
Breast-feeding Excreted in milk, avoid.
Counselling Do not drive or operate machinery. Do not drink alcohol.

PHENYTOIN

Injection, 50 mg/mL (2 mL) NRH/RRH/DH
Tablet/Capsule 100 mg NRH/RRH/DH/PHC

Therapeutic group Antiepileptic.
Indications and doses **All forms of epilepsy except absence seizures** ADULT: Initially 100-200 mg *PO,* Q24H to Q12H, increased slowly to usual dose of 800-1200 mg/day in divided doses; in some cases, higher doses may be needed; ELDERLY: Reduce initial dose; CHILD (1 month -11 years): Initially 1.5-2.5 mg/kg *PO,* Q12H, then adjusted according to response to 2.5-5 mg/kg, Q12H (max. per dose 7.5 mg/kg, Q12H); CHILD (12-17 years): Initially 75-150 mg *PO,* Q12H, then adjusted according to response to 150-200 mg, Q12H (max. per dose 300 mg, Q12H). **Status epilepticus** *by slow IV injection or infusion*, ADULT and CHILD (more than 12 years): 15 mg/kg (max. 2 g/dose) loading dose (at a rate not exceeding 1mg/kg/min), then 100 mg *slow IV injection* or *PO,* Q6-8H; CHILD (1 month-11 years) 15 mg/kg loading dose, then 2.5-5 mg/kg *slow IV injection,* Q12H.
Contraindications Acute porphyrias, with IV use (Second- and third-degree heart block, sino-atrial block, sinus bradycardia).
Cautions Enteral feeding, Heart failure, hypotension, alkaline injection solutions, respiratory depression.
Side effects GI disturbances including constipation, CNS symptoms including ataxia and confusion, Stevens-Johnson syndrome, visual disturbances (diplopia) are often associated with peak plasma concentrations. Generalized erythematous rash occasionally, gingival hypertrophy and many other symptoms have been reported with high doses.
Hepatic impairment Reduce dose to avoid toxicity.
Pregnancy category D
Breast-feeding Excreted in milk, use with caution.
Counselling Do not drive or operate machinery. Do not drink alcohol.

SODIUM VALPROATE

Tablet, 200 mg NRH/RRH/DH
Injection, 500 mg/mL (5 mL) NRH/RRH

Therapeutic group Antiepileptic.
Indications and doses **All forms of Epilepsy** ADULT and CHILD (12 years and above): Initially, 600 mg *PO,* Q12H, increasing by 200 mg/day at 3-day intervals to a max of 2.5 g daily in divided doses; CHILD (1 month-11 years): Initially 10-15 mg/kg, PO, Q12H to Q8H to a max. 600 mg daily. **Absence Seizures, Complex Partial seizure** ADULT: 10-15 mg/kg/day IV divided Q12hr infused over 1 hours; may increase dose by 5-10 mg/kg/day at 1-week intervals to a max. of 60 mg/kg/day; do not exceed 14 days.
Contraindications Active liver disease, family history of severe hepatic dysfunction, pregnancy.

Cautions Monitor liver function before therapy and during the first 6 months, benefit of treatment outweighs risk in pregnancy, folic acid supplement is however needed, monitor platelet function before surgery, may give false positive test for ketonuria in diabetes.
Side effects Gastric irritation and nausea, ataxia and tremor, transient hair loss, increased appetite, thrombocytopenia, impaired liver function (withdraw immediately if evidence of hepatitis).
Hepatic impairment Avoid in active liver disease.
Renal impairment Reduce dose.
Pregnancy category D
Breast-feeding Excreted in milk, use with caution.
Counselling Do not drive or operate machinery. Do not take alcohol. Take the tablet whole, preferably after food.

6. ANTI-INFECTIVE MEDICINES

6.1 Anthelmintic

6.1.1 Intestinal anthelmintics

ALBENDAZOLE

Tablet (chewable), 400 mg NRH/RRH/DH/PHC

Therapeutic group Anthelmintic.
Indications and dose **Roundworms, pinworm, whipworm and hookworm infestations** ADULT and CHILD (>2 years): 400 mg *PO,* STAT. **Strongyloides and tapeworm infestation** ADULT and CHILD (>2 years): 400 mg *PO,* Q24H x 3 days. ***Echinococcus granulosus*** ADULT and CHILD (above 2 years): 10mg/kg/day x 4-8 weeks; **Neurocysticercosis** ADULT: 400 mg *PO,* Q12H x 30 days; CHILD (1-2 years): Half the adult dose. **Hydatid cyst** ADULT (>60 kg): 400 mg *PO,* Q12H x 28 days; repeat after two weeks for up to 3 cycles; ADULT (<60 kg) and CHILD (less than 6 years): 7.5 mg/kg *PO,* Q12H (max. 400 mg per dose) x 28 days; repeat after two weeks for up to 3 cycles.
Contraindications Pregnancy before twelve weeks.
Cautions Liver function tests and blood counts before treatment and twice during each cycle (prolonged treatment).
Side effects GI disturbances, headache, dizziness, increase in liver enzymes, reversible alopecia.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.
Counselling Tablets should be chewed/crushed thoroughly and washed down with water. Patients should be advised to take it in an empty stomach if it is a single dose. For systemic infestation such as neurocysticercosis, it should be taken with food for better absorption.

NICLOSAMIDE

Tablet (chewable), 500 mg NRH/RRH/DH/PHC

Therapeutic group Intestinal anthelmintic.
Indications and dose ***Taenia solium*** ADULT and CHILD (over 6 years): 2 g *PO,* STAT on empty stomach followed by magnesium sulphate solution after 2 hours; CHILD (under 2 years): 500 mg *PO,* STAT*;* CHILD (2-6 years): 1000 mg *PO,* STAT. ***Taenia saginata and Diphyllobothrium latum*** As above but half of the dose on empty stomach and remainder one hour later, followed by a purgative 2 hours after the last dose. ***Hymenolepis nana*** ADULT and CHILD (over 6 years): 2 g *PO,* STAT on first day and then 1 g, Q24H x 6 days; CHILD (under 2 years): 500 mg *PO,* STAT on first day and then 250 mg, Q24H x 6 days; CHILD (2-6 years): 1 g *PO,* STAT on first day, then 500 mg, Q24H x 6 days.
Cautions Chronic constipation, a laxative should be given the night before treatment, or a purgative 2 hours after the medication.
Side effects Light-headedness, pruritus, mild GI disturbances.
Counselling Tablets should be chewed thoroughly (or crushed) before washing down with water.

6.1.2 Antifilarials

ALBENDAZOLE

Tablet (chewable), 400 mg — NRH/RRH/DH/PHC

Therapeutic group Anthelmintic.
Indications and dose **Lymphatic filariasis** 400 mg alone twice per year for areas co-endemic with Loiasis. 400 mg with ivermectin 200 mcg/kg in countries with onchocerciasis. 400 mg and diethylcarbamazine citrate (DEC) 6 mg/kg in countries without onchocerciasis. *For details, refer to page no. 36.*

6.2 Antibacterial

6.2.1 Access group antibiotics

AMOXICILLIN

Capsule/Tablet, 250 mg — NRH/RRH/DH/PHC
Syrup, 125 mg/mL (60 mL) — NRH/RRH/DH/PHC

Therapeutic group Antibacterial**.**
Indications and dose **Urinary tract infections, otitis media, sinusitis, PID, cholera, cholecystitis, peritonitis, bronchitis, pneumonia, dental abscess and other infections depending on culture sensitivity report** ADULT: 250-500 mg *PO,* Q8H, doubled in severe infections; ADULT (under 40 kg): 20-40 mg/kg/day, Q8H, or 25-45 mg/kg/day, Q12H; CHILD (up to 10 years): 125-250 mg *PO,* Q8H; INFANTS (less than 3 months): Max. dose 30 mg/kg/day, Q12H.
Cautions Acute lymphocytic leukaemia (increased risk of erythematous rashes), chronic lymphocytic leukaemia (increased risk of erythematous rashes), cytomegalovirus infection (increased risk of erythematous rashes), glandular fever (erythematous rashes common).
Side effects Nausea, vomiting, headache, diarrhoea, rash.
Renal impairment CrCl=10-30 mL/minute: 250-500 mg, Q12H; CrCl <10 mL/minute: 250-500 mg, Q24H.
Pregnancy category B
Breast-feeding Excreted in breast milk, use with caution.

AMOXICILLIN + CLAVULANIC ACID

Powder for injection, 500 mg/100 mg — NRH/RRH/DH

Therapeutic group Antibacterial.
Indications and dose **Erysipelas and cellulitis** ADULT: 1 g *IV injection,* Q8H; CHILD (under 3 months): 25 mg/kg *IV injection,* Q12H; CHILD (3 months and over): 25 mg/kg *IV injection,* Q8H; **Necrotizing infections** ADULT and CHILD (40 kg and over): 2 g *IV injection,* Q8H; CHILD (under 3 months): 50 mg/kg *IV injection,* Q12H; CHILD (3 months and over and < 40 kg): 50 mg/kg *IV injection,* Q8H. **Upper genital tract infection** ADULT: 1 g *IV injection,* Q8H.
Contraindications History of hypersensitivity to beta-lactam antibiotics, hepatic dysfunction.
Cautions Increased risk of hepatic dysfunction in elderly and/or males and with prolonged treatment; prolonged use may result in fungal or bacterial superinfection, including *C. difficile*-associated diarrhoea (CDAD) and pseudomembranous colitis.
Side effects Diarrhoea, nausea, vomiting, hepatic disorders, hypersensitivity reactions (anaphylaxis, angioedema, and urticaria).
Renal impairment CrCl=10-30: Q12H; CrCl<10 mL/min: Q24H.
Pregnancy category B

AMPICILLIN

Powder for injection, 500 mg — NRH/RRH/DH/PHC

Therapeutic group Antibacterial.

Indications and dose **Endocarditis** ADULT: 2 g *IV injection,* Q4H; CHILD: 50 mg/kg *IV injection,* Q6H. **Meningitis** ADULT: 2 g *IV injection,* Q4H; NEONATE: 50 mg/kg *IV injection,* Q6H; CHILD (3-12 years): 100 mg/kg *IV injection,* Q6H (max 12 g daily). **Septicaemia** ADULT: 500 mg *Iv injection,* Q4H to Q6H; CHILD (under 10 years): half the adult dose; NEONATE: 25 mg/kg *IV injection,* Q8H. **Peritonitis and cholangitis** ADULT: 500 mg *IV injection,* Q6H. **Pneumonia** NEONATE: 30 mg/kg *IV injection,* Q12H; CHILD (4 months-5 years): 200 mg/kg *IV injection,* Q6H.
Cautions History of allergy; renal impairment, erythematous rashes are common in patients with infectious mononucleosis, chronic lymphatic leukaemia and HIV.
Side effects Nausea, vomiting, diarrhoea, rashes (discontinue treatment).
Renal impairment CrCl >50 mL/minute: Q6H; CrCl=10-50 mL/minute: Q6-12H; CrCl <10 mL/minute: Q12-24H.
Pregnancy category B
Breast-feeding Excreted in milk, use with caution.
IV fluid compatibility Dextrose 5%, sodium chloride 0.9%.

BENZATHINE BENZYLPENICILLIN

Powder for injection, 1.44 g (2.4 million IU) NRH/RRH/DH/PHC

Therapeutic group Antibacterial.
Indications and dose **Primary syphilis** ADULT: 2.4 g *deep IM,* on two successive days; **Late syphilis** ADULT: 2.4 g *deep IM,* weekly for 3 weeks. **Prophylaxis of rheumatic fever** ADULT: 1.2 g *deep IM*, 3 weekly; CHILD (<10 years): Half the ADULT dose. **Congenital syphilis** (for infants born to seropositive mothers): 50000 IU/kg as a single dose
Note Do not administer IV, intra-arterial or subcutaneous.
Cautions Allergy (a test dose should be given); renal impairment, pregnancy, Breast-feeding and in hypertensive patients as it contains sodium.
Side effects Maculopapular eruptions, exfoliative dermatitis, urticarial, oedema, chills, fever, arthralgia, Jarsch-Herxheimer reaction, pseudomembranous colitis.
Pregnancy category B
Breast-feeding Excreted in milk, use with caution.

BENZYLPENICILLIN (Penicillin G)

Powder for injection, 3 g (5 million IU) NRH/RRH/DH/PHC

Therapeutic group Antibacterial.
Indications and dose **Mild to moderate susceptible infections; Throat infections; Otitis media; Cellulitis; Pneumonia** ADULT: 2 million IU *IV injection or infusion,* Q4H; CHILD: 0.15-0.2 million IU/kg/day *IV injection or infusion,* Q4H (max 20 million IU/day). **Bites and peritonitis** ADULT: 1 million IU *slow IV injection,* Q6H. **Neurosyphilis** ADULT: 1.2-2.4 million IU *slow IV injection,* Q4H; **Meningitis gonococcal** ADULT: 2.4 g *slow IV injection or infusion,* Q4H; CHILD: 50 mg/kg *IV infusion,* Q4-6H (max. per dose 2.4 g, Q4H).
Contraindication Avoid intra-arterial routes.
Cautions Accumulation of sodium can occur with high doses, history of allergy.
Side effects Anaphylaxis, angioedema, fever, hypersensitivity reactions, joint pains, rashes, serum sickness-like reaction, urticaria.
Renal impairment CrCl >10mL/min, full loading dose followed by half of the loading dose, Q4-5H; CrCl <10mL/min, full loading dose followed by half of the loading dose, Q8-10H.
Pregnancy category B
Breast-feeding Excreted in milk, compatible.
IV fluid compatibility Dextrose 5%, sodium chloride 0.9%.

CEPHALEXIN

Tablet/Capsule, 250 mg NRH/RRH/DH

Therapeutic group Antibacterial.

Indications and dose **Sensitive infections like urinary tract infections, skin and soft tissue infections, bone infections, biliary tract infections, intra-abdominal infections** by oral administration, ADULT: 500mg 12 hourly; CHILD: under 1 year, 125mg 12 hourly; CHILD: 1-5 years, 125mg 8 hourly; CHILD: 6-12 years, 250mg 8 hourly; doses should be doubled in severe infections.
Contraindications cephalosporin hypersensitivity.
Cautions penicillin hypersensitivity, renal impairment, false positive urinary glucose if tested for reducing substances, false positive Coombs' test.
Side effects diarrhoea, colitis, nausea and vomiting, allergic manifestations including rashes, pruritus and urticaria, also fever, arthralgia and anaphylaxis, abdominal discomfort, headache, erythema multiforme, toxic epidermal necrolysis, disturbances in liver enzymes, transient hepatitis and cholestatic jaundice.
Renal Impairment CrCl 10-50 mL/minute: 500 mg every 8-12 hours; CrCl <10: 250-500 mg every 12-24 hours.
Pregnancy category B
Breast feeding excreted in milk (small amount), use caution.
Counselling Complete with full course of treatment.

CEFAZOLIN

Powder for injection, 500 mg NRH/RRH/DH

Therapeutic group Antibacterial.
Indications and dose **Respiratory and genito-urinary tract infections that do not respond to penicillins; Skin and soft tissue; Bone and joint infections; septicaemia; Surgical prophylaxis; Endocarditis** ADULT: 500-1000 mg *IM or IV injection,* Q6-12H; CHILD: 25-50 mg/kg/day *IM or IV injection*, Q6-8H, increased to 100 mg/kg/day in severe infections.
Cautions Renal impairment**,** prolonged treatment.
Side effects Anorexia, diarrhoea, fever, eosinophilia, leukopenia, nausea and vomiting, pain at injection site, neutropenia, oral candidiasis.
Hepatic impairment Use with caution.
Renal impairment CrCl=35-54 mL/minute: Full dose Q8H; CrCl=11-34 mL/minute: Half dose, Q12H; CrCl=10 mL/minute: Half dose, Q18-24H.
Pregnancy category B
Breast-feeding Excreted in milk, use with caution.
IV fluid compatibility Dextrose 5%, Dextrose 5% sodium chloride 0.9%, compound solution of sodium lactate, sodium chloride 0.9%.

CHLORAMPHENICOL

Powder for injection, 1 g NRH/RRH/DH

Therapeutic group Antibacterial.
Indications and dose **Life threatening infections particularly those caused by *Haemophilus influenzae;* Typhoid fever** ADULT: 12.5 mg/kg *IV injection or IV infusion,* Q6H; in exceptional cases dose can be doubled for severe infections such as septicaemia and meningitis, providing high doses reduced as soon as clinically indicated; CHILD: 12.5 mg/kg *IV injection or IV infusion,* Q6H; dose may be doubled in severe infections such as septicaemia, meningitis and epiglottitis providing plasma-chloramphenicol concentrations are measured and high doses reduced as soon as indicated.
Contraindications Acute porphyrias, breastfeeding.
Cautions Acute porphyrias, G6PD deficiency, monitor complete blood count before and during treatment.
Side effects Blood disorders, depression, diarrhoea, dry mouth, erythema multiforme, glossitis, headache, nausea, nocturnal haemoglobinuria, optic neuritis, peripheral neuritis, reversible and irreversible aplastic anaemia (with reports of resulting leukaemia), stomatitis, urticaria, vomiting.
Hepatic impairment Reduce dose. Avoid if possible-increased risk of bone-marrow depression.
Renal impairment Avoid in severe renal impairment unless no alternative, dose-related depression of haematopoiesis.

Pregnancy category C
Breast-feeding Excreted in milk, avoid.
IV fluid compatibility Dextrose 5%, compound solution of calcium lactate, sodium chloride 0.9%.
Note *Associated with serious haematological side effects when given systemically and should therefore be reserved for the treatment of life-threatening infections.*

CLOXACILLIN

Capsule, 250 mg — NRH/RRH/DH
Powder for injection, 250 mg — NRH/RRH/DH

Therapeutic group Antibacterial.
Indications and dose **Osteomyelitis; Septic arthritis; Staphylococcal endocarditis** ADULT: 2 g *slow IV or infusion or, PO,* Q6H; CHILD, 50 mg/kg 6 hourly. **Brain abscess and meningitis** ADULT: 2 g *slow IV or infusion,* Q4H; **Cellulitis and paronychia nail infection.** ADULT: 250-500 mg *PO,* Q6H; CHILD (up to 2 years): 1/4th of the adult dose; CHILD (2-10 years): Half the adult dose.
Contraindications Jaundice in neonates.
Cautions History of allergy, renal impairment, hepatic disease.
Side effects Nausea and vomiting, diarrhoea, hypersensitivity reactions including urticaria, fever, joint pain, rash, angioedema, anaphylaxis, serum sickness-like reactions, haemolytic anaemia, and interstitial nephritis, neutropenia, thrombocytopenia, coagulation disorders, rarely antibiotic-associated colitis, hepatitis and cholestatic jaundice (may be delayed in onset), electrolyte disturbances, pain, inflammation, phlebitis, or thrombophlebitis at injection sites.
Hepatic impairment dose adjustment required.
Renal impairment Use with caution; rate of elimination is reduced.
Pregnancy category B
Breast-feeding Excreted in milk, use with caution.
Counselling Take the medicine at least half an hour before food.

SULFAMETHOXAZOLE + TRIMETHOPRIM (Co-trimoxazole)

Tablet, (400 mg + 80 mg) — NRH/RRH/DH/PHC
Syrup, (200 mg + 40 mg)/5mL (60 mL) — NRH/RRH/DH/PHC

Therapeutic group Antibacterial.
Indications **Upper respiratory infections; urinary tract infection; pneumonia** ADULT: 960 mg *PO,* Q12H; CHILD (over 5 years): 480 mg *PO,* Q12H; CHILD (6 months-5 years): 240 mg *PO,* Q12H; CHILD (6 weeks-6 months): 120 mg *PO,* Q12H. **Prophylaxis of *Pneumocystis jiroveci* pneumonia in HIV patients** ADULT: 960 mg *PO,* Q24H.
Contraindications Porphyria, pregnancy at term, infants under 6 weeks old, CrCl<15mL/min, severe hepatic impairment, megaloblastic or folate deficiency anaemia.
Cautions G6PD deficiency, renal or hepatic impairment, thyroid dysfunction, asthma, elderly patients, maintain adequate fluid intake.
Side effects Anorexia, Nausea, vomiting, vertigo, seizure, rashes, urticarial, toxic epidermal necrolysis, hyponatremia, agranulocytosis, aplastic anaemia, neutropenia, thrombocytopenia, anaphylaxis.
Renal Impairment CrCl=15-30 mL/minute: administer 50% of recommended dose, CrCl <15 mL/minute: not recommended.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.
Counselling Drink plenty of fluids with this medicine.
Note *In case of bacillary dysentery, oral rehydration remains the first requirement of treatment; mild cases may be prolonged by antibiotic treatment.*

DOXYCYCLINE

Tablet/Capsule, 100 mg — NRH/RRH/DH/PHC

Therapeutic group Antibacterial.
Indications and dose **Susceptible infections (e.g. chlamydia, rickettsia and mycoplasma)** ADULT: 200 mg *PO* on the first day, then 100mg *PO,* Q24H. **Severe infections** 200 mg *PO,* Q24H; **Early syphilis** ADULT: 100 mg *PO,* Q12H x 14 days. **Late latent syphilis** 200 mg *PO,* Q12H x 28 days. **Uncomplicated genital chlamydia; non-gonococcal urethritis** 100 mg *PO,* Q12H x 7 days (14 days in PID). **Acne** ADULT and CHILD (>12 years): 100 mg *PO,* Q24H.
Contraindications Children under 12 years, systemic lupus erythematosus.
Cautions Alcohol dependence patients.
Side effects Anorexia, anxiety, dry mouth, flushing, diarrhoea, dysphagia, and oesophageal irritation.
Pregnancy category D
Breast-feeding Excreted in breast milk, avoid.
Counselling Take this medicine with plenty of fluid during meals to reduce gastric irritation. Avoid exposure of skin to direct sunlight. Avoid oral iron preparations and antacids.

GENTAMICIN

Injection, 40 mg/mL (2 mL) NRH/RRH/DH/PHC

Therapeutic group Antibacterial.
Indications and dose **Gram-positive bacterial endocarditis or HACEK endocarditis (in combination with other antibacterial)** ADULT: 1 mg/kg *IM, or slow IV injection or IV infusion,* Q12H administered over at least 3 minutes. **Septicaemia; Meningitis and other CNS infections; Biliary tract infection; Acute pyelonephritis; Endocarditis; Pneumonia in hospital patients; Adjunct in listeria meningitis; Prostatitis** ADULT: Initially 5-7 mg/kg *IV infusion*, administered as once daily dose regimen; CHILD: Initially 7 mg/kg *IV infusion*, to be given in a once daily regimen (not suitable for endocarditis or meningitis). **Surgical prophylaxis** ADULT: 1.5 mg/kg *IV injection* administered over at least 3 minutes and 30 minutes before the procedure; dose repeated Q8H for high-risk procedures and up to 3 further doses may be given. **Pseudomonas infection in cystic fibrosis** CHILD: 3 mg/kg *slow IV injection over at least 3 minutes or IV infusion,* Q8H as a multiple daily dose regimen.
Contraindications Myasthenia gravis.
Cautions Care must be taken with dosage (the main side effects of the aminoglycosides are dose-related), conditions characterised by muscular weakness, if possible, dehydration should be corrected before starting an aminoglycoside, whenever possible. Parenteral treatment should not exceed 7 days; risk of ototoxicity, neurotoxicity and nephrotoxicity, renal failure.
Side effects Neurotoxicity (vertigo, ataxia), ototoxicity (auditory and vestibular), nephrotoxicity (decreased CrCl), oedema, rash, itching, drowsiness, headache, antibiotic-associated colitis, electrolyte disturbances, nausea, peripheral neuropathy, stomatitis, vomiting.
Renal impairment **Conventional dosing** CrCl >90 mL/min and 60 years: Q8H; CrCl = 60-90 mL/min: Q12H; CrCl=25-60 mL/min: Q24H; CrCl=10-25 mL/min: Q48H; CrCl <10 mL/minute: Q72H. **Once daily dose** ADULT and CHILD (above 1 year): Avoid, if CrCl <20 mL/ minute.
Pregnancy category D
Breast-feeding Excreted in milk, use with caution.
IV fluid compatibility Dextrose 5%, sodium chloride 0.9%.

METRONIDAZOLE

Injection, 5 mg/mL (100 mL) NRH/RRH/DH
Tablet, 400 mg NRH/RRH/DH/PHC

Therapeutic group Antibacterial and antiprotozoal.
Indications and dose **Anaerobic infections** ADULT: 400 mg *PO,* Q8H x 7-10 days; 500 mg *IV infusion administered over 20 minutes,* Q8H x 7 days (for 10-14 days in *Clostridium difficile* infection); CHILD (2 months-11 years): 7.5 mg/kg *PO,* Q8H (max.400 mg/dose) x 7 days; 7.5 mg/kg *IV infusion,* Q8H (max. 500 mg/dose) x 7 days (for 10-14 days in *Clostridium difficile* infection). **Invasive intestinal amoebiasis; Extra-intestinal amoebiasis (including liver abscess)** ADULT: 800 mg *PO,* Q8H; CHILD (1-2 years): 200 mg *PO,* Q8H x 7 days; CHILD (3-6 years): 200 mg *PO,*

Q6H; CHILD (7-9 years): 400 mg *PO,* Q8H; * *5 days for intestinal infection and 5-10 days in extra-intestinal infection.* **Urogenital trichomoniasis** ADULT: 200 mg *PO,* Q8H x 7 days, alternatively 2 g, STAT; CHILD (1-2 years): 50 mg *PO,* Q8H x 7 days; CHILD (3-6 years): 100 mg *PO,* Q12H x 7 days; CHILD (7-9 years): 100 mg *PO,* Q8H x 7 days. **Giardiasis** ADULT: 2 g *PO,* Q24H x 3 days, alternatively 400 mg, Q8H x 5 days; CHILD (1-2 years): 500 mg *PO,* Q24H x 3 days; CHILD (3-6 years): 600-800 mg *PO,* Q24H x 3 days; CHILD (7-9 years): 1 g *PO,* Q24H x 3 days. **Bacterial vaginosis (notably *Gardnerella vaginalis* infection)** ADULT: 400 mg *PO,* Q12 x 5-7 days, alternatively 2 g, STAT. **Acute ulcerative gingivitis** ADULT: 200 mg *PO,* Q8H x 3 days; CHILD (3-6 years): 100 mg *PO,* Q12H x 3 days; CHILD (7-9 years): 100 mg *PO,* Q8H x 3 days. **Acute oral infections** ADULT: 200 mg *PO,* Q8H x 3-7 days; CHILD (1-2 years): 50 mg *PO,* Q8H x 3-7 days; CHILD (3-6 years): 100 mg *PO,* Q12H x 3-7 days; CHILD (7-9 years): 100 mg *PO,* Q8H x 3-7 days. ***Helicobacter pylori* eradication; in combination with amoxicillin and omeprazole** ADULT: 400 mg *PO,* Q12H; CHILD (1-5 years): 100 mg *PO,* Q12H; CHILD (6-11 years): 200 mg *PO,* Q12H. **Pelvic inflammatory disease** ADULT and CHILD (12-17 years): 400 mg *PO,* Q12H x 14 days. **Surgical prophylaxis** ADULT: 400 mg *PO*, administered 2 hours before surgery, then 400 mg, Q8H if required for up to 3 doses (in high-risk procedures); 500 mg *IV infusion*, administered up to 30 minutes before the procedure, then 500 mg, Q8H if required for up to 3 further doses (in high-risk procedures); CHILD (1 month-11 years): 30 mg/kg (max. 500 mg/dose) *PO or IV infusion*, administered 2 hours before surgery.
Contraindications Hypersensitivity to nitroimidazoles, pregnancy (1st trimester), use of disulfiram within the past 2 weeks, use of alcohol during therapy or within 3 days of discontinuing therapy.
Cautions History of heart failure, renal impairment, severe hepatic impairment, pregnancy, breastfeeding.
Side effects Nausea, vomiting, unpleasant taste, GI disturbances, rashes, headache, dizziness, ataxia, darkening of urine, erythema multiforme, pruritus, urticaria, angioedema, and anaphylaxis, also reported abnormal liver function tests, thrombocytopenia, aplastic anaemia, myalgia, arthralgia, on prolonged or intensive therapy peripheral neuropathy, transient epileptic form seizures, and leukopenia.
Renal impairment CrCl <10mL/min: 50% of dose or Q12H.
Hepatic impairment In severe liver disease reduces the total daily dose to one-third, and administer once daily.
Pregnancy category B
Breast-feeding Excreted in milk, avoid.
Counselling Avoid alcohol intake and direct sunlight.
IV fluid compatibility Dextrose 5%, sodium chloride 0.9%.

NITROFURANTOIN

Tablet, 100 mg NRH/RRH/DH

Therapeutic group Antibacterial.
Indications and dose **Treatment of uncomplicated urinary-tract infections** ADULT and CHILD >12 years (*immediate-release*): 50-100 mg PO q6hr for 7 days or for 3 days after obtaining sterile urine; *Modified-release*: 100 mg PO q12hr for 7 days or for 3 days after obtaining sterile urine; CHILD (3 months-11 years): 3 mg/kg *PO,* Q6H x 3-7 days. **Prophylaxis of urinary-tract infection** ADULT: 50-100 mg *PO,* at night; CHILD (3 months-11 years): 1 mg/kg *PO,* at night.
Contraindications Renal impairment (CrCl <60 mL/minute), infants <3 months old (due to the possibility of haemolytic anaemia), pregnancy at term (38-42 weeks gestation), during labour and delivery, or when the onset of labour is imminent.
Cautions G6PD deficiency, in long-term therapy, anaemia, renal impairment, diabetes, vitamin B deficiency, electrolyte imbalance.
Side effects Anorexia, nausea, vomiting and diarrhoea are common, pulmonary reactions, peripheral neuropathy may occur, urticarial rash and pruritus, many other side effects have been noted.
Hepatic impairment Use with caution; cholestasis, jaundice and chronic active hepatitis reported.
Renal impairment Avoid in CrCl <60 mL/minute.
Pregnancy category B
Breast-feeding Excreted in small amounts, avoid.
Counselling Take some food or snack with every dose to avoid nausea and vomiting.

PHENOXYMETHYLPENICILLIN (Penicillin V)

Tablet, 250 mg — NRH/RRH/DH/PHC

Therapeutic group Antibacterial.
Indications and dose **Streptococcal infections; tonsillitis, otitis media, erysipelas; Pharyngitis caused by pneumococci and streptococci, gingivostomatitis; pneumococcal infections** ADULT: 500 mg *PO,* Q6H; CHILD (1-11 months): 62.5 mg *PO,* Q6H; CHILD (1-5 years): 125 mg *PO,* Q6H; CHILD (6-12 years): 250 mg *PO,* Q6H. **Secondary prophylaxis of rheumatic fever** ADULT: 500 mg *PO,* Q12H; CHILD (1-5 years): 125 mg *PO,* Q12H; CHILD (6-12 years): 250mg *PO,* Q12H.
Cautions Severe renal impairment, history with asthma, neonates, history of seizure disorders.
Side effects Diarrhoea, nausea and vomiting, oral candidiasis, seizures, anaemia, hypersensitivity.
Renal impairment CrCl=10-50 mL/minute: Q8-12H; CrCl<10 mL/minute: Q12-16H.
Pregnancy category B
Breast-feeding Excreted in breast milk, compatible.
Counselling Tablets should be taken at least 30 minutes before, or 2 hours after food.

6.2.2 Watch group antibiotics

CEFIXIME

Tablet, 200 mg — NRH/RRH

Therapeutic group Antibacterial.
Indications and dose **Respiratory tract infection** ADULT: 400 mg/day *PO,* Q24-12H. **Otitis media; Pharyngitis/tonsillitis; uncomplicated UTI** ADULT: 400 mg/day *PO,* Q24-12H; CHILD (6-12 months): 8 mg/kg/day *PO,* Q24-12H, *not to exceed 400 mg/day;* CHILD (>12 years): 400 mg/day *PO,* Q24H-12H. **Uncomplicated Gonorrhoea** ADULT: 400 mg PO once plus azithromycin 1 g PO once (preferred) or alternatively doxycycline 100 mg PO Q12hr for 7 days, if ceftriaxone unavailable.
Contraindications Hypersensitivity to beta lactams.
Cautions Renal impairment, pregnancy, breast-feeding.
Side effects Diarrhoea, colitis, nausea and vomiting, allergic manifestations including rashes, pruritus and urticaria, also fever, arthralgia and anaphylaxis, abdominal discomfort, headache, erythema multiforme, toxic epidermal necrolysis, disturbances in liver enzymes, transient hepatitis and cholestatic jaundice.
Renal impairment CrCl=21-60mL/min: 260mg/day; CrCl <20 mL/min: 200 mg.
Hepatic impairment Moderate dosage reduction is recommended in severe liver disease.
Pregnancy category B
Breast-feeding Excreted in milk, use with caution.

CEFOTAXIME

Powder for injection, 1 g — NRH/RRH

Therapeutic group Antibacterial.
Indications and dose **Infection due to sensitive gram-positive and gram-negative bacteria; Surgical prophylaxis; Haemophilia, Epiglottitis, Meningitis** (*preferred in neonate and preterm over ceftriaxone*) by IM or IV injection, ADULT: 1 g *IM or IV injection*, Q12H, increased up to 12 g/day, Q6-8H in severe infections; NEONATE: 50 mg/kg/day *IM or IV injection,* Q6-12H, increased to 150-200 mg/kg/day in severe infections; CHILD: 100-150 mg/kg/day *IM or IV injection*, Q6-12H, increased up to 200 mg/kg/day in very severe infections.
Cautions Penicillin hypersensitivity, renal impairment, false positive urinary glucose if tested for reducing substances, false positive Coombs' test.
Side effects History of colitis, renal impairment, concomitant use with other nephrotoxic medicines.
Renal impairment CrCl=10-50 mL/minute: Q8-12H; CrCl<10 mL/minute: Q24H.
Hepatic impairment Moderate dosage reduction in severe liver disease.
Pregnancy category B

Breast-feeding Excreted in milk, use with caution.
IV fluid compatibility Dextrose 5%, dextrose 5% sodium chloride 0.9%, Compound solution of sodium lactate, sodium chloride 0.9%.

CEFTRIAXONE

Powder for injection, 1 g — NRH/RRH
Powder for injection, 250 mg — NRH/RRH/DH/PHC

Therapeutic group Antibacterial.
Indications and dose **Meningitis; Pneumonia; Septicaemia** ADULT: 1 g *deep IM or IV injection over at least 2-4 minutes, or IV infusion*, Q24H; 2-4 g, Q24H in severe infections; IM doses over 1 g should be divided to more than one site; NEONATE: 20-50 mg/kg/day *IV infusion,* Q24H (max. 50 mg/kg/day); CHILD (under 12 years): 0.5-1 g *deep IM injection, or by IV injection over 2–4 minutes*, Q24H; *Doses of 50 mg/kg and over by IV infusion only.* **Surgical prophylaxis** ADULT: 1 g *IM or IV injection,* STAT administered before 30 minutes of procedure. ***250 mg injection:*** **Uncomplicated gonorrhoea** 250 mg *deep IM injection,* STAT.
Contraindications Concomitant calcium-ceftriaxone administration.
Cautions Dehydration (risk of ceftriaxone precipitation in gallbladder), treatment longer than 14 days, history of GI disease, breast-feeding women.
Side effects Induration after IM injection, eosinophilia, thrombocytosis, diarrhoea, rash, pain, induration at IV site, leukopenia.
Renal impairment In adults, if eGFR <10 mL/minute/1.73m^2: reduce dose (max. 2 g daily); in children, max. 50 mg/kg daily (max. 2 g/day) in severe renal impairment.
Pregnancy category B
Breast-feeding Excreted in milk, compatible.
IV fluid compatibility Dextrose 5%, sodium chloride 0.9%, water for injection.

CIPROFLOXACIN

Injection, 2 mg/mL (100 mL) — NRH/RRH/DH
Tablet, 500 mg — NRH/RRH/DH

Therapeutic group Antibacterial.
Indications and dose **Respiratory-tract infections** ADULT: 500 mg *PO,* Q12H; 400 mg *IV infusion,* Q8-12H administered over 60 minutes; CHILD: 20 mg/kg *PO,* Q12H (max. per dose 750 mg); 10 mg/kg *IV infusion,* Q8H (max. per dose 400 mg), administered over 60 minutes. **Pseudomonal lower respiratory-tract infection in cystic fibrosis** ADULT: 750 mg *PO*, Q12H; CHILD: 20 mg/kg *PO,* Q12H (max. per dose 750 mg). **Urinary-tract infections** ADULT: 25-750 mg *PO,* Q12H; 400 mg *IV infusion,* Q8-12H, administered over 60 minutes; CHILD: 10 mg/kg *PO,* Q12H, dose to be doubled in severe infection (max. 750 mg, Q12H); 6 mg/kg *IV infusion,* Q8H; increased to 10 mg/kg, Q8H (max. per dose 400 mg), in severe infection. **Acute uncomplicated cystitis in women** ADULT: 250 mg *PO,* Q12H x 3 days. **Acute or chronic prostatitis** ADULT: 500 mg *PO,* Q12H x 28 days; 400 mg *IV infusion,* Q8-12H administered over 60 minutes. **Anthrax (treatment and post-exposure prophylaxis)** ADULT: 500 mg *PO,* Q12H; 400 mg *IV infusion,* Q12H administered over 60 minutes; CHILD: 15 mg/kg *PO,* Q12H (max. per dose 500 mg); 10 mg/kg *IV infusion,* Q12H (max. per dose 400 mg). **Prevention of secondary case of meningococcal meningitis** CHILD (1 month-4 years): 30 mg/kg *PO,* STAT (max. per dose 125 mg); CHILD (5-11 years): 250 mg *PO,* STAT; CHILD (12-17 years): 500 mg *PO,* STAT. **Other infections** ADULT: Initially 500 mg *PO,* Q12H; increased to 750 mg, Q12H, in severe or deep-seated infection; 400 mg *IV infusion,* Q8-12H administered over 60 minutes.
Contraindications Tendinitis and tendon ruptures, peripheral neuropathy, history of myasthenia gravis.
Cautions Acute myocardial infarction, avoid excessive alkalinity of urine, bradycardia, congenital long QT syndrome, electrolyte disturbances, heart failure with reduced left ventricular ejection fraction, history of symptomatic arrhythmias.
Side effects Nausea, abdominal pain, diarrhoea, vomiting, headache, rashes; *with IV use*: flatulence, pain at injection site, phlebitis at injection site.
Hepatic impairment Use with caution.

Renal impairment CrCl 30-50 mL/min: 250-500mg *PO,* Q12H; CrCl 5-29 mL/min: 250-500 mg *PO,* Q18H or 200-400 mg *IV,* Q18-24H; Haemodialysis: 0.25-0.5 g *PO*, Q12H or 0.2-0.4 g *IV*, Q24H.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.
Counselling Advise patients to take medicine 2 hours before or after administration of antacids or products containing iron, calcium and zinc.
IV fluid compatibility Dextrose 5%, compound solution of calcium lactate, sodium chloride 0.9%.

CLARITHROMYCIN

Tablet, 250 mg NRH/RRH

Therapeutic group Antibacterial.
Indications and dose ***Helicobacter pylori* eradication in combination with a proton pump inhibitor and amoxicillin** ADULT: 500 mg *PO,* Q12H x 14 days; CHILD (1-5 years): 7.5 mg/kg *PO,* Q12H (max. per dose 500 mg); CHILD (6-11 years): 7.5 mg/kg *PO,* Q12H (max. per dose 500 mg).
Contraindications Hypersensitivity to macrolides, history of QT prolongation and cholestatic jaundice, co-administration with medicines which cause QT prolongation and statins.
Caution Renal impairment, hepatic dysfunction, pregnancy, myasthenia gravis.
Side effects General GI effects, Abnormal taste, diarrhoea, nausea and vomiting, abdominal pain, dyspepsia, headache, elevated liver enzymes, jaundice, leukopenia, neutropenia, pancreatitis, QT prolongation, seizures, rashes, Stevens-Johnson syndrome.
Renal Impairment CrCl<30 mL/minute, half the normal dose.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.

ERYTHROMYCIN STEARATE

Tablet, 250 mg NRH/RRH/DH

Therapeutic group Antibacterial.
Indications and dose **Susceptible infections in patients with penicillin hypersensitivity (e.g., respiratory-tract infections (including Legionella infection), skin and oral infections, and campylobacter enteritis)** ADULT: 250-500 mg *PO,* Q6H; increased to 500-1000 mg, Q6H in severe infections; CHILD (1 month-1 year): 125 mg *PO,* Q6H; increased to 250 mg, Q6H in severe infections; CHILD (2-7 years): 250 mg *PO,* Q6H; increased to 500 mg, Q6H in severe infections.
Contraindications Hypersensitivity to macrolides, co-administration with ergotamine and statins, severe hepatic impairment.
Cautions Hepatic and renal impairment, ventricular arrhythmias, pregnancy, breastfeeding.
Side effects Nausea, vomiting, abdominal discomfort, diarrhoea, urticaria, rashes, reversible hearing loss reported after large doses, cholestatic jaundice.
Hepatic impairment Use with caution.
Renal impairment Max. 1.5 g/day (ADULT) in severe renal impairment (ototoxicity).
Pregnancy category B
Breast-feeding Excreted in milk, use with cautions.

NORFLOXACIN

Tablet, 400 mg NRH/RRH

Therapeutic group Antibacterial.
Indications and dose **Lower urinary tract infections** 400 mg *PO,* Q12H x 7-10 days (3 days in uncomplicated lower urinary tract infections). **Chronic relapsing lower urinary tract infections** 400 mg *PO,* Q12H x 12 weeks; may be reduced to 400 mg, Q24H, if adequate suppression within the first 4 weeks. **Chronic prostatitis** 400 mg *PO,* Q12H x 30 days.

Contraindications Hypersensitivity to quinolones, all medicines or conditions that prolong QT interval, history of tendon disorders related to quinolone use, children.
Cautions Peripheral neuropathy, lactation, moderate renal impairment, history of convulsions, do not exceed the recommended dose, ensure adequate hydration, urinary output.
Side effects Nausea, vomiting, dizziness, headache, stomachache, weakness, heartburn, insomnia and seizures, rashes, fever, arthralgia.
Renal Impairment CrCl ≤ 30 mL/min: 400 mg, Q24H.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.

VANCOMYCIN

Powder for injection, 500 mg NRH/RRH

Therapeutic group Antibacterial.
Indications and dose **Infections due to Gram-positive bacteria including endocarditis, osteomyelitis, septicaemia and soft-tissue infections** ADULT: 1-1.5 g *IV infusion,* Q12H; ELDERLY: 500 mg *IV infusion,* Q12H, alternatively 1 g, Q24H; NEONATE (up to 29 weeks corrected gestational age): 15 mg/kg *IV infusion,* Q24H; NEONATE (29 weeks-35 weeks corrected gestational age): 15 mg/kg *IV infusion,* Q12H; NEONATE (35 weeks corrected gestational age and above): 15 mg/kg *IV infusion,* Q8H; CHILD: 15 mg/kg *IV infusion,* Q8H; max. 2 g/day. **Surgical prophylaxis (when high risk of MRSA)** ADULT: 1 g *IV infusion,* STAT.
Contraindications History of severe hearing loss.
Cautions Rapid IV administration, avoid extravasation, renal impairment, occlusive retinal vasculitis.
Side effects Erythematous rash on face and upper body (red man syndrome), chills, peripheral oedema, neutropenia, phlebitis, nephrotoxicity, ototoxicity, Stevens-Johnson syndrome, thrombocytopenia, vasculitis**.**
Renal impairment CrCl>50 mL/min: start with 15-20 mg/kg, Q12H; CrCl=20-49 mL/min: start with 15-20 mg/kg, Q24H; CrCl <20 mL/min: longer intervals.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.
IV fluid compatibility Dextrose 5%, dextrose 5% sodium chloride 0.9%, compound solution of sodium lactate, sodium chloride 0.9%.
Note Administer vancomycin with final concentration not to exceed 5 mg/mL by IV intermittent infusion over at least 60 minutes. Monitor IV site closely, extravasation will cause serious injury with possible necrosis and tissue sloughing. Rotate infusion sites frequently.

6.2.3 Anti-leprosy Medicines

CLOFAZIMINE

Capsule, 50 mg and 100 mg NRH/RRH/DH

Therapeutic group Anti-leprosy.
Indications **Multibacillary leprosy in combination with rifampicin and dapsone** ADULT: 300 mg *PO,* every month and 50 mg, Q24H, alternatively 100 mg, Q48H. **Lepromatous lepra reactions** ADULT: Increased to 300 mg *PO, Q24H x* max. 3 months. **Severe type II (erythema nodosum leprosum) reactions** ADULT: Increased to 100mg *PO,* Q8H x first month (with subsequent reductions), may take 4-6 weeks to attain full effect; CHILD (under 6 years): 1/4 ADULT dose; CHILD (6-12 years): ½ ADULT dose.
Cautions Avoid if persistent abdominal pain and diarrhoea; may discolour soft contact lenses**.**
Side effects Skin discoloration, ichthyosis, rash, pruritus, nausea, vomiting, abdominal pain, headache, tiredness.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.
Counselling Urine and saliva become red coloured. Take with or after food.

DAPSONE

Tablet, 50 mg NRH/RRH/DH/PHC

Therapeutic group Anti-leprosy.
Indications and dose **Multibacillary leprosy in combination with rifampicin and clofazimine; Paucibacillary leprosy in combination with rifampicin** ADULT (body weight up to 35 kg): 50 mg *PO,* Q24H; alternatively, 1-2 mg/kg Q24H; ADULT (body weight 35 kg and above): 100 mg *PO,* Q24H.
Contraindications Acute porphyrias.
Cautions Anaemia (treat severe anaemia before starting), cardiac disease, G6PD deficiency, pulmonary disease, susceptibility to haemolysis, hypersensitivity to sulfonamides.
Side effects haemolysis, methemoglobinemia, reactional states, insomnia, headache, exfoliative dermatitis, photosensitivity, nausea and vomiting, aplastic and haemolytic anaemia, agranulocytosis, cholestatic jaundice.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.

RIFAMPICIN

Tablet, 150 mg and 300 mg NRH/RRH

Therapeutic group Anti-leprosy.
Indications and dose **Multibacillary leprosy in combination with dapsone and clofazimine); Paucibacillary leprosy in combination with dapsone** ADULT: (body weight up to 35 kg): 450 mg *PO,* every month; ADULT (body weight 35 kg and above): 600 mg *PO,* every month; CHILD: 10-20 mg/kg *PO,* Q24H. *For details, refer to page no. 50*

6.2.4 Antituberculosis Medicines

6.2.4.1 First line medicines

ETHAMBUTOL (E)

Tablet, 100 mg and 400 mg NRH/RRH

Therapeutic group Antituberculosis.
Indications and dose **Tuberculosis, in combination with other antituberculosis medicines** ADULT: 15-25 mg/kg PO every day; CHILD: 15-25 mg/kg PO every day, max. 1200 mg per day.
For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update and National Guidelines for Management of Paediatric Tuberculosis in Bhutan 2nd Edition December 2020.
Contraindications Optic neuritis, use in children, unconscious patients, or any other patient who may be unable to discern and report visual changes.
Cautions Elderly and pregnancy.
Side effects Pruritus, rash, thrombocytopenia, urticaria, colour blindness, loss of visual acuity, optic neuritis, peripheral neuritis, red/green colour-blindness, restriction of visual fields, visual disturbances.
Hepatic impairment Use with caution.
Renal impairment ADULT: CrCl >30 mL/min: 15-25 mg/kg (max. 2.5 g), 3 times a week; CHILD: CrCl >30 mL/minute: 15-25 mg/kg (max. 2.5 g), 3 times a week; Avoid, if possible, renal impairment.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.
Note *Patients should be advised to discontinue therapy immediately if they develop deterioration in vision and promptly seek further advice.*

ETHAMBUTOL(E) + ISONIAZID(H) + PYRAZINAMIDE(Z) + RIFAMPICIN(R) [4 FDC]

Tablet, (275 mg+75 mg+400 mg+150 mg) NRH/RRH/DH

Therapeutic group Antituberculosis.
Indications and dose **Initial treatment of tuberculosis (intensive phase)** ADULT: E 15-25 mg/kg + H 4-6 mg/kg + Z 20-30 mg/kg + R 8-12 mg/kg per day; CHILD: E 15-25 mg/kg (max. 1200 mg) + H 7-15 mg/kg (max. 300 mg) + Z 30-40 mg/kg (max. 2000 mg) + R 10-20 mg/kg (max. 600 mg) per day.
For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update and National Guidelines for Management of Paediatric Tuberculosis in Bhutan 2nd Edition December 2020.
Contraindications Hypersensitivity to any medicines in the combination; medicine induced liver diseases.
Side effects Nausea, vomiting, loss of appetite; refer to individual medicine components.
Hepatic impairment: Use with caution in patients with hepatic impairment; dosage reduction may be necessary.
Pregnancy category C
Brest-feeding Excreted in milk, avoid.
Counselling Take the medicine 30 minutes to one hour before food and preferably at the same time of the day consistently.

ETHAMBUTOL(E) + ISONIAZID(H) + RIFAMPICIN(R) [3 FDC]

Tablet, (275 mg+ 75 mg+150 mg) NRH/RRH/DH

Therapeutic group Antituberculosis.
Indications and dose **Treatment of tuberculosis with liver disorder (intensive phase)** ADULT: E 15-25 mg/kg + H 4-6 mg/kg + R 8-12 mg/kg per day in combination streptomycin; CHILD: E 15-25 mg/kg (max. 1200 mg) + H 7-15 mg/kg (max. 300 mg) + R 10-20 mg/kg (max. 600 mg) per day.
For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update and National Guidelines for Management of Paediatric Tuberculosis in Bhutan 2nd Edition December 2020.
Side effects Nausea, vomiting, loss of appetite; refer to individual medicine components.
Contraindications Hepatic impairment, concurrent use with saquinavir/ritonavir and other protease inhibitors.
Hepatic impairment Dose reduction may be necessary to reduce hepatotoxicity.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.
Counselling Take the medicine half an hour to one hour before food and preferably at the same time of the day consistently.

ISONIAZID(H)

Tablet, 100 mg and 300 mg NRH/RRH

Therapeutic group Antituberculosis.
Indications and dose ***T*uberculosis, in combination with other medicines** ADULT: 4-6 mg/kg per day; CHILD: H 7-15 mg/kg (max. 300 mg) per day. **Treatment for latent tuberculosis infection** ADULTS: 5 mg/kg/day, for 6 months; CHILD: 10 mg/kg/day (range, 7–15 mg/kg/day) max. 300 mg for 6 months.
For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update and National Guidelines for Management of Paediatric Tuberculosis in Bhutan 2nd Edition December 2020.
Cautions Acute porphyrias, alcohol dependence, diabetes mellitus, epilepsy, history of psychosis, HIV infection, malnutrition, alcohol use.
Side effects Peripheral neuropathy, loss of appetite, nausea, vomiting, stomach-ache, weakness, dizziness, slurred speech, lethargy, agranulocytosis, anaemia, megaloblastic anaemia, thrombocytopenia, systemic lupus erythematosus, convulsions.
Hepatic impairment Use with caution.
Renal impairment Risk of ototoxicity and peripheral neuropathy; prophylactic pyridoxine hydrochloride recommended.
Pregnancy category C

Breast-feeding Excreted in milk, compatible.
Counselling Take the medicine half an hour to one hour before food and preferably at the same time of the day consistently.

ISONIAZID(H) + PYRAZINAMIDE(Z) + RIFAMPICIN(R) (3 FDC)

Tablet, (50 mg+150 mg+75 mg) NRH/RRH/DH

Therapeutic group Antituberculosis.
Indications and dose **Treatment of tuberculosis (intensive phase) in paediatric patients** CHILD: H 7-15 mg/kg (max. 300 mg) + Z 30-40 mg/kg (max. 2000 mg) + R 10-20 mg/kg (max. 600 mg) in combination with ethambutol E 15-25 mg/kg (max. 1200 mg) per day.
For details, refer to National Guidelines for Management of Paediatric Tuberculosis in Bhutan 2nd Edition December 2020.
Contraindications Hepatic impairment, concurrent use with saquinavir/ritonavir and other protease inhibitors.
Side effects Nausea, vomiting, loss of appetite; refer to individual medicine components.
Hepatic impairment Dose reduction may be necessary to reduce hepatotoxicity.
Counselling Take the medicine half an hour to one hour before food and preferably at the same time of the day. Consistently.

ISONIAZID + RIFAMPICIN (2 FDC)

Tablet, (75 mg + 150 mg) NRH/RRH/DH
Tablet, (60 mg + 60 mg) NRH/RRH/DH
Tablet, (50 mg + 75 mg) NRH/RRH/DH

Therapeutic group Antituberculosis.
Indications and dose **Treatment of tuberculosis (continuation phase)** ADULT: H 4-6 mg/kg + R 8-12 mg/kg; CHILD: H 7-15 mg/kg (max. 300 mg) + R 10-20 mg/kg (max. 600 mg) per day.
For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update and National Guidelines for Management of Paediatric Tuberculosis in Bhutan 2nd Edition December 2020.
Contraindications Hypersensitivity to the medicines in the combination; hepatic and renal impairment, epilepsy, history of psychosis, alcohol dependence, malnutrition, diabetes.
Side effects Nausea and vomiting, skin rash, psychotic problems, depression, seizures, peripheral neuropathy may develop by isoniazid, red or orange urine by rifampicin.
Hepatic impairment Use with caution in patients with hepatic impairment; dosage reduction may be necessary.
Pregnancy category C
Brest-feeding Excreted in milk, avoid.

PYRAZINAMIDE

Tablet, 500 mg NRH/RRH

Therapeutic group Antituberculosis.
Indications and dose **Tuberculosis in combination with other medicines** ADULT: 20-30 mg/kg per day; CHILD: 30-40 mg/kg (max. 2000 mg) per day.
For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update and National Guidelines for Management of Paediatric Tuberculosis in Bhutan 2nd Edition December 2020.
Cautions History of alcoholism, renal failure, diabetes, chronic gout.
Side effects Anorexia, arthralgia, dysuria, fever, flushing, hepatomegaly, hepatotoxicity, jaundice, liver failure, nausea, photosensitivity, rash, splenomegaly, thrombocytopenia, vomiting.
Hepatic impairment Reduce dose.
Renal impairment CrCl < 30 mL/min: 25-35 mg/kg/dose.

Pregnancy category C
Breast-feeding Excreted in milk, use with caution.
Counselling Seek medical attention if there are signs of liver disorder: persistent nausea, vomiting, malaise, jaundice.

RIFAMPICIN

Tablet, 150 mg and 300 mg NRH/RRH

Therapeutic group Antituberculosis.
Indications and dose **Tuberculosis, in combination with other medicines** ADULT: 8-12 mg/kg per day; CHILD: 10-20 mg/kg (max. 600 mg) per day.
For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update and National Guidelines for Management of Paediatric Tuberculosis in Bhutan 2nd Edition December 2020.
Contraindications Hypersensitivity to rifamycins, concomitant administration of live bacterial vaccines, concurrent use with saquinavir/ritonavir and other protease inhibitors.
Cautions Diabetes mellitus, liver dysfunction, porphyria, alcoholism, discolours soft contact lenses.
Side effects Elevated liver function test, rash, epigastric distress, anorexia, nausea, vomiting, diarrhoea, cramps, pancreatitis, headache, drowsiness, hepatotoxicity, agranulocytosis, anaphylaxis.
Hepatic impairment Avoid or do not exceed 8 mg/kg daily. In patients with hepatic impairment, monitor liver function regularly and particularly frequently in the first 2 months.
Patients and their family should be informed to seek immediate medical attention, if symptoms such as persistent nausea, vomiting, malaise, jaundice develop.
Renal impairment Use with caution if doses above 10 mg/kg/day (CHILD) and above 600 mg/day (ADULT).
Pregnancy category C
Breast-feeding Excreted in milk, avoid.w
Counselling Urine and saliva may become red coloured; Take 30 minutes to one hour before food.
Note *Effectiveness of hormonal contraceptives will reduce, alternative family planning advice should be offered.*

RIFAPENTINE

Tablet, 150 mg NRH/RRH/DH/PHC

Therapeutic group Antituberculosis.
Indications and doses **Tuberculosis, Active** (*medicine-susceptible*) ADULT *Initial phase:* 600 mg twice weekly (with an interval ≥72 hours between doses) for 2 months in combination with isoniazid or other anti-tuberculosis agent; *Continuation phase:* 600 mg once weekly for 4 months in combination with isoniazid or other anti-tuberculosis agent. **Tuberculosis, latent** ADULT Administer for 3 months in combination with isoniazid, body weight:

- 25.1 to 32 kg - 600 mg once weekly
- 32.1 to 49.9 kg - 750 mg once weekly
- ≥50 kg - 900 mg once weekly

Tuberculosis, active pulmonary infection CHILD: *Initial phase:* 600 mg twice weekly (with an interval ≥72 hours between doses) for 2 months in combination with isoniazid or other anti-tuberculosis agent. *Continuation phase:* 600 mg once weekly for 4 months in combination with isoniazid or other anti-tuberculosis agent. **Tuberculosis, latent infection** CHILD (≥2 years and Adolescents): In combination with isoniazid, body weight:

- 10 to 14 kg - 300 mg once weekly
- 14.1 to 25 kg - 450 mg once weekly
- 25.1 to 32 kg - 600 mg once weekly
- 32.1 to 49.9 kg - 750 mg once weekly
- ≥50 kg - 900 mg once weekly

Contraindications Preexisting porphyria, hypersensitivity to rifamycin's analog.

Cautions If *clostridium difficile*-associated diarrhoea (superinfection), hypersensitivity or anaphylaxis, and Steven-Johnson syndrome occur, discontinue the therapy. Monitor liver function test prior to therapy and every 2-4 weeks during therapy.
Side effects Anaemia, neutropenia, lymphopenia, leukopenia, thrombocytosis, diarrhoea, nausea, vomiting, anorexia, skin rash, increase ALT/AST, headache, arthralgia, proteinuria, pyuria, hematuria, gout, hyperglycemia, relapse of pulmonary tuberculosis, cough, conjunctivitis.
Hepatic impairment Pre-existing hepatic problems should have liver function tests; Monitor every 2-4 weeks during therapy.
Renal Impairment No dose adjustment necessary.
Pregnancy category C
Breast-feeding Outweigh the potential benefits against potential risk of breast-feeding mother before prescribing. Monitor infants exposed to rifapentine for hepatotoxicity such as yellowing eyes, loss of appetite, vomiting and colour change in urine and stool.
Counselling Take with/without food. Advise patients for liver function (ALT/AST) test every 2-4 weeks. Remove contact lenses during therapy since permanent staining may occur. Advise breast-feeding mothers of potential risk of rifapentine for their infants. It should be taken under Directly Observed Therapy (DOT) or Self Administration Therapy (SAT). Inform patients about red-orange discoloration skin, teeth, and body fluids.

6.2.4.2 Second line medicines (MDR-TB)

AMIKACIN

Injection, 250 mg (2 mL) NRH/RRH

Therapeutic group Anti-tuberculosis in MDR-TB.
Indication and dose **Medicine-resistant tuberculosis in combination with other medicines** ADULT and > 14 years: 15-20 mg/kg once daily; CHILD: 15-20 mg/kg once daily.
For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update and National Guidelines for Management of Paediatric Tuberculosis in Bhutan 2nd Edition December 2020.

BEDAQUILINE

Tablet, 100 mg NRH/RRH

Therapeutic group Anti-tuberculosis in MDR-TB.
Indication and dose **Medicine-resistant tuberculosis in combination with other medicines** ADULT and > 14 years: (100 mg tablet) 4 tabs of for first 2 weeks, then 2 tabs once day on Monday, Wednesday and Friday for 22 weeks; CHILD: first 14 days, 6 mg/kg/day then 3-4 mg/kg thrice weekly.
For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update and National Guidelines for Management of Paediatric Tuberculosis in Bhutan 2nd Edition December 2020.

CLOFAZIMINE

Capsule, 50 mg and 100 mg NRH/RRH/DH

Therapeutic group Anti-tuberculosis in MDR-TB.
Indication and dose **Medicine-resistant tuberculosis in combination with other medicines** ADULT and > 14 years: (50 mg tablet) 2 tabs per day, max. 100 mg per day. CHILD: 2-5mg/kg/day.
For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update and National Guidelines for Management of Paediatric Tuberculosis in Bhutan 2nd Edition December 2020.

CYCLOSERINE

Tablet, 250 mg NRH

Therapeutic group Anti-tuberculosis in MDR-TB.
Indication and dose **Medicine-resistant tuberculosis in combination with other medicines** ADULT and > 14 years: 10-15 mg/kg/day, max. 1 g per day; CHILD: 15-20 mg/kg/day.
For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update and National Guidelines for Management of Paediatric Tuberculosis in Bhutan 2nd Edition December 2020.

ETHIONAMIDE

Tablet, 250 mg NRH

Therapeutic group Anti-tuberculosis in MDR-TB.
Indications and dose **Medicine-resistant tuberculosis in combination with other medicines** ADULT and > 14 years: 15-20 mg/kg, max. 1 g per day; CHILD: 15-20mg/kg/day.
For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update and National Guidelines for Management of Pediatric Tuberculosis in Bhutan 2nd Edition December 2020.
Contraindications Severe hepatic dysfunction.
Cautions Diabetes mellitus, thyroid disease, psychiatric symptoms, alcoholic.
Side effects GI disorders, postural hypotension, depression, dizziness, drowsiness, headache, nausea, vomiting, diarrhoea, hepatitis.
Renal impairment CrCl <30 mL/min: 250-500 mg/day.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.

LEVOFLOXACIN

Tablet, 250 mg NRH/RRH/DH

Therapeutic group Anti-tuberculosis in MDR-TB.
Indications and dose **Medicine-resistant tuberculosis in combination with other medicines** ADULT and > 14 years (30-45 kg body weight): (250 mg) 3 tablets per day; 46-to >70 kg body: 4 tablets, max. 1.5 g per day; CHILD: 15-20mg/kg/day.
For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update and National Guidelines for Management of Paediatric Tuberculosis in Bhutan 2nd Edition December 2020.
Contraindications Hypersensitivity to quinolones.
Cautions G-6-PD deficiency, moderate to severe hepatic and renal failure, seizures, pregnancy and breast-feeding exposure to strong sunlight and UV light.
Side effects Constipation, flatulence, hyperhidrosis, dyspnoea.
Renal impairment **For normal renal function dosing of 750 mg/day** CrCl 20-49 mL/min: 750 mg, Q48H; CrCl 10-19 mL/min: 750 mg initial dose, then 500 mg, Q48H; **Normal renal function dosing of 500 mg/day** CrCl 20-49 mL/min: 500 mg initial dose, then 250 mg, Q24H; CrCl 10-19 mL/min: 500 mg initial dose, then 250 mg, Q48H; **Normal renal function dosing of 250 mg/day** CrCl 20-49 mL/min: No dose adjustment required; CrCl 10-19 mL/min: 250 mg, Q48H (except in uncomplicated UTI, where no dosage adjustment is required).
Hepatic impairment Use with caution.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.

LINEZOLID

Tablet, 600 mg NRH/RRH

Therapeutic group Anti-tuberculosis in MDR-TB.

Indications and dose **Medicine-resistant tuberculosis in combination with other medicines** ADULT and > 14 years (30-45 kg body weight): dose ???; 46-to >70 kg body: (600 mg tablet) 1 tablet, max. 1.2 g per day; CHILD: < 16 kg body weight: 15 mg/kg once daily; >16 kg body weight: 10-12mg/kg/day.
For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update and National Guidelines for Management of Paediatric Tuberculosis in Bhutan 2nd Edition December 2020.

MOXIFLOXACIN

Tablet, 400 mg NRH/RRH

Therapeutic group Anti-tuberculosis in MDR-TB.
Indications and dose **Medicine-resistant tuberculosis in combination with other medicines** ADULT and > 14 years: (400 mg tablet) 1 tablet per day, max. 400 mg per day; CHILD: 10-15mg/kg/day.
For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update and National Guidelines for Management of Paediatric Tuberculosis in Bhutan 2nd Edition December 2020.
Contraindications Hypersensitivity to quinolone group of antibiotics, acute myocardial infarction, bradycardia, congenital long QT syndrome, electrolyte disturbances, heart failure with reduced left ventricular ejection fraction, history of symptomatic arrhythmias.
Cautions Risk of tendon inflammation or rupture with concurrent corticosteroid, organ transplant recipients and in patients more than 60 years old.
Side effects Nausea, diarrhoea, dizziness, immune hypersensitivity reaction, prolonged QT interval.
Hepatic impairment No dosage adjustment required, use with caution in severe hepatic impairment.
Pregnancy category C
Counselling Use sunscreen and protective clothing and avoid excessive exposure to sunlight. Take the medicine at least 4 hours before or 8 hours after products containing iron, zinc, magnesium, or aluminium.

PARA-AMINOSALICYLATE SODIUM

Delayed release granules, 60% w/w (4 g) NRH/RRH/DH

Therapeutic group Anti-tuberculosis in MDR-TB.
Indications and dose **Medicine-resistant tuberculosis in combination with other medicines** ADULT and > 14 years: 8-12 g/day in 2-3 divided doses, max. 12 g; CHILD: 200 mg/kg/day.
For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update and National Guidelines for Management of Pediatric Tuberculosis in Bhutan 2nd Edition December 2020.
Cautions Gastric ulcer, hepatic and renal impairment, sensitivity to tartrazine dyes, nasal polyps, and asthma.
Side effects Pericarditis, vasculitis, encephalopathy, fever, skin eruptions, goitre, hypoglycaemia, abdominal pain, diarrhoea, nausea, vomiting, agranulocytosis, anaemia (haemolytic), leukopenia, thrombocytopenia, hepatitis, jaundice, optic neuritis, eosinophilic pneumonia.
Renal Impairment CrCl 10-50 mL/min: 50 - 75% of dose; CrCl <10 mL/min: 50% of dose.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.
Counselling GI disturbances may be minimised by taking the medicine with or after meals or with an antacid.

STREPTOMYCIN

Powder for injection, 1 g NRH/RRH

Therapeutic group Anti-tuberculosis in MDR-TB.
Indications and dose **Medicine-resistant tuberculosis in combination with other medicines** ADULT and > 14 years: 12-18 mg/kg, max. 1 g.

For details, refer to Integrated National Guidelines for Management of Tuberculosis in Bhutan 7th Edition December 2020 Update.
Contraindications Pregnancy, myasthenia gravis.
Cautions Use with caution to patients with pre-existing renal, vestibular or auditory problems, infants and the elderly.
Side effects Pain at the injection site, ototoxicity (vestibular and auditory damage), nephrotoxicity, electrolyte, vertigo, tinnitus, imbalance, rarely, allergic reactions.
Hepatic impairment Use with caution.
Renal impairment Should preferably be avoided; If essential, CrCl 10-50 mL/min: Q24-72H; CrCl <10 mL/min: Q72-96H.
Pregnancy category D
Breast-feeding Excreted in milk, avoid.
Note *IV administration is not recommended*.

6.3. Antifungals medicines

AMPHOTERICIN B

Liposomal powder for injection (with microfilter), 50 mg NRH/RRH

Therapeutic group Antifungal.
Indications and dose **Systemic fungal infection** *LIPOSOMAL* ADULT: 3 mg/kg *IV infusion,* Q24H, max. 5 mg/kg/day; CHILD: 3mg/kg *IV infusion,* Q24H, max. 5mg/kg/day. **Cryptococcal meningitis** *LIPOSOMAL* ADULT: 6 mg/kg/day *IV infusion*; CHILD: same as adult dose. **Visceral leishmaniasis** *LIPOSOMAL: Immunocompetent patients* ADULT: 3 mg/kg *IV infusion,* Q24H on days 1-5, 14 and 21; CHILD: same as adult; *Immunocompromised patients* ADULT: 4 mg/kg *IV infusion,* Q24H on days 1-5, 10, 17, 24, 31 and 38; CHILD: same as adult.
Cautions Avoid rapid infusion, co-administration with other medicines that cause hypokalemia and other nephrotoxic medicines.
Side effects Abdominal pain, abnormal liver function (discontinue treatment), anaemia, arrhythmias, blood disorders, blood pressure changes, cardiovascular effects, chest pain, diarrhoea, disturbances in renal function, dyspnoea, electrolyte disturbances, febrile reactions, headache, hypokalaemia, hypomagnesaemia, nausea, rash, renal tubular acidosis, thrombocytopenia, vomiting.
Renal impairment Use only if no alternative, nephrotoxicity may be reduced with use of liposomal formulation.
Pregnancy category B
Breast-feeding Excretion in milk unknown, use with caution.
IV fluid compatibility Dextrose 5%.
Note *Liposomal formulation to be used in severe systemic or deep mycoses where toxicity precludes the use of conventional formulation. Liposomal formulation is contraindicated in children under 1 month of age. Test dose of 1 mg should be given over 15 minutes.*

CLOTRIMAZOLE

Pessary, 100 mg NRH/RRH/DH/PHC

Therapeutic group Antifungal (vaginal insert).
Indications and dose **Vaginal Candidiasis** Pessary *by vagina*, 100 mg, Q12H x 3 days or 100 mg, before bedtime x 6 nights.
Side effects Occasionally, local irritation or mild inflammation.
Pregnancy category B
Counselling Place the pessary high up the vagina just before you go to sleep.

FLUCONAZOLE

Tablet, 150 mg NRH/RRH

Therapeutic group Antifungal (triazole).

Indications and dose **Systemic mycoses** ADULT: 200 mg daily up to 6 months; CHILD over 2 years: 3-6 mg/kg daily up to 6 months. **Cryptococcal meningitis** ADULT: 400 mg on Day 1, then 200 mg daily for up to 8 weeks; CHILD: 6 -12 mg/kg daily for up to 8 weeks (every 72 hours in neonate up to 2 weeks old). **Prophylaxis of cryptococcal meningitis in immunocompromised patients**: 200 mg daily. **Systemic candidiasis**: 200 mg daily for up to 4 weeks; CHILD: 6-12 mg/kg daily (every 72 hours in NEONATE up to 2 weeks old). **Oesophageal and oropharyngeal candidiasis** ADULT: 200 mg on Day 1, then 100 mg daily for until symptoms resolve; CHILD: 6 mg/kg on day 1, followed by 3 mg/kg daily (every 72 hours in NEONATE up to 2 weeks old). **Vaginal candidiasis** ADULT: 150 mg as a single dose.
Contraindications concurrent use of medicines that cause QT prolongation.
Cautions hypersensitivity to other azoles, proarrhythmic conditions, hepatic, renal impairment.
Side effects nausea, vomiting, flatulence and diarrhoea, headache, taste disturbances, dizziness, seizure, alopecia pruritus, rash, toxic epidermal necrolysis and Stevens-Johnson syndrome, hyperlipidaemia, leukopenia, thrombocytopenia, hypokalaemia.
Renal impairment For multiple dosing, administer usual load then adjust daily doses as follows.
CrCl ≤50 mL/minute: administer 50% of recommended dose or administer every 48 hours.
Pregnancy category C
Breast feeding Excrete in breast milk, not recommended.
Counselling Take with or after food. take at regular intervals and complete the full course.

GRISEOFULVIN

Tablet, 250 mg NRH/RRH/DH

Therapeutic group Antifungal.
Indications **Dermatophyte infections of the skin, scalp, hair and nails where topical therapy has failed or is inappropriate** ADULT: 500 mg *PO,* Q24H, alternatively 1 g *PO,* Q24H; higher dose for severe infections, reduce dose when response occurs; CHILD (1 month-11 years): 10 mg/kg/day (max. 500 mg/dose), increased if necessary to 20 mg/kg/day (max. 1 g/dose) for severe infections. **Tinea capitis caused *by Trichophyton tonsurans*** ADULT: 1 g *PO,* Q24H; alternatively, 1 g/day in divided doses; CHILD (1 month-11 years): 15-20 mg/kg *PO,* Q24H (max. 1 g/dose).
Contraindications Severe liver disease, lupus erythematosus and related conditions, porphyria and pregnancy.
Cautions Pregnancy, intense exposure to sunlight.
Side effects Headache, nausea, vomiting, rashes, photosensitivity, dizziness, fatigue, leukopenia, systemic lupus erythematosus, erythema multiforme, toxic epidermal necrolysis, peripheral neuropathy, and confusion.
Hepatic impairment Avoid in severe liver disease.
Pregnancy category C
Breast-feeding Avoid.
Counselling Take with or after food. Take at regular intervals and complete the full course.
Note *Long courses of treatment are needed (6 weeks for skin; 3 months for nails infections). Effective contraception required during and for at least 1 month after administration to women (important: effectiveness of oral contraceptives may be reduced, additional contraceptive precautions e.g. barrier method, required); Men should avoid fathering a child during and for at least 6 months after administration.*

MICONAZOLE

Cream, 2% (15 g) NRH/RRH/DH

Therapeutic group Antifungal (topical).
Indications and dose **Susceptible fungal infection of skin and mucous membrane** *by topical application*, apply thin layer over infected area twice daily for two to four weeks depending on severity.
Cautions For topical use only, avoid contact with eyes.
Side effects Occasional irritation, burning, allergic dermatitis, maceration.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.

Counselling Treatment should be prolonged for 10 days after all lesions have disappeared to prevent relapse.

NYSTATIN

Tablet, 500,000 units NRH/RRH/DH
Nystatin oral paste (extemporaneous) NRH/RRH/DH

Therapeutic group Antifungal.
Indications and dose **Intestinal candidiasis** ADULT: 500,000 -1,000,000 units *PO,* Q6H, double in severe infections; **Oral candidiasis** NEONATE and INFANT: 1 mL *topically in mouth,* Q6H after meals; CHILD and ADULT: 1 mL *swish in the mouth and retain for as long as possible before swallowing,* Q6H.
Side effects Nausea, vomiting, stomach pain, diarrhoea.
Pregnancy category C (Oral paint).
Breast-feeding Excretion in milk unknown, use with caution.

6.4 Antiviral medicines

6.4.1 Anti-herpes medicines

ACYCLOVIR

Tablet, 400 mg NRH/RRH/DH
Lyophilised powder for injection, 500 mg NRH/RRH

Therapeutic group Anti-herpes.
Indications and dose **Herpes simplex, suppression** ADULT and CHILD (12-17 years): 400 mg *PO,* Q12H; increased to 400 mg, Q8H; dose may be increased if recurrences occur on standard suppressive therapy or for suppression of genital herpes during late pregnancy (from 36 weeks' gestation), therapy interrupted every 6-12 months to reassess recurrence frequency, consider restarting after two or more recurrences. **Herpes simplex, prophylaxis in the immunocompromised** ADULT: 200-400 mg *PO,* Q6H; CHILD (1 month-1 year): 100-200 mg *PO,* Q6H; CHILD (2-17 years): 200-400 mg *PO,* Q6H; ADULT: 5 mg/kg IV every 8 hours for 5 to 7 days. **Herpes simplex (non-genital); Herpes simplex, (non-genital) in immunocompromised or if absorption impaired** ADULT: 200 mg *PO,* Q4H x 5 days (longer if new lesions appear during treatment or if healing incomplete). **Herpes simplex, treatment; Herpes Simplex, treatment in immunocompromised or if absorption impaired** CHILD (1 month-23 months): 100 mg *PO,* Q4H x 5 days; CHILD (2-17 years): 200 mg *PO,* Q4H x 5 days; *Longer duration if new lesions appear during treatment or if healing incomplete*. **Genital herpes simplex, treatment of first episode** ADULT: 400 mg *PO,* Q8H x 5 days (400 mg, 5 times a day for 7-10 days for immunocompromised). **Genital herpes simplex, treatment of recurrent infection** ADULT: 800 mg *PO,* Q8H x 2 days (for 5-10 days in immunocompromised patients). **Severe genital herpes simplex, initial infection treatment of herpes simplex in the immunocompromised** ADULT: Initially 5 mg/kg IV every 8 hours for 5 days, alternatively 10 mg/kg every 8 hours for at least 14 days in encephalitis (at least 21 days if also immunocompromised). **Herpes simplex encephalitis** CHILD: 3 months-12 years 20 mg/kg IV every 8 hours for 10 days; ≥ 12 years and ADULT: 10 mg/kg IV every 8 hours for 10 days. **Herpes simplex mucocutaneous** CHILD: 3 months-12 years 10 mg/kg IV every 8 hours for 7 days; ≥ 12 years and ADULT (immunocompromised): 5 mg/kg IV every 8 hours for 7 days. **Varicella zoster (chickenpox), treatment; Herpes zoster (shingles), treatment** ADULT: 800 mg *PO,* Q4H (5 times daily) x 7 days; CHILD (1 month-1 year): 200 mg *PO,* Q6H x 5 days; CHILD (2-5 years): 400 mg *PO,* Q6H x 5 days; CHILD (6-11 years): 800 mg *PO,* Q6H x 5 days; ADULT: 5 mg/kg IV every 8 hours for 5 days. **Varicella zoster (chickenpox), treatment; Herpes zoster (shingles), treatment in immunocompromised** ADULT: 10 mg/kg IV every 8 hours for 5 days. **Herpes zoster (shingles), treatment in immunocompromised** ADULT: 800 mg *PO,* Q4H (5 times daily) continued for 2 days after crusting of lesions; CHILD (1 month-1 year): 200 mg *PO,* Q6H continued for 2 days after crusting of lesions; CHILD (2-5 years): 400 mg *PO,* Q6H continued for 2 days after crusting of lesions; CHILD (6-11 years): 800 mg, *PO,* Q6H continued for 2 days after crusting of lesions. **Herpes zoster, treatment in encephalitis; Varicella zoster, treatment in encephalitis** ADULT and CHILD: 10 mg/kg *PO,* Q6H x 7 days, to be started 1 week after exposure; ADULT: 10 mg/kg IV every 8 hours for 10–14 days, possibly longer in immunocompromised or if severe infection.

Cautions Renal failure, elderly, maintain adequate hydration, immunocompromised patient, patient on nephrotoxic medicines.
Side effects Malaise, nausea, vomiting, diarrhoea, headache, abdominal pain, fatigue, pruritus, rashes, urticaria.
Renal Impairment **ORAL** CrCl 10-25 mL/minute/1.73 m^2: if normal dosing regimen 800 mg every 4 hours: administer 800 mg every 8 hours; CrCl <10 mL/minute/1.73 m^2: if normal dosing regimen 200 mg every 4 hours, 200 mg every 8 hours, or 400 mg every 12 hours: administer 200 mg every 12 hours; if normal dosing regimen 800 mg every 4 hours: administer 800 mg every 12 hours.
INTRAVENOUS CrCl 25-50 mL/minute/1.73 m^2: administer recommended dose every 12 hours; CrCl 10-25 mL/minute/1.73 m^2: administer recommended dose every 12 hours; CrCl <10 mL/minute/1.73 m^2: administer 50% recommended dose every 24 hours.
Pregnancy category B
Breast-feeding Excreted in milk, use with caution.
Note *Avoid rapid infusion, infuse over 1 hour to prevent renal damage. Maintain adequate hydration of patients. Check for phlebitis and rotate infusion sites. Avoid I.M. or Subcutaneous administration.*

6.4.2 Antiretrovirals

6.4.2.1 Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs)

ABACAVIR

Tablet, 300 mg NRH/RRH
Syrup, 20 mg/mL (240 mL) NRH/RRH

Therapeutic group Antiretroviral.
Indications and dose **Treatment of HIV infections in combination with other antiretroviral agents** ADULT: 300 mg twice daily or 600 mg once daily; CHILD (3 months to 16 years): 8 mg/kg body weight twice daily (max: 300 mg twice daily) in combination with other antiretroviral agents.
For details, refer to National Guidelines on Treatment & Management of HIV & AIDS 3rd edition 2020.
Contraindications Patients who are HLA-B*5701-positive, moderate or severe hepatic impairment.
Cautions Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, reported with nucleoside analogs, including abacavir, most of these cases have been in women, female gender and obesity may be risk factors, suspend dosing in those who develop clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity.
Side effects Nausea, headache, malaise/fatigue, Hypersensitivity reaction, diarrhoea, musculoskeletal pain, hypertriglyceridemia, hepatic: AST increased, depression, fever/chills, viral respiratory and ear/nose/throat infections rash, anxiety.
Hepatic impairment Mild dysfunction (Child-Pugh score 5-6): 200 mg twice daily (oral solution is recommended). Moderate-to-severe dysfunction: use is contraindicated.
Renal impairment No dose adjustment required.
Counselling May be taken with or without food. If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up.

LAMIVUDINE (3TC)

Tablet, 150 mg NRH/RRH
Syrup, 10 mg/mL (240 mL) NRH/RRH

Therapeutic group Antiretroviral.
Indications and dose **HIV infection in combination with other antiretroviral medicines** ADULT: 150 mg PO twice daily or 300 mg PO once daily; CHILD (Neonates): 2 mg/kg PO Q12hr; ≥ 1 month: 4 mg/kg PO Q12hr; ≥ 3 months: 5 mg/kg PO Q12.
For details, refer to National Guidelines on Treatment & Management of HIV & AIDS 3rd edition 2020.
Caution Renal impairment, obesity, history of pancreatitis in children, hepatic decompensation, anaemia, neutropenia.

Side effects Cough, fatigue and malaise, fever, musculoskeletal pain, headache, nausea, diarrhoea, abdominal pain and insomnia, peripheral neuropathy.
Renal impairment CrCl 30-49 mL/min: 50 mg, Q24H; CrCl 15-29 mL/min: 150 mg first dose, then 100 mg, Q24H; CrCl 5-14 mL/min: 150 mg first dose, then 50 mg, Q24H; CrCl <5 mL/min: 50 mg first dose, then 25 mg, Q24H.
Pregnancy category C
Breast-feeding Excreted in breast milk, avoid.

ZIDOVUDINE (AZT)

Tablet, 300 mg NRH/RRH
Syrup 10 mg/mL (240 mL) NRH/RRH

Therapeutic group Antiretroviral.
Indications and dose **HIV infection in combination with other antiretroviral medicines** ADULT: 300 mg PO twice daily; CHILD (Birth to 4 weeks): 4mg/kg PO Q12hr; >4 weeks: 12 mg/kg PO Q12hr.
For details, refer to National Guidelines on Treatment & Management of HIV & AIDS 3rd edition 2020.
Contraindications Acute porphyria, abnormally low haemoglobin concentration, abnormally low neutrophil counts.
Side effects Anaemia, anorexia, diarrhoea, fever, granulocytopenia, severe headache, leukopenia, nausea, pain, rash, vomiting, weakness, hyperpigmentation of nails (bluish brown).
Renal impairment Reduce oral dose to 300-400 mg/day in divided doses.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.

6.4.2.2 Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

EFAVIRENZ (EFV)

Tablet, 200 mg NRH/RRH

Therapeutic group Antiretroviral.
Indications and dose **HIV infection in combination with other antiretroviral medicines** ADULT: 400 mg PO hs once daily; CHILD (body weight base):

- 3.5 - < 5 kg: 100 mg Q24hr
- 5 - < 7.5 kg: 150 mg Q24hr
- 7.5 - < 15 kg: 200 mg Q24hr
- 15 - < 20 kg: 250 mg Q24hr
- 20 - < 25 kg: 300 mg Q24hr
- 25 - < 32.5 kg: 350 mg Q24hr
- 32.5 - < 40 kg: 400 mg Q24hr
- ≥ 40 kg: 600 mg Q24hr

For details, refer to National Guidelines on Treatment & Management of HIV & AIDS 3rd edition 2020.
Cautions Acute porphyrias, elderly, history of psychiatric disorders, history of seizures.
Side effects Total cholesterol increased; diarrhoea, HDL increased, dizziness, rash, fever, depression, insomnia, cough, vomiting, anxiety, nausea.
Hepatic impairment Not recommended in moderate to severe impairment.
Pregnancy category D
Breast-feeding Excretion in milk unknown, avoid.
Counselling Take on an empty stomach preferably at bedtime. Tablets should not be broken.

6.4.2.3 Protease Inhibitors

LOPINAVIR/RITONAVIR (LPV/r)

Tablet, LPV/r (200/50 mg) NRH/RRH
Syrup, LPV/r (80/20 mg)/mL (160 mL) NRH/RRH

Therapeutic group Antiretroviral.
Indications and dose **Treatment of HIV infection in combination with other antiretroviral agents** ADULT: 400 mg/100 mg (LPV/r) PO twice daily; CHILD 7 - <15 kg: 12 mg/kg/dose Q12hr based on lopinavir component; 15 – 40 kg: 10 mg/kg/dose Q12hr based on lopinavir component; > 40 kg: same as adults.
For details, refer to National Guidelines on Treatment & Management of HIV & AIDS 3rd edition 2020.
Contraindications Co-administration with medications highly dependent upon CYP3A4 for clearance, co-administration with strong CYP3A4 inducers.
Cautions Cardiac conduction disorders, pancreatitis, patients at high risk of cardiovascular disease (especially if 10-year cardiovascular risk greater than 20%), structural heart disease.
Side effects Diarrhoea, nausea, rash, headache, weakness, abdominal pain, insulin resistance, fat accumulation and hyperlipidaemia, elevated transaminase (SGOT and SGTP).
Hepatic impairment Use with caution.
Renal impairment Use with caution.
Pregnancy category C
Breast-feeding Excretion in milk unknown, avoid.

6.4.2.4 Integrase inhibitors

DOLUTEGRAVIR (DTG)

Tablet, 50 mg NRH/RRH

Therapeutic group Antiretroviral.
Indications and dose **HIV infection without resistance to other integrase inhibitors, in combination with other antiretrovirals** ADULT 50 mg PO once daily; CHILD (12-17 years, body weight > 40 kg) 50 mg PO once daily. **HIV infection in patient resistance to other integrase inhibitors is suspected, in combination with other antiretrovirals** ADULT 50 mg PO twice daily. **HIV non-occupational exposure; prophylaxis** (*initiate therapy within 72 hours of exposure*) ADULT**:** 50 mg PO once daily, in combination with emtricitabine 200 mg or tenofovir disoproxil fumarate 300 mg PO once daily, treatment duration is 28 days. **HIV infection in combination with other antiretrovirals in patients with concomitant enzyme inducers** CHILD (12-17 years, body weight > 40 kg): 50 mg PO twice daily.
HIV infection in 4 weeks and older, body weight (Tablet for oral suspension):

- 3 kg to < 6 kg: 5 mg PO once daily
- 6 kg to <10 kg: 15 mg PO once daily
- 10 kg to <14 kg: 20 mg PO once daily
- 14 kg to < 20 kg: 25 mg PO once daily or 40 mg PO once daily (film coated tablet)
- >20 kg: 30 mg PO once daily or 50 mg PO once daily (film coated tablet).

Note *Do not interchange tablets and tablets for oral suspension on a mg-per-mg basis. Dose must be adjusted for the new dosage formulation if switching from one formulation to the other.*
Contraindications Concomitant use with dofetilide, hypersensitivity to dolutegravir, woman planning to become pregnant and first trimester.
Cautions Hepatitis B and C, severe hepatic impairment-not recommended, severe renal impairment.
Side effects Anxiety, depression, diarrhea, dizziness, fatigue, flatulence, gastrointestinal discomfort, headache, nausea, skin reactions, osteonecrosis, sleep disorders, arthralgia, hepatic disorders, hypersensitivity, immune reconstitution inflammatory syndrome, myalgia, suicidal tendencies.
Pregnancy category X
Breastfeeding Excreted in milk in animal studies. Infant risk cannot be ruled out, instruct mothers not to breastfeed if they are receiving this therapy.
Counselling Administer at least 2 hours before or 6 hours after taking cation-containing antacids or laxatives. Advised woman of childbearing potential to use effective contraception. Perform pregnancy test before initiation of Dolutegravir.
Missed dose: *If a dose is more than 20 hours late on the once daily regimen (or more than 8 hours late on the twice daily regimen), the missed dose should not be taken and the next dose should be taken at the normal time.*

6.4.2.5 Fixed-dose combinations

DOLUTEGRAVIR (DTG) + LAMIVUDINE (3TC) + TENOFOVIR (TDF)

Tablet, DTG + 3TC + TDF (50 mg + 300 mg + 300 mg) NRH/RRH

Therapeutic group Antiretroviral (3-FDC).
Indications and dose **Treatment of HIV infection in combination with other antiretroviral agents** ADULT: DTG 50 mg PO once daily; 3TC 150 mg PO twice daily or 300 mg PO once daily; TDF 300 mg once daily; CHILD: DTG (12-17 years, body weight > 40 kg): 50 mg PO once daily; 3TC (Neonates): 2 mg/kg PO Q12hr; ≥ 1 month: 4 mg/kg PO Q12hr; ≥ 3 months: 5 mg/kg PO Q12; TDF not recommended in child age < 10 years.
For details, refer to National Guidelines on Treatment & Management of HIV & AIDS 3rd edition 2020.
Contraindications as under individual medicines.
Cautions as under individual medicines.
Side effects as under individual medicines.
Renal/ hepatic impairment as under individual medicines.
Pregnancy category as under individual medicines.
Breast-feeding as under individual medicines.
Counseling Take after meals at regular intervals.

LAMIVUDINE (3TC) + TENOFOVIR (TDF)

Tablet, (3TC + TDF) (300 mg + 300 mg) NRH/RRH

Therapeutic group Antiretroviral (2-FDC).
Indications and dose **Treatment of HIV infection in combination with other antiretroviral agents; Pre exposure prophylaxis (PrEP)** ADULT: 3TC 150 mg PO twice daily or 300 mg PO once daily; TDF 300 mg once daily; CHILD: 3TC (Neonates): 2 mg/kg PO Q12hr; ≥ 1 month: 4 mg/kg PO Q12hr; ≥ 3 months: 5 mg/kg PO Q12; TDF not recommended in child age < 10 years.
For details, refer to National Guidelines on Treatment & Management of HIV & AIDS 3rd edition 2020.
Contraindications as under individual medicines.
Cautions as under individual medicines.
Side effects as under individual medicines.
Renal impairment as under individual medicines.
Pregnancy category as under individual medicines.
Breast-feeding as under individual medicines.

6.4.3 Anti-hepatitis medicines

6.4.3.1 Medicines for hepatitis B

TENOFOVIR

Tablet, 300 mg NRH/RRH

Therapeutic group Antiviral.
Indications and dose **Chronic hepatitis B infection** ADULT 300 mg *PO,* Q24H.
Cautions Hepatic impairment, lactic acidosis, renal impairment, elderly patient.
Side effects Pruritus, rash, nausea, abdominal pain, vomiting, dizziness, insomnia, fever, lactic acidosis, hepatomegaly, angioedema.
Renal impairment CrCl 30-49 mL/min: 300 mg, Q48H; CrCl 10-29 mL/min: 300 mg, Q72-96H; CrCl <10 mL/min: no recommendation available; avoid.
Pregnancy category B
Breast-feeding Excretion in milk unknown, avoid.

6.5 Antiprotozoal medicines

6.5.1 Anti-amoebic medicines

METRONIDAZOLE

Injection, 5 mg/mL (100 mL) NRH/RRH/DH

Therapeutic group Antiprotozoal.
Indications and dose **Invasive intestinal amoebiasis; Extra-intestinal amoebiasis (including liver abscess)** ADULT: 800 mg *PO,* Q8H; CHILD (1-2 years): 200 mg *PO,* Q8H x 7 days; CHILD (3-6 years): 200 mg *PO,* Q6H; CHILD (7-9 years): 400 mg *PO,* Q8H; * *5 days for intestinal infection and 5-10 days in extra-intestinal infection.* **Giardiasis** ADULT: 2 g *PO,* Q24H x 3 days, alternatively 400 mg, Q8H x 5 days; CHILD (1-2 years): 500 mg *PO,* Q24H x 3 days; CHILD (3-6 years): 600-800 mg *PO,* Q24H x 3 days; CHILD (7-9 years): 1 g *PO,* Q24H x 3 days.
For details, refer to page no. 41.

6.5.2 Anti-leishmaniasis medicines

AMPHOTERICIN B

Powder for injection (liposomal), 50 mg NRH/RRH

Therapeutic group Anti-leishmaniasis.
Indications and dose **Visceral leishmaniasis** *Immunocompetent patients* ADULT: 3 mg/kg *IV infusion,* Q24H on days 1-5, 14 and 21; CHILD, same as adult; *Immunocompromised patients* ADULT: 4 mg/kg *IV infusion,* Q24H on days 1-5, 10, 17, 24, 31 and 38; CHILD: same as adult. *For details, refer to page no. 54*

6.5.3 Antimalarials medicines

6.5.3.1 For curative treatment

ARTHEMETHER + LUMEFANTRINE

Tablet, (20 mg + 120 mg) NRH/RRH/DH/PHC

Therapeutic group Antimalarial.
Indications and dose **Treatment of acute uncomplicated falciparum malaria** (except pregnant women in their first trimester) **chloroquine-resistant non-falciparum malaria A**DULT and CHILD: a total dose of 5–24 mg/kg body weight of artemether and 29–144 mg/ kg body weight of lumefantrine. Recommended dosage regimen: Artemether + lumefantrine is given twice a day for 3 days (total, six doses). The first two doses should, ideally, be given 8 h apart.

Body weight (kg)	Dose (mg) of artemether + lumefantrine given twice daily for 3 days
5 to < 15	20 + 120
15 to < 25	40 + 240
25 to < 35	60 + 360
≥ 35	80 + 480

Contraindications History of arrhythmias, clinically relevant bradycardia, and of congestive heart failure accompanied by reduced left ventricular ejection fraction, family history of sudden death or of congenital QT interval prolongation, breastfeeding.
Cautions Electrolyte disturbances, concomitant use with other medicines known to cause QT-interval prolongation, hepatic impairment, renal impairment, pregnancy, monitor patients unable to take food (greater risk of recrudescence).
Side effects Abdominal pain, anorexia, diarrhoea, vomiting, nausea, palpitations, cough, headache, dizziness, sleep disturbances, asthenia, arthralgia, myalgia, pruritus, rashes.
Hepatic impairment Use with caution.
Renal impairment Use with caution.

Pregnancy category C
Breast-feeding Excreted in milk, use with caution.

ARTESUNATE

Powder for injection, 30 mg NRH/RRH/DH/PHC

Therapeutic group Antimalarial.
Indications and dose **Treatment of *P. vivax* and *P. falciparum* malaria** ADULT and CHILD (20 kg and greater): 2.4 mg/kg IV (slow bolus over 1 to 2 minutes) at 0 hours, at 12 hours, at 24 hours, and then once daily until parasite density is 1% or less; MAX. 7 days. Follow with a full course of oral antimalarial therapy when patient can tolerate oral medications; administer with an antimalarial agent that is active against the hypnozoite liver stage forms of *Plasmodium*, such as primaquine, to patients with severe malaria due to *P. vivax* or *P. ovale*. CHILD (Less than 20 kg): 3 mg/kg IV at 0 hours, at 12 hours, at 24 hours, and then once daily, if necessary, until parasite density is 1% or less; MAX duration, 7 days. Follow with a full course of oral antimalarial therapy when patients can tolerate oral medications.
Contraindications Known serious hypersensitivity artesunate.
Cautions Consider discontinuing if hypotension, dyspnoea, urticaria, or generalised rash occurs. Post-treatment haemolytic anaemia, sometimes requiring transfusion.
Side effects Anaemia, increased transaminase, thrombocytopenia, hyperbilirubinemia, leukocytosis,
Hepatic impairment No specific dosage adjustments are needed.
Renal impairment No specific dosage adjustments are needed.
Pregnancy category No data available.

CHLOROQUINE

Tablet, 150 mg NRH/RRH/DH/PHC

Therapeutic group Antimalarial.
Indications and dose **Acute attacks of malaria due to P. vivax, P. malariae, P. ovale, and susceptible strains of P. falciparum** ADULT: 1 g PO, then 500 mg PO after 6-8 hrs, then 500 mg PO at 24 hr and 48 hr after initial dose; total dose of 2500 mg in 3 days; CHILD: first dose, 10 mg base/kg (not to exceed 600-mg base/dose); second dose (6 hr after first dose) 5 mg base/kg (not to exceed 300 mg base/dose); third dose (24 hr after first dose) 5 mg base/kg (not to exceed 300 mg base/dose); fourth dose (36 hr after first dose) 5 mg base/kg (not to exceed 300 mg base/dose), total dose of 25 mg base/kg. **Prophylaxis of malaria in geographic areas where resistance to chloroquine is not present** ADULT: 500 mg PO weekly on the same day each week; begin 1-2 weeks before travel, during travel, and for 4 weeks after leaving endemic area; CHILD: 5 mg/kg PO weekly, not to exceed 500 mg, on the same day each week; begin 1-2 weeks before travel, during travel, and for 4 weeks after leaving endemic area.
Note *Dosing is based on chloroquine base; chloroquine phosphate 16.6 mg is equivalent to 10 mg chloroquine base.*
Contraindications Psoriasis; porphyria, retinal or visual field changes.
Cautions Diabetes, history of auditory damage, alcoholism, epilepsy, heart failure, hepatic impairment, acute porphyrias.
Side effects GI disturbances, headache, pruritus, rashes, skin reactions, visual disturbances, keratopathy and non-reversible retinopathy can occur, skin reactions, hair loss, and discoloration of skin, nails, and mucous membranes.
Hepatic impairment Use with caution in patients with hepatic impairment, alcoholism, or concurrent therapy with hepatotoxic agents.
Renal impairment CrCl <10 mL/min: 50% of dose.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.
Counselling Take after food.

DOXYCYCLINE

Tablet/Capsule, 100 mg NRH/RRH/DH/PHC

Therapeutic group Antibacterial.

Indications and dose **Malaria; *uncomplicated* (Adjunct)** ADULT: 100 mg PO twice daily for 7 days; give in combination with quinine sulphate 650 mg PO 3 times daily for 3 days**;** CHILD (*8 years or older*): 2.2 mg/kg (max. 100 mg) PO every 12 hours for 7 days; give in combination with quinine sulphate 10 mg/kg PO 3 times daily for 3 days (or 7 days if infection is acquired in Southeast Asia); ***Severe***: 100 mg PO twice daily for 7 days; give in combination with quinidine gluconate 10 mg/kg IV loading dose over 1 to 2 hours, then 0.02 mg/kg/min IV continuous infusion for at least 24 hours; CHILD (≥ *8 years,* ≥ *45 kg*): 100 mg PO twice daily for 7 days; give in combination with quinidine gluconate 10 mg/kg IV loading dose over 1 to 2 hours, then 0.02 mg/kg/min IV continuous infusion for at least 24 hours; CHILD *(≥8 years,* <*45 kg*): 2.2 mg/kg PO every 12 hours for 7 days; give in combination with quinidine gluconate 10 mg/kg IV loading dose over 1 to 2 hours, then 0.02 mg/kg/min IV continuous infusion for at least 24 hours, continue for 3 days if infection acquired in Africa or South America or 7 days if infection is acquired in Southeast Asia; may switch to oral quinine once parasite density is less than 1%. **Malaria; Prophylaxis** ADULT: 100 mg PO once a day beginning 1 to 2 days prior to travel; CHILD (>8 years): 2 mg/kg PO MAX. 100 mg/day once a day beginning 1 to 2 days prior to travel continued during travel, and for 4 weeks after travel to malarious area. *For details, refer to page no. 40*

PRIMAQUINE

Tablet, 7.5 mg — NRH/RRH/DH/PHC

Therapeutic group Antimalarial.
Indications and dose **Prevention of relapse of *P. vivax* and *P. ovale* malaria** ADULT: 30 mg PO daily for 14 days; CHILD: 0.8 mg/kg PO once daily (0.5 mg base/kg/dose) for 14 days, max. 52.6 mg/day (equivalent to 30 mg of primaquine base) in combination with appropriate blood-stage antimalarial agents. **Chemoprophylaxis in *P. vivax* and *P. ovale* malaria** ADULT: 30 mg PO daily for 14 days after departure from malaria-endemic area; CHILD: 0.5 mg/kg (max. 30 mg/day), start 1-2 days prior to travel and continue for 7 days after departure from malaria endemic area. **Treatment of uncomplicated *P. vivax* and *P. ovale* malaria** ADULT: 30 mg PO daily for 14 days with chloroquine or hydroxychloroquine. Alternatively, for mild G6PD deficiency or as an alternative to daily regimen: 45 mg PO weekly for 8 weeks; CHILD: 0.5 mg/kg (max. 30 mg/day) daily for 14 days with chloroquine or hydroxychloroquine.
Contraindications Acutely ill patients who tend to develop granulocytopenia (e.g., rheumatoid arthritis, SLE), concurrent use with other medications causing haemolytic anaemia or myeloid bone marrow suppression, concurrent use with or recent use of quinacrine.
Cautions G-6-PD deficiency, systemic disease associated with granulocytopenia (e.g., rheumatoid arthritis), pregnancy and breastfeeding.
Side effects Nausea, vomiting, anorexia, abdominal pain.
Hepatic impairment Use with caution.
Renal impairment CrCl <10 mL/min: 50% of dose.
Pregnancy category D
Breast-feeding Excretion in milk unknown, use with caution.
Counselling Take this medicine on an empty stomach.

QUININE

Tablet, 300 mg — NRH/RRH/DH
Injection, 300 mg/mL (2 mL) — NRH/RRH/DH

Therapeutic group Antimalarial.
Indications and dose **Non-complicated *P. falciparum malaria*** ADULT: 648 mg PO Q8hr for 7 days; CHILD: 30 mg/kg/day PO divided three times per day for 3–7 days; should not exceed the usual adult PO dosage. **Chloroquine-resistant *P falciparum* malaria** ADULT: 648 mg PO Q8hr x 3-7 days with concomitant tetracycline, doxycycline, or clindamycin; CHILD: 30 mg/kg/day PO divided three times per day for 3-7 days, with concomitant doxycycline, tetracycline or clindamycin; should not exceed the usual adult PO dosage. **Chloroquine-resistant *P vivax* malaria** ADULT: 648 mg PO Q8hr for 3-7 days with concomitant doxycycline (or tetracycline) and PO primaquine; CHILD: 30 mg/kg/day PO three times per day x 3–7 days, with concomitant doxycycline & PO primaquine; should not exceed the usual adult PO dosage.

Contraindications Myasthenia gravis, optic neuritis, G6PD deficiency, thrombotic thrombocytopenic purpura, haemolytic uremic syndrome, thrombocytopenia, pregnancy.
Cautions Atrial fibrillation, heart block, hepatic impairment, elderly.
Side effects Agitation, tinnitus, abdominal pain, acute renal failure, angioedema, blood disorders, cardiovascular effects, cinchonism, confusion, diarrhoea, dyspnoea, flushed skin, headache, hearing impairment, hot skin, hypersensitivity reactions, hypoglycaemia (especially after parenteral administration), intravascular coagulation, muscle weakness, nausea, photosensitivity, rashes, temporary blindness, thrombocytopenia, vertigo, visual disturbances, vomiting.
Hepatic impairment Use with caution.
Renal impairment: CrCl 10-50 mL/min: Q8-12H; CrCl <10 mL/min: Q24H.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.

6.5.3.2 For chemoprevention

CHLOROQUINE

Tablet, 150 mg NRH/RRH/DH/PHC

Therapeutic group Antimalarial. *For details, refer to page no. 62*

DOXYCYCLINE

Tablet/Capsule, 100 mg NRH/RRH/DH/PHC

Therapeutic group Antimalarial. *For details, refer to page no. 40*

6.5.4 Antipneumocystis and antitoxoplasmosis medicines

SULFAMETHOXAZOLE (SMZ) + TRIMETHOPRIM (TMP) (Co-trimoxazole)

Tablet, (400 mg + 80 mg) NRH/RRH/DH/PHC
Syrup, (200 mg + 40 mg)/5mL (60 mL) NRH/RRH/DH/PHC

Therapeutic group Pneumocystis and toxoplasmosis medicine.
Indications and dose **Prophylaxis of *Pneumocystis (Carinii) Jiroveci* pneumonia in HIV patients** ADULT: 80 -160 mg TMP PO every day or 160 mg TMP 3 times/week on consecutive or alternate days; CHILD > 2 months: 150 mg TMP/m²/day PO divided Q12 hr for 3 days/week on consecutive or alternate days. **Treatment** ADULT: 5-20 mg TMP/kg/day PO/IV divided Q6-8 hr; CHILD>2 months: 15-20 mg TMP/kg/day PO/IV divided Q6-8 hr for 21 days. **HIV-infection-Toxoplasma encephalitis** ADULT: Initial therapy, SMZ/TMP 25/5 mg/kg PO or IV twice daily for 6 weeks; CHILD >2 months 10-15 mg TMP PO/IV in divided Q 8-12 hours for ≥6 week; *Chronic maintenance* ADULT: SMZ/TMP 800/160 mg PO once or twice daily; CHILD >2 months: 150 mg TMP/m²/day in 2 divided doses. **HIV-infection Toxoplasma encephalitis primary prophylaxis** ADULT: SMZ/TMP 800/160 mg PO daily or SMZ/TMP 800/160 mg PO 3 times weekly; CHILD >2 months: 150 mg TMP/m²/day in 2 divided doses. *Children <2 months, not recommended*. *For details, refer to page no. 40*

7. ANTIMIGRAINE MEDICINES

7.1 For treatment of acute attack

ASPIRIN

Tablet, (soluble) 300 mg NRH/RRH/DH

Therapeutic group Non-steroidal Anti-inflammatory Medicines (NSAIMs).
Indications and dose **Acute migraine** ADULT: 900 mg for 1 dose, to be taken as soon as migraine symptoms develop. *Not recommended in children below 16 years.*

Contraindications hypersensitivity to aspirin or other NSAIMs; use other than as an antiplatelet in children and adolescents under 16 years (Reye's syndrome), active peptic ulceration, haemophilia, other bleeding disorders.
Cautions Asthma, uncontrolled hypertension, pregnancy, breastfeeding.
Side effects Bronchospasm, gastrointestinal haemorrhage, vomiting, upset stomach, heartburn, drowsiness, headache.
Counselling To be taken after or with meals.

IBUPROFEN

Tablet, 400 mg — NRH/RRH/DH/PHC

Therapeutic group Non-steroidal Anti-inflammatory Medicines (NSAIMs).
Indications and dose **Acute migraine** ADULT: 400 mg *PO,* at the onset of attack, then 400 mg, Q8H; increased if necessary up to 600 mg, Q6H. *For details, refer to page no. 17*

PARACETAMOL

Syrup, 125 mg/5 mL (60 mL) — NRH/RRH/DH/PHC
Tablet, 500 mg — NRH/RRH/DH/PHC

Therapeutic group Non-steroidal Anti-inflammatory Medicines (NSAIMs).
Indications and dose **Acute migraine** ADULT: 1 g PO for 1 dose, at the onset of attack, followed by 2 tablets, Q4H if required; max. 6 tablets/day. *For details, refer to page no. 19*

ERGOTAMINE + CAFFEINE

Tablet, (1 mg + 100 mg) — NRH/RRH/DH

Therapeutic group Antimigraine.
Indications and dose **Acute migraine** ADULT: 1 tablet, to be taken at onset, then 1 tablet every 30 minutes if required; max. 3 tablets in 24 hours; max. 4 tablets per attack; max. 6 tablets in one week; max. 2 courses of treatment in one month; CHILD: not recommended.
Contraindications Pregnancy and breastfeeding, sepsis, acute porphyria, peripheral or coronary vascular disease, severe hypertension, severe hepatic and renal impairment.
Cautions Anaemia, cardiac disease, dependence, elderly, risk of peripheral vasospasm.
Side effects Abdominal pain, dizziness, malaise, nausea and vomiting, cyanosis, peripheral vasoconstriction, weakness in extremities.
Over dosage Chronic self-poisoning can lead to sustained vasoconstriction and eventual gangrene. Acute overdose may occur with only 2-3 times the normal dose; symptoms include vomiting, diarrhoea, thirst, paraesthesia, cold extremities, rapid and weak pulse, confusion, convulsion and coma.
Hepatic impairment Avoid in severe impairment.
Renal impairment Avoid.
Pregnancy category X
Breastfeeding Excreted in milk, avoid.
Note *Only use ergotamine if the headache is unresponsive to simple analgesics.*

7.2 For prophylaxis

PROPRANOLOL

Tablet, 40 mg — NRH/RRH/DH

Therapeutic group Antimigraine.
Indications and dose **Prophylaxis of migraine** ADULT: 80 mg/day *PO* divided Q6-8H; increased by 20-40 mg/day every 3-4 weeks; not to exceed 160-240 mg/day divided Q6-8H.
Note *Withdraw therapy if satisfactory response is not seen after 6 weeks. For details, refer to page no. 84.*

AMITRIPTYLINE

Tablet, 25 mg — NRH/RRH/DH

Therapeutic group Antidepressant.
Indications and dose **Prophylaxis of migraine** ADULT: 12.5-25 mg *PO,* Q24H; then increased if necessary to 50-75 mg, Q24H (max. 150 mg/dose); dose to be taken at bedtime. *For details, refer to page no.145.*

8. IMMUNOMODULATORS AND ANTINEOPLASTICS

8.1 Immunomodulators for non-malignant disease

CYCLOSPORINE (Neoral®)

Capsule, 25 mg, 50 mg and 100 mg — NRH

Therapeutic group Immunosuppressant.
Indications and dosage **Organ transplants** (used alone) ADULTs and CHILD (> 3 months): 10-15 mg/kg *PO*, administered 4-12 hours prior to transplantation; followed by 10-15 mg/kg/day for 1-2 weeks postoperatively; maintenance dose 2-6 mg/kg/day. **Nephrotic syndrome** ADULT: 5 mg/kg/day *PO,* Q12H; CHILD: 5-6 mg/kg/day *PO,* Q12H.
Contraindications Abnormal renal function, malignancy, uncontrolled hypertension and infections, use with tacrolimus, breastfeeding.
Cautions Monitor kidney function, liver function, and blood pressure, measure serum potassium especially in marked renal dysfunction, measure blood lipids before treatment and thereafter as appropriate, pregnancy and breastfeeding.
Side effects Abdominal pain, anorexia, diarrhoea, fatigue, gingival hyperplasia, headache, hypercholesterolemia, hepatic dysfunction, hyperkalemia, hyperlipidemia, hypertension, hyperuricemia, hypomagnesaemia, muscle cramps, myalgia, nausea, paraesthesia, renal dysfunction, tremor, vomiting.
Hepatic impairment Adjust dose based on bilirubin and liver enzymes.
Renal impairment Reduce dose by 25–50% if serum creatinine increases more than 30% above baseline.
Pregnancy category C
Breastfeeding Excreted in milk, avoid.
Counselling Avoid excessive exposure to UV light (sunlight).
Note *Due to differences in bioavailability, care should be taken when switching between different brands of cyclosporine, lower doses are required when used with other immunosuppressants.*

MYCOPHENOLATE MOFETIL (Cellcept®)

Capsule, 250 mg — NRH
Capsule, 500 mg — NRH/RRH

Therapeutic group Immunosuppressant.
Indications and dose **Prophylaxis of acute renal transplant rejection (in combination with a corticosteroid and cyclosporine)** ADULT: 1 g *PO,* Q12H, starting within 72 hours of transplantation; CHILD: 600 mg/m^2 *PO,* Q12H; max. 2g/day. **Prophylaxis of acute rejection in renal transplantation (in combination with a corticosteroid and tacrolimus)** CHILD: 300 mg/m^2 *PO,* Q12H; max. 2g/day. **Prophylaxis of acute cardiac transplant rejection** ADULT: 1.5 g *PO,* Q12H, starting within 5 days of transplantation.
Cautions Elderly, children, active serious GI disease, delayed graft function, increased susceptibility to skin cancer (avoid exposure to strong sunlight).
Side effects Diarrhoea, vomiting, and abdominal pain, GI ulceration and bleeding, abnormal liver function tests, hepatitis, jaundice, pancreatitis, oedema, tachycardia, hypertension, hypotension, vasodilatation, cough, dyspnea, insomnia, agitation, tremor, dizziness, headache, influenza-like syndrome infections, hyperglycemia, renal impairment, increased risk of malignancies, particularly of the skin, blood disorders (including leukopenia, anaemia, thrombocytopenia, pancytopenia), disturbances of electrolytes and blood lipids, arthralgia, alopecia, acne, rash.
Renal impairment GFR <25 mL/min/1.73 m^2: not to exceed 1 g, Q12H.
Pregnancy category D

Breast-feeding Excreted in milk, avoid.
Counselling Patients should be warned to report immediately any signs or symptoms of bone marrow suppression e.g. infection or inexplicable bruising or bleeding.
Note *Monitor complete blood counts every week for 4 weeks, then twice a month for 2 months then every month in the first year (neutropenia warrants interruption of treatment).*

TACROLIMUS (Pangraf®)

Tablet, 1 mg NRH

Therapeutic group Immunosuppressant.
Indications and dose **Prophylaxis of graft rejection following liver transplantation, starting 12 hours after transplantation** ADULT: 100-200 mcg/kg/day *PO,* Q12H; CHILD: 150 mcg/kg *PO,* Q12H. **Prophylaxis of graft rejection following kidney transplantation, starting within 24 hours of transplantation** ADULT: 200-300 mcg/kg/day *PO,* Q12H; CHILD: 150 mcg/kg *PO,* Q12H.
Contraindications Hypersensitivity to castor oil and macrolides.
Cautions UV light (avoid excessive exposure to sunlight and sunlamps), increased risk of infections, lymphoproliferative disorders, malignancies, neurotoxicity, QT-interval prolongation.
Side effects Acne, alopecia, anaemia, anorexia, arthralgia, ascites, bloating, blood disorders, cholestasis, confusion, constipation, depression, diarrhoea, dizziness, dyspepsia, dyspnea, electrolyte disturbances, flatulence, gastro-intestinal inflammation, haemorrhage, headache, hepatic dysfunction, hyperglycemia, hyperkalemia, hypertension, hyperuricemia, hypokalemia, impaired hearing, ischemic events, photosensitivity.
Hepatic impairment Dose reduction necessary in moderate and severe impairment.
Renal impairment Use lower end of dosing range, monitor renal function and adjust dose accordingly.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.
Counselling Avoid excessive exposure to UV light (sunlight).
Note *To ensure maintenance of therapeutic response, when a patient is stabilised on a particular brand, oral tacrolimus products should be prescribed and dispensed by brand name only.*

8.2 Antineoplastics and supportive medicines

8.2.1 Cytotoxic medicines

CYCLOPHOSPHAMIDE

Powder for injection, 200 mg NRH
Tablet/Capsule, 50 mg NRH/RRH

Therapeutic group Cytotoxic.
Indications and dose **Acute myeloid leukaemia; Breast cancer**; **Burkitt's lymphoma; Chronic lymphoid leukaemia; Chronic myeloid leukaemia; Hodgkin's disease, Stages III and IV; Malignant histiocytosis**; **Malignant lymphoma - mixed small and large cell; Mantle cell lymphoma, Stages III and IV; Multiple myeloma; Mycosis fungoides, Advanced; Neuroblastoma, Disseminated disease; non-Hodgkin's lymphoma; Ovarian cancer, Adenocarcinoma; Retinoblastoma; Small lymphocytic lymphoma, Nodular or diffuse;** (*Single agent*) ADULT and CHILD: 40 to 50 mg/kg IV in divided doses over 2 to 5 days OR 10 to 15 mg/kg IV every 7 to 10 days OR 3 to 5 mg/kg IV twice weekly; *ORALLY* (*single agent*) 1 to 5 mg/kg/day PO for both initial and maintenance dosing. **Lupus nephritis** ADULT and CHILD (*Induction, low-dose regimen)*: 500 mg IV every 2 weeks for a total of 6 doses; ADULT (*Induction, high-dose regimen)*: 500-1000 mg/m^2 BSA IV once monthly for 6 months; CHILD (*Induction, high-dose regimen):* 500 to 750 mg/m(2) IV pulse dose; if tolerated, increase to 750 mg/m(2)/pulse (MAX 1000 to 1200 mg/pulse) and administer 6 monthly pulses. **Systemic lupus erythematosus** *Organ- or life-threatening disease* ADULT: 0.75 to 1 g/ m^2 BSA IV once monthly for 6 months.
Contraindications Severe bone marrow depression, and pre-existing hemorrhagic cystitis.

Cautions Hepatic and renal impairment, leukopenia, thrombocytopenia, recent radiation therapy or chemotherapy, diabetes melitus.
Side effects Leukopenia, alopecia, hemorrhagic cystitis occurs in 5-10% of patients, anorexia, cardiotoxicity, disturbances of carbohydrate metabolism, interstitial pulmonary fibrosis, pancreatitis, pigmentation of nails, palms and soles, urothelial toxicity.
Hepatic impairment Dose reduction may be required.
Renal impairment Reduce dose if serum creatinine concentration greater than 120 micromol/litre.
Pregnancy category D
Breast-feeding Excreted in milk, avoid.
IV fluid compatibility Dextrose 5%, sodium chloride 0.9%.
Counselling Take the tablets on an empty stomach. Drink plenty of water with this medicine. Use effective contraception during and for at least 3 months after treatment in men or women to prevent conception.
Note *Manufacturer's literature should be consulted for specific dosage information.*

DOXORUBICIN

Powder for injection, 10 mg NRH

Therapeutic group Cytotoxic.
Indications and dose **Chemotherapy of neoplastic disease (alone or in combination with other cytotoxic medicines)** ADULT: 60-75 mg/m^2 *Iv infusion,* Q21 days, or 25-30 mg/m^2/day on 2 or 3 successive days, repeated every 3 to 4 weeks, or 20 mg/m^2 once a week; CHILD: 30 mg/ m^2/day on three successive days every 4 weeks.
Contraindications Hepatic impairment, myelosuppression, myocardial infarction, myocardial insufficiency.
Caution Cardiac diseases, hypertension and previous myocardial irradiation.
Side effects Dehydration, diarrhoea, red coloration of the urine.
Hepatic impairment Reduce dose according to bilirubin or avoid in severe impairment.
Pregnancy category D
Breast-feeding Excretion in milk unknown, avoid.
IV fluid compatibility Dextrose 5%.
Note *Great care should be taken to prevent exposure of skin to doxorubicin, any doxorubicin solution that comes in contact with the skin or mucosa should be washed off thoroughly with soap and water.*

FLUOROURACIL (5-FU)

Injection, 50 mg/mL (10 mL) NRH

Therapeutic group Cytotoxic.
Indications and dose **Treatment of some solid tumours including GI tract cancers and breast cancer; In combination with folinic acid in advanced colorectal cancer** ADULT: 500 mg/m^2 *IV injection,* days 1-5 OR 450-600 mg/m^2 *IV injection* weekly OR 200-400 mg/m^2 *IV infusion,* Q24H; Max. 800 mg/day.
Contraindications Poor nutritional status, bone marrow suppression, serious infection, recent surgery, dihydropyrimidine dehydrogenase deficiency.
Cautions Discontinue in case of stomatitis, oesophagopharyngitis, leukopenia, thrombocytopenia, GI bleeding, haemorrhage and diarrhoea, pregnancy.
Side effects Loss of appetite, headache, nausea and vomiting, diarrhoea, mucositis, myelosuppression, alopecia, photosensitivity, hand-foot syndrome.
Hepatic impairment Use with caution.
Pregnancy category D
Breast-feeding Excretion in milk unknown, avoid.
IV fluid compatibility Dextrose 5%, sodium chloride 0.9%.

FOLINIC ACID

Injection, 10 mg/mL (5 mL) NRH

Therapeutic group Chemotherapy rescue agent.
Indications and dose **Prevention of methotrexate-induced adverse effects** ADULT: 15 mg *IM or IV injection or IV infusion,* Q6H x 24 hours, started 12-24 hours after start of methotrexate infusion. **Suspected methotrexate over dosage** ADULT: Initial dose equal to or exceeding dose of methotrexate, to be given at a maximum rate of 160mg/minute. **Metabolic disorders leading to folate deficiency** CHILD: 15 mg *IV infusion,* Q24H, larger doses may be required in older children.
Contraindications Vitamin B12 deficiency anaemia, pernicious anaemia, intrathecal injection.
Cautions Pernicious anaemia or other megaloblastic anemias caused by vitamin B12 deficiency; avoid simultaneous administration of methotrexate.
Side effects Diarrhoea, nausea, vomiting, stomatitis, thrombocytosis.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.
IV fluid compatibility Dextrose 5%, compound solution of sodium lactate, sodium chloride 0.9%, water for injection.

METHOTREXATE

Tablet, 2.5 mg NRH/RRH/DH

Therapeutic group Antineoplastic medicine.
Indications and dose **Active rheumatoid arthritis (RA)** *by oral administration*, 7.5 mg once weekly (as a single dose or divided into 3 doses of 2.5 mg given at intervals of 8 hour) adjusted according to response; max total weekly dose: 20 mg. **Psoriasis** 10 to 25 mg once weekly, adjusted according to response. *Not recommended for the children; Reduce dose in elderly.*
Contraindications Significant renal impairment and haematological failure, significant pleural effusion or ascites is present, liver impairment, pregnancy and lactation**.**
Cautions Blood counts should be monitored.
Side effects Ulcerative stomatitis, leukopenia, hepatotoxicity, nausea, abdominal distress, malaise, fatigue, chills, fever, dizziness, decreased resistance to infection, rash, bone marrow depression, gingivitis, renal failure, headache, blurred vision; uncommon with low dose maintenance therapy.
Note *Pulmonary toxicity may be a special problem in RA. Patient to seek advice if dyspnea, cough or fever develops.*

8.2.2 Hormones and antihormones

DEXAMETHASONE

Injection, 4 mg/mL (2 mL) NRH/RRH/DH/PHC
Tablet, 4 mg NRH/RRH

Therapeutic group Corticosteroid.
Indications and dose **Allergic conditions and inflammation** ADULT: 4mg *PO,* Q12H; CHILD: 0.5-2 mg/kg *PO,* Q12H. **Cerebral oedema** ADULT: 10 mg *IV injection*, STAT, then 4 mg *IM injection,* Q6H until clinical improvement is observed. **Shock** ADULT: 20 mg *IV injection*, then 3 mg/kg/day by continuous IV infusion. **Multiple Sclerosis** ADULT: 30mg/day *PO,* for 1 week followed by 4-12mg/day for 1 month.
Contraindicated Systemic fungal infection, cerebral malaria, administration of live vaccines.
Cautions Prolonged use of steroids increases susceptibility to infections and severity of infections; see under prednisolone.
Side effects Hypertension, cataract, raised intraocular pressure, corneal oedema, depression, euphoria, cardiomyopathy, hyperglycemia.
Pregnancy Category C
Breastfeeding Excreted in milk, avoid.
IV fluid compatibility Dextrose 5%, sodium chloride 0.9%.

HYDROCORTISONE SODIUM SUCCINATE

Injection, 100 mg/mL (2 mL) NRH/RRH/DH

Therapeutic group Adrenal hormones and synthetic substitutes (corticosteroid).
Indications and dose **Thyrotoxic crisis (thyroid storm)** ADULT: 100 mg, *IV injection,* Q6H; **Acute hypersensitivity reactions such as angioedema of the upper respiratory tract and anaphylaxis (adjunct to adrenaline)** ADULT: 100-300 mg, *IV injection*. **Adrenocortical Insufficiency** ADULT: 100-150 mg *IM, or slow IV injection or IV infusion,* Q8H-Q6H or when required. **Severe inflammatory bowel disease** ADULT: 100-500 mg *slow IV injection or IV infusion,* Q8H-Q6H or when required. **Severe acute asthma; Life-threatening acute asthma** ADULT: 100 mg *IV injection,* Q6H until conversion to oral prednisolone is possible; CHILD: 4 mg/kg *IV injection,* Q6H (max. 100 mg/dose) until conversion to oral prednisolone is possible. **Acute hypersensitivity reactions; Angioedema** CHILD (1-5 months): Initially 25 mg *IM or IV injection,* Q8H, adjusted according to response; CHILD (6 months-5 years): Initially 50 mg *IM or IV injection,* Q8H, adjusted according to response; CHILD (6-11 years): Initially 100 mg *IM or Iv injection,* Q8H, adjusted according to response; CHILD (12-17 years): Initially 200 mg *IM or IV injection,* Q8H, adjusted according to response.
Contraindications Hypersensitivity to corticosteroids, systemic fungal infections, concurrent administration of live vaccines, intrathecal administration, serious infections, use in premature infants.
Cautions Cirrhosis, hypertension, ocular herpes simplex, diverticulitis, myasthenia gravis, peptic ulcer disease, ulcerative colitis, psychotic tendencies, pregnancy, diabetes, cardiovascular disorder, renal insufficiency, ocular disease, head injury.
Side Effects Acne, adrenal suppression, arthralgia, bladder dysfunction, cardiomegaly, Cushing syndrome, delayed wound healing, diabetes, fat embolism, hyperglycemia, indigestion, insomnia, osteoporosis, syncope, tachycardia, vertigo.
Hepatic impairment Use with caution.
Renal impairment Use with caution, fluid retention may occur.
Pregnancy category C
Breastfeeding Excreted in breast milk, use with caution.
IV fluid compatibility Dextrose 5%, dextrose 10%, Compound solution of sodium lactate, sodium chloride 0.9%.

METHYLPREDNISOLONE SUCCINATE

Powder for injection, 500 mg NRH/RRH

Therapeutic group Adrenal hormones and synthetic substitutes (corticosteroid).
Indications and dose **Suppression of inflammatory and allergic disorders; Cerebral oedema associated with malignancy** ADULT: Initially 10-500 mg *IM or slow IV injection or IV infusion;* CHILD: 0.5-1.7 mg/kg/day *IM or slow Iv injection or IV infusion,* Q6H-Q12H, divide *doses depending on condition and response.* **Treatment of graft rejection reactions** ADULT: Up to 1 g/day *Iv infusion,* up to 3 days; CHILD: 10-20 mg/kg *IV injection,* Q24H x 3 days. **Severe erythema multiforme; Lupus nephritis; Systemic onset juvenile idiopathic arthritis** CHILD: 10-30 mg/kg *IV injection* Q24H.
Contraindications Hypersensitivity to corticosteroids, systemic fungal infections, concurrent administration of live vaccines; intrathecal administration, serious infections, use in premature infants.
Cautions Cirrhosis, hypertension, ocular herpes simplex, diverticulitis, myasthenia gravis, peptic ulcer disease, ulcerative colitis, psychotic tendencies, pregnancy, diabetes, cardiovascular disorder, renal insufficiency, ocular disease; head injury.
Side Effects Acne, adrenal suppression, arthralgia, bladder dysfunction, cardiomegaly, Cushing syndrome, delayed wound healing, diabetes, fat embolism, hyperglycemia, indigestion, insomnia, osteoporosis, syncope, tachycardia, vertigo.
Hepatic impairment Use with caution.
Renal impairment Use with caution, fluid retention may occur.
Pregnancy category C
Breastfeeding Excreted in breast milk, use with caution.
IV fluid compatibility Dextrose 5%, dextrose 5% sodium chloride 0.9%, sodium chloride 0.9%.

PREDNISOLONE

Tablet, 5 mg and 20 mg NRH/RRH/DH

Therapeutic group Adrenal hormones and synthetic substitutes.
Indications and dose **Suppression of inflammatory and allergic disorders; Immuno-suppression; Rheumatic disease; Nephrotic syndrome** ADULT: 10-20 mg *PO*, Q24H, may increase to 1 mg/kg (up to 60mg/day in severe disease), preferably taken in the morning after breakfast; ***Maintenance***: 2.5-15 mg/day can be increased with need; CHILD: 1-2 mg/kg (max. 60 mg) *PO,* Q24H x 3 days, longer if necessary. **Multiple Sclerosis** ADULT: 200 mg *PO,* Q24H x 1 week, then 80 mg, Q48H x 1 month. **Acute exacerbation of COPD** ADULT: 30-40 mg *PO,* Q24H x 7-14 days. **Mild to moderate acute asthma; Severe or life-threatening acute asthma** ADULT: 40-50 mg *PO,* Q24H x at least 5 days; CHILD (1 month-11 years): 1-2 mg/kg *PO,* Q24H (max. 40 mg/dose) x up to 3 days, longer if necessary; CHILD (12-17 years): 40-50 mg *PO,* Q24H x at least 5 days. **Ulcerative colitis; Crohn's disease** ADULT: Initially 20-40 mg *PO,* Q24H until remission occurs, followed by reducing doses, up to 60 mg/day, doses preferably taken in the morning after breakfast; CHILD (2-17 years): 2 mg/kg *PO,* Q4H (max. 60 mg/dose) until remission occurs, followed by reducing doses.
Contraindications Systemic fungal infection, varicella, superficial herpes simplex keratitis, administration of live or attenuated virus vaccines.
Cautions Cirrhosis, hypertension, ocular herpes simplex, diverticulitis, myasthenia gravis, peptic ulcer disease, ulcerative colitis, psychotic tendencies, pregnancy, diabetes, cardiovascular disorder, renal insufficiency, ocular disease, head injury.
Side effects Acne, adrenal suppression, delayed wound healing, diabetes mellitus, GI perforation, glucose intolerance, hepatomegaly, insomnia, menstrual irregularity, myopathy, peptic ulcer, psychosis, urticaria, weight gain, osteoporosis, vertigo, ulcerative esophagitis.
Hepatic impairment Use with caution.
Renal impairment Use with caution.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.
Counselling To be taken after or with meals.
Note *In acute asthma, tail off steroids within 7-10 days to avoid adrenal suppression.*

8.2.3 Supportive medicines

ALLOPURINOL

Tablet, 100 mg NRH/RRH/DH

Therapeutic group Medicine used to treat gout (xanthine oxidase inhibitor).
Indications and dose **Prophylaxis of gout** ADULT: Initially 100 mg PO daily, preferably after food, then adjusted according to plasma uric acid concentration; **Usual maintenance dose in mild conditions**: 100-200 mg PO daily; **Usual maintenance dose in moderately severe conditions**: 300-600 mg PO in divided doses daily (Max. per dose 300 mg); **Usual maintenance dose in severe conditions**: 700-900 mg PO daily in divided doses (Max. per dose 300 mg). **Prophylaxis of hyperuricemia associated with cancer chemotherapy and hyperuricemia nephropathy, enzyme disorders causing increased serum urate e.g. Lesch-Nyhan syndrome (children)** ADULT: 600-800 mg in divided doses, starting before 1-2 days before chemotherapy; CHILD (1 month-14 years): 10-20 mg/kg PO daily; Max. 400 mg per day; CHILD (15-17 years): Initially 100 mg PO daily; dose to be increased according to response, up to 900 mg daily in divided doses (max. per dose 300 mg).
Contraindications Not a treatment for acute gout but continue if attack develops when already receiving allopurinol and treat attack separately.
Cautions Prophylactic administration of NSAIMs (not aspirin) is recommended until a month after the uric acid level becomes normal, adequate fluid intake must be ensured (2-3 litres/day).
Side effects GI disorders, rashes, sometimes with fever may be seen (If mild, withdraw therapy and then re-introduce cautiously at a very low dose and increase gradually, discontinue immediately if recurrence occurs).

Pregnancy category C
Breast-feeding Excreted in milk, not known to be harmful.
Hepatic impairment Reduce dose.
Renal impairment Max. 100 mg daily, increased only if response is inadequate. In severe impairment, reduce daily dose below 100 mg, or increase dose interval.
Counselling Take after food with plenty of fluids.

9. ANTIPARKINSONISM MEDICINES

CARBIDOPA + LEVODOPA

Tablet, (25 mg +250 mg) NRH/RRH/DH

Therapeutic group Antiparkinsonian medicine.
Indications and dose **Parkinson disease** ADULT: Initially half to one tablet *PO,* Q6-8H, adjust according to response; ***maintenance dose*** 200-2000 mg/day (8 tablets), Q6-8H; CHILD: safety and efficacy not established.
Contraindications Narrow-angle glaucoma, concurrent administration of MAOIs or use within the last 4 days.
Cautions History of MI with residual atrial, nodal or ventricular arrhythmias, peptic ulcer, seizure, severe cardiovascular, respiratory, renal, hepatic or endocrine disease, bronchial asthma patients, major psychotic disorder, glaucoma.
Side effects Abnormal dreams, anorexia, anxiety, arrhythmias, chorea, confusion, dementia, depression, dizziness, drowsiness, dry mouth, dyskinesia, dystonia, euphoria, fatigue, insomnia, nausea, palpitations, postural hypotension, psychosis, syncope, taste disturbances, vomiting.
Hepatic impairment Use with caution.
Renal impairment Use with caution.
Pregnancy Category C
Breastfeeding Excreted in milk, avoid.
Counselling Advise patients to avoid activities requiring mental alertness or coordination until medicine effects are realised, as medicine may cause somnolence or sudden sleep onset. Inform patient to report symptoms of depression, suicidal behavior, or psychotic behavior, including hallucinations. Advise patients that medicine may discolour saliva, sweat, or urine to a dark red, brown, or black colour; garments may be discoloured. Instruct patients to avoid change in diet to high-protein foods as this may delay absorption.

TRIHEXYPHENIDYL

Tablet, 2 mg NRH/RRH/DH

Therapeutic group Antiparkinsonian medicine.
Indications **Parkinsonism; Medicine-induced extrapyramidal symptoms (but not tardive dyskinesia)** ADULT: 1 mg *PO,* Q24H, then increased in steps of 2 mg every 3-5 days; adjusted according to response; ***maintenance*** 5-15 mg/day, Q6-8H (max. 20 mg/day). **Parkinson's disease (in combination with levodopa/carbidopa** ADULT: 2-6mg/day *PO,* in divided doses. **Dystonia** CHILD (3 months-17 years): Initially 1-2 mg/day *PO,* Q12-24H, then increased in steps of 1 mg every 3-7 days, dose to be adjusted according to response and side-effects (max. 2 mg/kg/day).
Contraindications Angle-closure glaucoma, cardiovascular disease, GI obstruction, myasthenia gravis.
Cautions GI obstruction, urinary retention, elderly, prostatic hypertrophy, hypertension.
Side effects Dry mouth, GI disturbances, dizziness, blurred vision, less commonly urinary retention, tachycardia, hypersensitivity, nervousness, mental confusion, excitement and psychiatric disturbances in some susceptible patients (at high doses).
Hepatic impairment Use with caution.
Renal impairment Use with caution.
Pregnancy Category C
Breastfeeding Excreted in milk, avoid.
Counselling Tablets should be taken with or after food. Do not drive or operate machineries.
Note *Avoid abrupt withdrawal in patients taking long-term treatment.*

10. MEDICINES AFFECTING THE BLOOD

10.1 Anti-anemia medicines

FERROUS SULPHATE + FOLIC ACID

Tablet, (60 mg + 0.4 mg) NRH/RRH/DH/PHC

Therapeutic group Antianemic medicine.
Indications and dose **Severe anaemia** ADULT: One tablet *PO,* Q12H x 3 months; CHILD: 1-2 mg/kg/day up to a maximum of 15 mg/day. **Prevention of iron and folate deficiencies in pregnancy** ADULT: One tablet *PO,* Q12H throughout pregnancy.
Contraindications Hemochromatosis, hemolytic anaemia, anemias due to causes other than iron deficiency.
Cautions Avoid use in peptic ulcer diseases, ulcerative colitis, enteritis, patient receiving frequent blood transfusion. Avoid use in premature infants until the vitamin E stores, deficient at birth, are replenished. Administration of iron for >6 months should be avoided except in patients with continuous bleeding or menorrhagia.
Side effects GI irritation, vomiting, constipation (dose related), diarrhoea, faecal impaction.
Pregnancy category A
Breast-feeding Excreted in breast milk, safe.
Counselling Take this medicine after food and take an iron rich diet like green vegetables, liver, beef, beans and peaches; May discolour stools, do not worry.

FOLIC ACID

Tablet, 5 mg NRH/RRH/DH/PHC

Therapeutic group Antianemic medicine.
Indications and dose **Folate-deficiency megaloblastic anaemia** ADULT: 5 mg *PO,* Q24H x 4 months (until term in pregnant women), in malabsorption states, doses up to 15 mg/day may be required; CHILD (1-11 months): Initially 500 mcg/kg *PO,* Q24H (max. 5 mg/dose) x up to 4 months, in malabsorption states, doses up to 10 mg/day may be required. **Prevention of neural tube defects (women at a low risk of conceiving a child with a neural tube defect)** ADULT: 400 mcg, *PO* Q24H, to be taken before conception and until week 12 of pregnancy. **Prevention of neural tube defects (women in the high-risk group)** ADULT: 5 mg *PO,* daily until week 12 of pregnancy. **Prevention of methotrexate-induced side effects in rheumatic disease, Crohn's disease and severe psoriasis** ADULT and CHILD: 5 mg *PO* once weekly, dose to be taken on a different day to methotrexate dose. **Prophylaxis in chronic hemolytic states** ADULT: 5 mg *PO,* every 1-7 days, frequency dependent on underlying disease. **Prophylaxis of folate deficiency in dialysis** ADULT: 5 mg *PO,* every 1-7 days; CHILD (1 month-11 years): 250 mcg/kg *PO,* Q24H (max. 10 mg/dose). **Hemolytic anaemia; Metabolic disorders** ADULT: 5-10 mg *PO,* Q24H; CHILD (1 month-11 years): 2.5-5 mg *PO,* Q24H.
Cautions Should never be given alone for pernicious anaemia (may precipitate subacute combined degeneration of spinal cord).
Side effect Gastro-intestinal disturbances (rare).
Pregnancy category A
Breast-feeding Excreted in breast milk, safe.

IRON SUCROSE

Injection, 20 mg elemental iron/mL (5 mL) NRH/RRH/DH/PHC

Therapeutic group Anti-anemia.
Indications and dose **Iron deficiency anaemia associated with chronic kidney disease; Haemodialysis-dependent CKD**: 100 mg elemental iron IV (injection or infusion over 2-5 min) per dialysis session not to exceed total cumulative dose of 1000 mg divided in 3 doses/week. **Non-dialysis-dependent CKD**: 200 mg IV injection for 5 doses in over 14 days (cumulative 1000 mg in 14-day period). **Peritoneal dialysis-dependent** CKD: 300 mg IV infusion (1.5 hour) for 2 doses 14 days apart, THEN 400 mg IV infusion (2.5 hour) 14 days later (cumulative 1000 mg divided in 3

doses/week). *CHILD≥2 years:* **Haemodialysis-dependent:** 0.5 mg/kg IV Q2 weeks for 12 weeks; not to exceed 100 mg/dose. **Non-dialysis dependent or peritoneal-dependent (on erythropoietin):** 0.5 mg/kg IV Q4 weeks for 12 weeks; not to exceed 100 mg/dose.
Contraindications below 2 years of age, hypersensitivity to iron sucrose and any content of it.
Cautions a test dose of 1 mL should be given by IM route and patient kept under observation for 30 minutes; adrenaline injection should be available in case of anaphylaxis.
Side effects Hypotension, muscle cramps, headache, nausea.

ERYTHROPOIETIN

Injection, 2000 IU (0.5 mL) NRH/RRH

Therapeutic group Hematopoietic.
Indications and dose **CKD on dialysis**, By IV injection, initiate treatment when haemoglobin (Hgb) level < 10 g/dL, ADULT: initially 50-100 units/kg 3 times weekly. **CKD not on dialysis**, by IV/SC injection, ADULT: 50-100 units /kg 3 times weekly initially. Reduce dose by 25% if Hgb approaches 12 g/dL **or** increases >1 g/dL in any 2-week period. Increase by 25% If haemoglobin <10 g/dL and does not increase by 1 g/dL after 4 weeks of therapy. ***Note:*** *Haemoglobin levels should not exceed 12 g/dL and should not rise >1 g/dL per 2-week time period during therapy in any patient.* **Chemotherapy related anaemia**, by SC injection, ADULT: 150 units/kg 3 times weekly initially; alternatively, 40,000 units SC once weekly until completion of chemotherapy course.
Contraindications hypersensitivity to human albumin, patients unable to receive thromboprophylaxis, pure red cell aplasia following erythropoietin therapy, uncontrolled hypertension.
Cautions Concurrent infection, epilepsy, malignant disease, cardiovascular disease, sickle-cell disease, thrombocytosis.
Side effects Fever, headache, cardiovascular events, diarrhoea, hypertensive crisis, influenza-like symptoms, nausea, vomiting, shunt thrombosis.
Pregnancy category C
Breastfeeding Excretion in breast milk unknown, use caution.

VITAMIN B_{12} (Mecobalamin)

Injection, 1 mg/mL (1 mL) NRH/RRH/DH

Therapeutic group Antianemic medicine.
Indications and dosage **Pernicious anaemia** ADULT: 1 mg *IM or SC injection,* Q24H x 7 days, then weekly for 1 month, then monthly; CHILD: 0.03-0.05 mg/day x 2 or more weeks (to a total dose of 1-5 mg), then with 0.1 mcg/month as maintenance dosage. **B_{12} Deficiency** ADULT: Initial, 0.30 mcg *IM injection*, Q24H x 5-10 days; ***Maintenance*** 0.1-0.2 mg monthly; CHILD: 0.2 mcg/kg/day *IM injection* x 2 days, followed by 1 mg/day x 2-7 days; then 0.1 mcg/week for 1 month; ***Maintenance*** 100 mcg.
Cautions Leber optic nerve atrophy, nasal disease.
Side effects Arthralgia, dizziness, headache, nasopharyngitis, hypokalemia.
Pregnancy category A
Breastfeeding Excreted in milk, safe.
Counselling Avoid IV route; Anaphylactic shock has occurred.

10.2 Medicines affecting coagulation

DABIGATRAN

Capsule, 110 mg NRH/RRH

Therapeutic group Anticoagulant.
Indications and Dose **Deep-vein thrombosis (DVT)and pulmonary embolism (PE). Prophylaxis of recurrent DVT and recurrent PE:** ADULT (18–74 years) 150 mg PO twice daily, (75–79 years) 110–150 mg PO twice daily, and (≥80 years) 110 mg PO twice daily. *Oral therapy should be initiated following at least 5 days treatment with a parenteral*

anticoagulant. **DVT and PE in patients with moderate renal impairment and at increased risk of bleeding (both treatment and prophylaxis):** ADULT 110–150 mg PO twice daily, following at least 5 days treatment with a parenteral anticoagulant. **DVT and PE in patients receiving concomitant verapamil (both treatment and prophylaxis):** ADULT 110 mg PO twice daily, following at least 5 days treatment with a parenteral anticoagulant. **Prophylaxis of stroke and systemic embolism in nonvalvular atrial fibrillation and with one or more risk factors*:** ADULT (18–74 years) 150 mg PO twice daily, (75–79 years) 110–150 mg PO twice daily and (≥80 years) 110 mg PO twice daily. **Prophylaxis of stroke and systemic embolism in nonvalvular atrial fibrillation and with one or more risk factors in patients receiving concomitant verapamil:** ADULT 110 mg PO twice daily. **Prophylaxis of stroke and systemic embolism in nonvalvular atrial fibrillation and with one or more risk factors in patients at increased risk of bleeding and with moderate renal impairment:** ADULT 110–150 mg PO twice daily. **Prophylaxis of venous thromboembolism (VTE) following total hip replacement surgery:** ADULT (18–74 years) 110 mg PO to be taken 1–4 hours after surgery, followed by 220 mg PO once daily for 28–35 days initiated on the first day after surgery, (75 years and above) 75 mg PO, to be taken 1–4 hours after surgery, followed by 150 mg PO once daily for 28–35 days initiated on the first day after surgery. **Prophylaxis of VTE following total hip replacement surgery in patients on concomitant amiodarone or verapamil:** ADULT (18 years and above) 75 mg, PO to be taken 1–4 hours after surgery, followed by 150 mg PO once daily for 28–35 days, initiated on the first day after surgery. **Prophylaxis of VTE following total knee replacement surgery:** ADULT (18–74 years) 110 mg PO to be taken 1–4 hours after surgery, followed by 220 mg once daily for 10 days, initiated on the first day after surgery, (≥75 years) 75 mg, to be taken 1–4 hours after surgery, followed by 150 mg once daily for 10 days, initiated on the first day after surgery. **Prophylaxis of VTE following total knee replacement surgery in patients receiving concomitant amiodarone or verapamil:** ADULT (18–74 years) 75 mg PO to be taken 1–4 hours after surgery, followed by 150 mg once daily for 28–35 days, initiated on the first day after surgery, (≥75 years) 75 mg PO to be taken 1–4 hours after surgery, followed by 150 mg once daily for 28–35 days initiated on the first day after surgery. **Heparin-induced thrombocytopenia (HIT) with thrombosis** ADULT: 150 mg PO twice daily after 5 or more days of treatment with a parenteral non-heparin anticoagulant; **Without thrombosis**:150 mg PO twice daily until platelet count recovery. **Treatment and prophylaxis of venous thromboembolism (VTE) following treatment with parenteral anticoagulant for at least 5 days** CHILD *8 to 18 years* (11 to <16 kg): 75 mg PO twice daily; (16 to <26kg): 110 mg PO twice daily; (26 to <41kg): 150 mg PO twice daily; (41 to <61kg): 185 mg PO twice daily; (61 to <81kg): 220 mg PO twice daily; and (>81 kg): 260 mg PO twice daily. **Surgery:** Discontinue dabigatran 1 to 2 days (CrCl ≥50 mL/min) or 3 to 5 days (CrCl <50 mL/min) before invasive or surgical procedures because of the increased risk of bleeding.

Risk factors* *for stroke and systemic embolism includes previous stroke or transient ischemic attack, symptomatic heart failure, age 75 years and above, diabetes mellitus, hypertension, etc.*

Note *Dabigatran oral capsule or tablet is indicated only in adults and children 8 to 18 years of age. Do not substitute different dosage forms (e.g. capsules) for oral pellets on a milligram-to-milligram basis and do not combine more than 1 dosage form to achieve the total dose.*

Contraindications Active pathological bleeding, mechanical prosthetic heart valve, serious hypersensitivity reaction (e.g.: anaphylaxis to Dabigatran, or any excipients of the product). Concomitant use with other anticoagulants.

Cautions Anesthesia with postoperative indwelling epidural catheter (risk of paralysis -give initial dose at least 2 hours after catheter removal and monitor neurological signs); bacterial endocarditis; bleeding disorders; body weight less than 50 kg; elderly >75 years; gastritis; gastro-esophageal, reflux; esophagitis; recent biopsy; recent major trauma; thrombocytopenia.

Hepatic impairment Avoid use in severe impairment; consider avoiding those with liver enzymes greater than 2 times the upper limit of normal.

Renal impairment Avoid use if creatinine clearance less than 30 mL/minute.

Side effects Impaired hepatic functions, anaemia, diarrhoea, haemorrhage, nausea, vomiting, wound complications, angioedema, and skin reactions, GI discomfort, thrombocytopenia.

Pregnancy category C

Breastfeeding Excreted in breast milk in less amounts, Infant risk cannot be ruled out.

Counselling When given concomitantly with amiodarone or verapamil, doses should be taken at the same time.

DESMOPRESSIN

Tablet. 100 mcg NRH/RRH

Therapeutic group Haemostatic.
Indications and dosage **Management of diabetes insipidus** by SC, IM or IV injection, ADULT and CHILD > 12 years, 2 to 4 mcg in 2 divided doses; CHILD (3 months above to 12 years) IV/SC injection, 0.4 mcg once daily. By oral administration, Adults, 100 mcg three times a day, adjusting within the range 200 mcg to 1200 mcg daily according to response; Child 2 -11 years, 50 mcg twice daily. **Treatment haemophilia A and Willebrand disease (type1) By intravenous injection;** INFANTS > 3 MONTHS, CHILDREN AND ADULT, 0.3 mcg/kg over 15 - 30 minutes.
Contraindications Cardiac insufficiency, condition treated with diuretics, hyponatremia, moderate to severe renal impairment.
Cautions Pregnancy, psychogenic polydipsia, congestive heart failure, children, elderly, asthma.
Side effects Facial flushing, headache and dizziness, hyponatremia, water intoxication, palpitation, edema, tachycardia, weight gain, dry mouth.
Renal dose adjustment Avoid in patients with moderate to severe renal impairment (creatinine clearance <50mL/min).
Pregnancy category B
Breast feeding Amount too small to be harmful.

ENOXAPARIN

Injection, 10 mg/0.1 mL (0.6 mL) NRH/RRH

Therapeutic group Anticoagulant.
Indications and dose **Prophylaxis of deep-vein thrombosis in surgical patients** ADULT: 20-40 mg *SC injection*, 2 hours before surgery and then 20-40 mg, Q24H x 7 to 10 days. **Prophylaxis for deep vein thrombosis in medical patients**: 40 mg *SC injection,* Q24H for at least 6 days; CHILD (< 2 months): 0.75 mg/kg *SC injection,* Q12H; CHILD (≥2 months): 0.5 mg/kg *SC injection,* Q12H. **Treatment of deep vein thrombosis and pulmonary embolism**: 1.5 mg/kg *SC injection,* Q24H for at least 5 days (and until oral anticoagulation established); CHILD (< 2 months): 1.5 mg/kg *SC injection,* Q12H; CHILD (≥ 2 months): 1 mg/kg *SC injection,* Q12H. **Treatment of unstable angina and non ST-segment- elevation myocardial infarction** ADULT: 1 mg/kg *SC injection,* Q12H x 2 to 8 days.
Contraindications Acute bacterial endocarditis, major bleeding disorder, hemorrhagic stroke, medicine induced thrombocytopenia.
Cautions Renal or hepatic impairment; history of GI ulceration, uncontrolled hypertension, spinal or epidural anaesthesia; lactation and pregnancy; elderly, hyperkalemia.
Side effects Thrombocytopenia, injection site irritation, pain and ecchymosis, skin necrosis; hypersensitivity, erythema, anaemia, hemorrhagic complications, atrial fibrillation, pulmonary oedema, pneumonia and osteoporosis on prolonged use.
Renal impairment Dosage adjustment needed if CrCl <30 mL/minute.
Pregnancy category B
Breast-feeding Excreted in milk, avoid.
IV fluid compatibility Dextrose 5%, sodium chloride 0.9%.

HEPARIN (Unfractionated)

Injection, 5000 IU/mL (5 mL) NRH/RRH/DH

Therapeutic group Anticoagulant.
Indications and dose **Hemodialysis** ADULT: 1000-5000 units initially by IV injection, followed by (by continuous IV infusion) 250-1000 units/hour. **Maintenance of line patency (line flushing)** ADULT and CHILD: 100 units/mL to be flushed through Q4-8H; INFANTS (<10 kg): 10 units/mL. **DVT Prophylaxis** ADULT: 5000 units *SC injection,* Q8-12H. **ST Elevation Myocardial Infarction** ADULT: Concurrent bolus of 60 units/kg (max. 4000 units), then 12 units/kg/hour (max. 1000 units/hour) as continuous *IV infusion*; Check aPTT Q4-6H; adjust to target of 1.5-2 times the upper limit of control (50-70 seconds); usual range 10-30 units/kg/hour. **Unstable angina; non-ST-elevation myocardial infarction**

ADULT: Initial bolus of 60 units/kg (max. 4000 units), followed by an initial infusion of 12 units/kg/hour (max. 1000 units/hour); **Treatment of venous thromboembolism** ADULT: 80 units/kg (or 5000 units) *IV injection* followed by *continuous IV infusion* of 18 units/kg/hour (or 1300 units/hour).
Contraindications Severe thrombocytopenia, uncontrolled active bleeding, suspected intracranial haemorrhage, intramuscular use, hypersensitivity to pork products.
Cautions Elderly, bacterial endocarditis, haemophilia, severe hypertension, gastrointestinal ulceration, hepatic disease.
Side effects Thrombocytopenia, local irritation, erythema, injection site ulcer, increased liver aminotransferase, haemorrhage, hematoma, osteoporosis, hyperkalemia.
Renal Impairment Risk of bleeding increased in severe impairment; dose may need to be reduced.
Hepatic impairment Risk of bleeding increased; Reduce dose or avoid in severe impairment.
Pregnancy category C
Breast-feeding Compatible
IV fluid compatibility Dextrose 5%, sodium chloride 0.9%.

PHYTOMENADIONE (Vit K)

Injection, 10 mg/mL (1 mL) NRH/RRH/DH/PHC

Therapeutic group Anticoagulant antagonist.
Indications and dosage **Hemorrhagic disease of the newborn, Prophylaxis** 0.5-1 mg *IM injection,* within 1 hour of birth. **Hemorrhagic disease of the newborn, Treatment** 1 mg/dose/day *IM or SQ injection*, higher doses may be necessary if mother has been receiving oral anticoagulants. **Major bleeding in patients on warfarin** ADULT: 5 mg *slow IV infusion,* STAT; **INR > 8.0 with minor bleeding in patients on warfarin** 1-3 mg *slow IV infusion*, dose may be repeated if INR still too high after 24 hours; **INR > 8.0 with no bleeding in patients on warfarin** 1-5 mg *PO (IV preparation to be used orally)*, repeat dose if INR still too high after 24 hours; **INR 5.0-8.0 with minor bleeding in patients on warfarin** 1-3 mg *PO.*
**Stop warfarin treatment and restart if INR level falls below 5.*
Cautions Any risk factors for haemorrhage, elderly**,** rapid IV injection can lead to fatal collapse.
Side effects Cyanosis, flushing, hypotension, scleroderma-like lesions.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.
Note *Phytomenadione does not neutralise heparin, use protamine sulphate instead. Protect from light, the agent is rapidly degraded.*

PROTAMINE SULPHATE

Injection, 10 mg/mL (5 mL) NRH/RRH

Therapeutic group Medicine affecting coagulation.
Indications and dose **Overdose with intravenous injection of unfractionated heparin** ADULT: Dose to be administered at a rate not exceeding 5 mg/minute *IV injection*, 1 mg neutralises 80-100 units of heparin when given within 15 minutes; if longer than 15 minutes since heparin, less protamine required (consult product literature for details) as heparin rapidly excreted; maximum 50 mg. **Over dosage with intravenous infusion of unfractionated heparin** ADULT: 25-50 mg *IV injection*, to be administered once heparin infusion stopped at a rate not exceeding 5 mg/minute. **Over dosage with subcutaneous injection of unfractionated heparin** ADULT: Initially 25-50 mg *IV injection*, to be administered at a rate not exceeding 5 mg/minute, 1mg neutralises 100 units of heparin, then (*by IV infusion*), any remaining dose to be administered over 8-16 hours; maximum 50 mg per course. **Over dosage with subcutaneous injection of low molecular weight heparin** ADULT: Dose to be administered by intermittent IV injection at a rate not exceeding 5 mg/minute; 1 mg neutralises approx. 100 units of low molecular weight heparin (consult product literature of low molecular weight heparin for details); max. 50 mg.
Contraindications Hypersensitivity to fish.

Cautions Excessive doses can have an anticoagulant effect, increased risk of allergic reaction to protamine (includes previous treatment with protamine or protamine insulin, allergy to fish, men who are infertile or who have had a vasectomy and who may have antibodies to protamine), rapid administration, repeated doses.
Side effects Anaphylaxis, angioedema, back pain, bradycardia, dyspnea, flushing, hypertension, hypotension, lassitude, nausea, pulmonary oedema, rebound bleeding, vomiting.
Pregnancy category C
Breast-feeding Excretion in milk, unknown, use with caution.
Note *The long half-life of low molecular weight heparins should be taken into consideration when determining the dose of protamine, the effects of low molecular weight heparins can persist for up to 24 hours after administration. Protamine does not neutralise oral anticoagulants.*

TRANEXAMIC ACID

Injection, 50 mg/mL (5 mL) NRH/RRH
Capsule, 250 mg NRH

Therapeutic group Antifibrinolytic agent.
Indications and dose **Treatment and prophylaxis of haemorrhage associated with excessive fibrinolysis; To control bleeding during neurosurgical operations** ADULT: 1-1.5 g *PO*, Q8-12H, alternatively 15-25 mg/kg *PO,* Q8-12H; 0.5-1g *Slow IV injection*, Q8-12H administered at a rate not exceeding 100 mg/minute; dose followed by 25-50 mg/kg *continuous IV infusion*, dose given over 24 hours.
Contraindications Active intravascular clotting, history of convulsion, thromboembolic disease.
Cautions Irregular menstrual bleeding, massive hematuria, patients receiving OCP.
Side effects Nausea, vomiting, diarrhoea, infrequently hypotension, thrombosis.
Renal impairment Dose reduction required in impairment.
Pregnancy category B
Breast-feeding Excreted in milk unknown, use with caution.
IV fluid compatibility Dextrose 5%, sodium chloride 0.9%.

WARFARIN

Tablet, 1 mg, 3 mg and 5 mg NRH/RRH/DH

Therapeutic group Anticoagulant.
Indications and dose **Prophylaxis of venous thrombosis, stroke and thromboembolism; Cardiac valve replacement; Post myocardial infarction** ADULT: *Induction dose*, 10 mg *PO,* daily for 2 days; subsequent daily maintenance dose (3-9 mg/day) to be determined depending upon the prothrombin time.
Contraindications Avoid use within 48 hours of postpartum, haemorrhage stroke, significant bleeding, cerebrovascular haemorrhage.
Cautions Peptic ulcer, severe hypertension, bacterial endocarditis.
Side effects Haemorrhage, rash, alopecia, diarrhoea.
Renal impairment Use with caution in mild to moderate impairment; In severe renal impairment, monitor INR more frequently.
Hepatic impairment Avoid in severe impairment.
Pregnancy category X
Breast-feeding Excreted traces amount in milk, use with caution.
Counselling Do not start or stop any other medicines without checking with the doctor; do regular blood tests, take medication at the same time each day with food or without food.
Note *Warfarin usually takes 3-5 days to reach steady state, use heparin during this period. Dose adjusted according to the International Normalised Ratio (INR)*.

11. BLOOD PRODUCTS OF HUMAN ORIGIN AND PLASMA SUBSTITUTES

11.1 Blood and blood components

FRESH FROZEN PLASMA (FFP)

Fresh frozen plasma NRH/RRH

Therapeutic group Blood and blood components.
Indications Multiple factor deficiencies, severe liver disease, DIC, warfarin reversal.
Fresh frozen plasma *prepared from whole blood within 6 hours of collection and frozen immediately in a plasma freezer. It contains both stable and unstable coagulation factors like fibrinogen, factor V and VIII.*
Precautions It should not be used simply for volume correction in the absence of coagulation deficit nor as a source of albumin or immunoglobulin. FFP should not be used where a suitable alternative product is available. Once thawed the plasma should be used immediately especially for correction of unstable clotting factors. It cannot be refrozen after thawing. Integrity of the bag should be checked before use.
Side effects Acute allergic reactions are common, febrile (non hemolytic reaction), viral transmission, bacterial contamination - sepsis.
Note *Transfusion of FFP or liquid plasma does not require crossmatching.*

PLATELETS

Platelets NRH/RRH

Therapeutic group Blood and blood components.
Indications Bleeding due to low platelet count or impaired function.
Platelet *is a component obtained by centrifugation of fresh blood within 6 to 8 hours. One unit of platelet concentrate increases the platelet count by 10,000 to 20,000/ul of blood.*
Contraindications Not generally indicated for prophylaxis of bleeding in surgical patients, unless known to have significant preoperative platelet deficiency.
Precautions Repeated transfusions can lead to production of antibodies against platelets causing destruction of platelets. The clinician advising platelet transfusions should keep this in mind Presence of hypersplenism, DIC or septicemia can affect the increase in platelet count.
Not indicated Immune*/Idiopathic thrombocytopenia (ITP), thrombotic thrombocytopenia (TTP)*.
Side effects Febrile, non-haemolytic and allergic reactions are common in patients receiving multiple transfusions.
Note *Cross-matching is not required unless gross red cell contamination is seen in the unit chosen for transfusion*.

RED BLOOD CELLS

Red blood cells NRH/RRH

Therapeutic group Blood and blood components.
Indications Chronic symptomatic anaemia, acute blood loss.
Red blood cells *a component obtained by removal of part of the plasma either by sedimentation method or centrifugation of whole blood. Precautions: -Same as for whole blood.*
Side effects Same as whole blood.

WHOLE BLOOD

Whole blood NRH/RRH

Therapeutic group Blood and blood components.
Indications Acute blood loss, exchange transfusion and massive transfusion.
Whole blood *freshly drawn blood maintains all the properties for a limited period usually 24 hours. Changes in the whole blood after 24 hours*:

1. *Decreased unstable coagulation blood factors like V and VIII.*
2. *Decreased platelet viability. Whole blood after 48 hours of storage contains no viable platelets.*

3. *Decreased 2, 3 DPG levels – (However it regenerates after transfusion in the circulation of the recipient) Increased potassium level in plasma due to release of the intracellular potassium.*
4. *Increased acidity of the plasma.*

Precautions Identical ABO group or ABO compatible blood should be used. Rh negative patients should get Rh negative blood especially women in childbearing age groups.
Contraindications Patients with chronic, decompensated anaemia.
Side effects Circulatory overload in cases of decompensated anaemia, heart and renal failure. Formation of antibodies in the patient against donor red cell antigens and human leukocyte antigens (HLA) leading to transfusion reactions. Transfusion transmitted infections (TTIs). Citrate intoxication in neonates and in patients with impaired liver function getting massive transfusion. Hyperkalemia in massive transfusion.

11.2 Plasma-derived medicines

11.2.1 Human immunoglobulins

ANTI-TETANUS IMMUNOGLOBULIN (HUMAN)

Injection, 500 IU NRH/RRH/DH

Therapeutic group Sera and immunoglobulin.
Indications and dose **Post exposure prophylaxis** By IM injection, ADULT: initially 250 units, then increased to 500 units, dose is only increased if more than 24 hours have elapsed or there is risk of heavy contamination or following burns; CHILD: initially 250 units, then increased to 500 units, dose is only increased if more than 24 hours have elapsed or there is risk of heavy contamination or following burns. **Treatment of tetanus infection,** By IM injection, ADULT: 150 units/kg, dose may be given over multiple sites.
Contraindications hypersensitivity to gamma globulins, IgA, thimerosal.
Cautions thrombocytopenia or coagulation disorder, IgA deficiency, interference with live virus vaccines.
Side effects injection site pain, lethargy, chest tightness, anaphylaxis (rare), serum sickness, with fever, vomiting, diarrhoea, bronchospasm and urticaria may often occur 7-10 days after the injection.
Pregnancy Category C
Breastfeeding excretion unknown, no adverse effects reported.
Note *Immunoglobulins should be protected from light. Opened multi-dose vials must be used within the period recommended in the product literature.*

11.2.2 Plasma substitutes

HUMAN ALBUMIN

Injection, 20% (100 mL) NRH/RRH

Therapeutic group Plasma volume expander.
Indications and dose **Ascites and large volume paracentesis (refractory to sodium restriction (90 mmol/day)** *Normal premorbid renal function*: 1 unit (100 mL) *IV infusion,* STAT following every 3 litres of ascites drained; *Renal function is impaired:* 100 mL, *IV infusion,* per 2 litres of ascites**. Spontaneous bacterial peritonitis (SBP) and cirrhosis** 1.5 g/kg *IV infusion* within 6-hours of detection (day 1) and 1 g/kg on day 3**. Hepatorenal Syndrome (HRS) confirmed** 25-50 g /day *IV infusion,* for a total of 72 hours. **Hypoproteinemia in the acutely ill patient** 50-75 g *IV infusion,* administered not exceeding 2 mL/minute. **Shock** Initial dose of 20 g *IV infusion,* administered at a rate of 2-4 mL/minute; with rate of infusion increased in emergencies and repeated in 15-30 minutes if necessary; Max. 2 g/kg in absence of active bleeding. **Burns** 20-80 g/day *IV infusion* administered at the rate of about 1 mL per minute; *Beyond 24 hours*, the goal is the maintenance of a plasma albumin concentration of 25 g/L or a colloid osmotic pressure of 20 mmHg. **Adult respiratory distress syndrome** 50 g *IV infusion* over the first 24 hours together with diuretic therapy; then dose adjusted according to requirement.

Note *Albumin 25% can be diluted with sodium chloride 0.9% or dextrose 5%. When dosing albumin, the 5% solution should be used in hypovolemic patients and the 25% solution should be used in patients in whom fluid and sodium intake is restricted. Albumin should not be diluted with sterile water because this can cause hemolysis.*
Contraindications Severe anaemia, cardiac failure.
Cautions Rapid infusion may cause vascular overload, chronic renal insufficiency, patients on sodium restriction, preterm infants.
Side effects Hypersensitivity reaction, oedema, fever, chill, headache, flushing, nausea.
Renal impairment Use with caution in patients with renal impairment.
Hepatic impairment Use with caution in patients with hepatic impairment.
Pregnancy category C
Breast-feeding Compatible.
IV fluid compatibility Dextrose 5%, dextrose 10%, compound solution of sodium lactate, dextrose 5% in sodium chloride 0.45%.

12. CARDIOVASCULAR MEDICINES

12.1 Antianginal medicines

AMLODIPINE

Tablet, 5 mg NRH/RRH/DH

Therapeutic group Medicine use for heart failure, antianginal, antiarrhythmic and antihypertensive.
Indications and dose **Hypertension and Prophylaxis of angina** ADULT: Initially 5 mg *PO,* Q24H, max. 10 mg/day. **Hypertension** Child (1 month-11 years): Initially 100-200 mcg/kg *PO,* Q24H; increased if necessary up to 400 mcg/kg Q24H, adjusted at intervals of 1-2 weeks; max. 10 mg/day.
Contraindications Cardiogenic shock, unstable angina, significant aortic stenosis.
Cautions Hepatic impairment.
Side effects Abdominal pain, dizziness, fatigue, flushing, headache, nausea, oedema, palpitation, sleep disturbances.
Hepatic impairment Dose reduction.
Pregnancy category C
Breast-feeding Excretion in milk unknown, avoid.

ASPIRIN

Tablet (Enteric coated), 75 mg NRH/RRH/DH/PHC
Tablet (soluble), 300 mg NRH/RRH/DH

Therapeutic group Antianginal.
Indications and dose **Cardiovascular disease (secondary prevention)** ADULT: 75 mg *PO,* Q24 hr; CHILD (1 month-11 years): 1-5 mg/kg *PO,* Q24hr (max. 75 mg/dose); CHILD (12-17 years): 75 mg *PO,* Q24 hr. **Management of unstable angina and non-ST-segment elevation myocardial infarction (NSTEMI); Management of ST-segment elevation myocardial infarction (STEMI)** ADULT: 325 mg, chewed or dispersed in water. **Suspected transient ischemic attack** ADULT: 300 mg *PO,* Q24 hr until diagnosis established. **Transient ischemic attack; Ischemic stroke not associated with atrial fibrillation** ADULT: 75 mg *PO,* Q24 hr. **Acute ischemic stroke** ADULT: 325 mg *PO,* Q24hr x 14 days, to be initiated 24 hours after thrombolysis or as soon as possible within 48 hours of symptom onset in patients not receiving thrombolysis. **Atrial fibrillation following a disabling ischemic stroke (before being considered for anticoagulant treatment)** ADULT: 325 mg *PO,* Q24 hr x 14 days. **Following disabling ischemic stroke in patients receiving anticoagulation for a prosthetic heart valve and who are at significant risk of hemorrhagic transformation** ADULT: 325 mg *PO,* Q24hr, anticoagulant treatment stopped for 7 days and to be substituted with aspirin; **Following coronary by-pass surgery** ADULT: 75-325 mg *PO,* Q24 hr.
Contraindications Active peptic ulceration, bleeding disorders, children under 16 years (risk of Reye's syndrome), haemophilia, previous peptic ulceration, severe cardiac failure.

Cautions Allergic disease, anaemia, asthma, dehydration, elderly, G6PD deficiency, preferably avoid during fever or viral infection in children, previous peptic ulceration, thyrotoxicosis, uncontrolled hypertension.
Side effects Blood disorders, bronchospasm, confusion, GI haemorrhage, GI irritation, haemorrhage including subconjunctival haemorrhage, increased bleeding time, skin reactions in hypersensitive patients, tinnitus.
Overdose *The main features of salicylate poisoning are hyperventilation, tinnitus, deafness, vasodilatation, and sweating. Coma is uncommon but indicates very severe poisoning.*
Hepatic impairment Avoid in severe impairment.
Renal impairment Avoid in severe impairment.
Pregnancy category C
Breastfeeding Excreted in milk, use with caution.
Counselling Take after or with meals.

BISOPROLOL

Tablet, 5 mg NRH/RRH

Therapeutic group Medicine use for heart failure, antianginal, antiarrhythmic and antihypertensive.
Indications and dose **Congestive heart failure** ADULT: Initially 1.25 mg once daily for 1 week, then increased if tolerated to 2.5 mg once daily for 1 week. Can be increased in the order of 3.75 mg once daily for 1 week, 5 mg once daily for 4 weeks, 7.5 mg once daily for 4 weeks, and 10 mg once daily if tolerated according to patient conditions, maximum 10 mg per day. **Hypertension and Angina** ADULT: Initially 5 mg once daily, titrate up to 10 mg or 20 mg once daily if necessary to achieve adequate response. **Arrhythmias** 2.5 mg once daily, titrate the dose as needed MAX: 10 mg per day.
Contraindications Acute or decompensated heart failure requiring intravenous inotropes and sino-atrial block, severe bradycardia.
Cautions Gradually increase the dose in stable heart failure.
Side effects Constipation, muscle cramps, muscle weakness, postural hypotension.
Hepatic impairment Hepatitis or cirrhosis: Initial, 2.5 mg orally once daily, titrate cautiously.
Renal impairment CrCl less than 40 mL/min: Initial, 2.5 mg orally once daily, titrate cautiously.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use caution.

CARVEDILOL

Tablet, 3.125 mg and 12.5 mg NRH/RRH

Therapeutic group Medicine use for heart failure, antianginal, antiarrhythmic and antihypertensive.
Indications and dose **Angina** ADULT: Initially 12.5 mg *PO,* Q12H x 2 days, then increased to 25 mg, Q12H. **Hypertension** ADULT: Initially 12.5 mg *PO,* Q24H x 2 days, then increased to 25 mg, Q24H; increased if necessary up to 50 mg/day, dose to be increased at intervals of at least 2 weeks as a single dose or in divided doses; ELDERLY: Initially 12.5 mg *PO,* Q24H. **Adjunct to diuretics, digoxin, or ACE inhibitors in symptomatic chronic heart failure** ADULT: Initially 3.125 mg *PO,* Q12H, then increased to 6.25 mg, Q12H, then increased to 12.5 mg, Q12H, then increased to 25 mg, Q12H, dose should be increased at intervals of at least 2 weeks up to the highest tolerated dose; Max. 25 mg, Q12H in patients with severe heart failure or body-weight less than 85 kg; max. 50 mg, Q12H in patients over 85 kg.
Contraindications Bronchial asthma, bronchospasm, COPD, 20/30 AV block, cardiogenic shock, severe bradycardia, decompensated heart failure requiring intravenous inotropes, severe hepatic impairment.
Cautions Anesthesia or surgery, cerebrovascular insufficiency, diabetes mellitus, hyperthyroidism or thyrotoxicosis, liver disease, peripheral vascular disease, compromised left ventricular function, heart failure, pheochromocytoma, and myasthenia gravis, avoid beta-blocker use in non-allergic bronchospasm. Sudden discontinuance can exacerbate angina and lead to myocardial infarction, mild to moderate hepatic impairment, elderly.

Side effects Dizziness, fatigue, hypotension, weight gain, hyperglycemia, diarrhoea, bradycardia, nausea, cough, headache, atrioventricular block, oedema, angina, hypercholesterolemia, hypertriglyceridemia, vomiting, dyspnea, syncope.
Hepatic impairment Avoid in hepatic impairment.
Pregnancy category C; D in second and third trimester.
Breast-feeding Excretion in milk unknown, avoid.
Counselling Take medication with food and don't stop the medication suddenly.
Note *Beta-blocker therapy in patients with heart failure can be extremely difficult to manage, the initiation and up-titration should be undertaken in consultation with a specialist.*

ISOSORBIDE DINITRATE

Tablet, 5 mg (sublingual) and 10 mg NRH/RRH/DH

Therapeutic group Antianginal (nitrates).
Indications and dose **Prophylaxis of angina** ADULT: 2.5-5 mg *sublingually,* 15 minutes before performing activities likely to cause angina; 20-240 mg/day *PO,* in divided doses. **Treatment of angina** ADULT: 2.5-5 mg *sublingually*; repeated Q5-10 minutes; not to exceed 3 doses in 15-30 minute. **Resistant congestive heart failure; left ventricular failure** 30-120mg/day in divided doses, up to 240 mg/day in heart failure.
Contraindications Severe anaemia, shock, markedly low blood pressure, closed angle glaucoma, head trauma, cerebral haemorrhage.
Cautions Allergies to nitrates, head trauma/cerebral haemorrhage, hypertrophic cardiomyopathy, increased intraocular pressure, postural hypotension, acute myocardial infarction (MI), congestive heart failure, hyperthyroidism.
Side effects Throbbing headache, flushing, postural hypotension, tachycardia; paradoxical bradycardia.
Pregnancy category C
Breast-feeding Excretion in breast milk unknown, use with caution.
Counselling Sublingual tablet to place under your tongue and let it dissolve slowly.
Note *Regular prophylaxis with oral medication is effective if given regularly at adequate dosage and is considerably cheaper; for mild or occasional chest pain, immediate sublingual treatment is preferred.*

METOPROLOL SUCCINATE

Tablet, 25 mg NRH/RRH

Therapeutic group Antianginal, antihypertensive (beta-blockers).
Indications and dose **Hypertension, Treatment** 25-100 mg/day *PO,* STAT or Q12H; dose increased every week as needed up to 400 mg Q24H; CHILD (≥ 6 Years): 1 mg/kg *PO,* Q24H (max. 50 mg/dose/day; 2 mg/kg; 200 mg/day). **Angina, Treatment** 100 mg *PO,* STAT; dose increased at weekly intervals as needed up to 400 mg/day. **Heart failure** 25 mg *PO,* Q24H x 2 weeks in patients with NYHA Class II heart failure and 12.5 mg *PO,* Q24H in patients with more severe heart failure; Double the dose every two weeks to up to 200 mg.
Contraindications Child <6 years, Severe bradycardia, second- or third-degree heart block, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome.
Cautions Bronchospastic disease, major surgery, diabetes and hypoglycemia, thyrotoxicosis, hepatic impairment, peripheral vascular disease, pheochromocytoma.
Side effects Tiredness, dizziness, depression, shortness of breath, bradycardia, hypotension, diarrhoea, pruritus, rash.
Hepatic impairment Reduce dose in severe impairment.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.
Note *For treatment of angina, if treatment is to be discontinued, reduce the dosage gradually over a period of 1 to 2 weeks.*

NIFEDIPINE

Tablet (Sustained Release), 20 mg NRH/RRH/DH

Therapeutic group Antianginal (calcium channel blockers).
Indications and dosage **Angina prophylaxis**; **Hypertension** 20 mg *PO,* Q12H, increased up to max. of 40 mg, Q12H.
Contraindications Cardiogenic shock, acute attacks of angina, unstable angina and within 1 month of myocardial infarction.
Cautions Diabetes mellitus, elderly, heart failure, poor cardiac reserve, severe hypotension.
Side effects Asthenia, dizziness, GI disturbance, headache, hypotension, lethargy, oedema, palpitation, vasodilatation.
Hepatic impairment reduces the dose in severe liver disease.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.
Counselling SR tablets should not be broken and swallowed whole.

NITROGLYCERIN

Injection, 5 mg/mL (5 mL) NRH/RRH/DH

Therapeutic group Antianginal.
Indications and dose **Induction of controlled hypotension during surgery; Congestive heart failure; Unstable angina** 5 mcg/minute *IV infusion,* increase by 5 mcg/minute, every 3-5 minutes to 20 mcg/minute; If no response at 20 mcg/minute increase by 10mcg/minute, every 3-5 minutes, up to 200 mcg/minute.
Note *injection is to be used only after suitable dilution, final concentration should not exceed 400 mcg/mL.*
Contraindications Hypersensitivity to nitrates, hypotensive conditions and hypovolemia, hypertrophic obstructive cardiomyopathy, aortic stenosis, cardiac tamponade, constrictive pericarditis, mitral stenosis, marked anaemia, head trauma, cerebral haemorrhage, closed angle glaucoma.
Cautions Heart failure due to obstruction, hypothermia, hypothyroidism, hypoxemia, malnutrition, recent history of myocardial infarction, susceptibility to angle-closure glaucoma, tolerance, ventilation and perfusion abnormalities.
Side effects Dizziness, postural hypotension, tachycardia, throbbing headache, flushing, heartburn, nausea, rash, syncope, temporary hypoxemia, vomiting; *With transdermal use* Application site reactions; *With IV use* abdominal pain, apprehension, diaphoresis, muscle twitching, palpitation, restlessness, retrosternal discomfort, severe hypotension.
Hepatic impairment Caution in severe impairment.
Renal impairment Use with caution in severe impairment.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.
IV fluid compatibility Dextrose 5% sodium chloride 0.9%, compound solution of sodium lactate.

PROPRANOLOL

Tablet, 40 mg NRH/RRH/DH

Therapeutic group Antianginal.
Indications and dose **Hypertension** ADULT: Initially 80 mg *PO,* Q12H, dose should be increased at weekly intervals as required; ***maintenance*** 160-320 mg/day; CHILD (1 month-11 years): Initially 0.25-1 mg/kg *PO,* Q8H, then increased to 5 mg/kg/day in divided doses, dose increased at weekly intervals; CHILD (12-17 years): Initially 80 mg *PO,* Q12H, then increased if necessary up to 160-320 mg/day, dose increased at weekly intervals. **Prophylaxis of variceal bleeding in portal hypertension** ADULT: Initially 40 mg *PO,* Q12H, then increased to 80 mg, Q12H (max. 160 mg/dose, Q12H), dose to be adjusted according to heart rate. **Angina** ADULT: Initially 40 mg *PO,* Q8-12H; ***maintenance*** 120-240 mg/day. **Hypertrophic cardiomyopathy; Anxiety tachycardia** ADULT: 10-40 mg *PO,* Q6-8H. **Anxiety with symptoms such as palpitation, sweating and tremor** ADULT: 40 mg *PO,* Q24H, then increased if necessary to 40 mg, Q8H. **Prophylaxis after myocardial infarction** ADULT: Initially 40 mg *PO,* Q6H x 2-3 days, then 80 mg, Q12H, start treatment 5 to 21 days after infarction. **Essential tremor** ADULT: Initially 40 mg *PO,* Q8-12H; ***maintenance*** 80-160 mg/day. **Migraine prophylaxis** ADULT: 80-240 mg daily in divided doses; CHILD (2-11 years): Initially 200-500 mcg/kg *PO,* Q12H; usual dose 10-20mg, Q12H (max. 2 mg/kg/dose, Q12H); CHILD (12-17 years): Initially 20-40 mg *PO,* Q12H; usual dose 40-80 mg, Q12H (max. 120 mg/dose); max. 4mg/kg/day. **Arrhythmias** ADULT: 10-40 mg *PO,* Q6-8H; CHILD: 250-500 mcg/kg *PO,* Q6-8H (max. 1 mg/kg, Q6H), max. 160 mg/day.

Hyperthyroidism with autonomic symptoms CHILD: Initially 250-500 mcg/kg *PO,* Q8H, adjusted according to response; increased if necessary up to 1 mg/kg, Q8H (max. 40 mg/dose, Q8H). **Thyrotoxicosis (adjunct)** ADULT: 10-40 mg *PO* Q6-8H; CHILD: Initially 250-500 mcg/kg *PO,* Q8H, adjusted according to response; increased if necessary up to 1 mg/kg, Q8H (max. 40 mg/dose, Q8H). **Tetralogy of Fallot** NEONATE: 0.25-1 mg/kg *PO,* Q8-12H (max. 2 mg/kg/dose, Q8H); CHILD (1 month-11 years): 0.25-1 mg/kg *PO,* Q6-8H; max. 5 mg/kg/day in divided doses.
Contraindications Asthma, cardiogenic shock, hypotension, marked bradycardia. metabolic acidosis, second-degree AV block, severe peripheral arterial disease, sick sinus syndrome, third-degree AV block, uncontrolled heart failure.
Cautions Diabetes, first-degree AV block, history of obstructive airways disease (introduce cautiously), myasthenia gravis, portal hypertension, psoriasis, symptoms of hypoglycemia and thyrotoxicosis may be masked.
Side effects Dry eyes and rashes (reversible on withdrawal), alopecia, bradycardia, bronchospasm, coldness of the extremities, conduction disorders, dizziness, dyspnea, exacerbation of psoriasis, fatigue, GI disturbances, headache, heart failure, hyperglycemia and hypoglycemia (in patients with or without diabetes), hypotension, paraesthesia, peripheral vasoconstriction, sexual dysfunction, sleep disturbances (with nightmares), vertigo, visual disturbances.
Hepatic impairment Reduce dose.
Renal impairment Dose reduction may be required.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.

VERAPAMIL

Tablet, 40 mg — NRH/RRH

Therapeutic group Antianginal, antiarrhythmic.
Indications and dose **Supraventricular arrhythmias** 40-120 mg *PO,* Q8H; CHILD (2-17 years): 40-120 mg *PO,* Q8-12H. **Angina** 80-120 mg *PO,* Q8H, not to exceed 480 mg/day. **Hypertension** ADULT: 240-480 mg/day *PO,* Q8-12H; CHILD (2-17 years): 40-120mg *PO,* Q8-12H. **Prophylaxis of cluster headache** ADULT: 240-960 mg/day *PO,* Q6-8H.
Contraindications Acute porphyrias, atrial flutter or fibrillation associated with accessory conducting pathways, bradycardia, cardiogenic shock, history of heart failure and significantly impaired left ventricular function (even if controlled by therapy), hypotension, second- and third-degree AV block, sick sinus syndrome, sino-atrial block.
Cautions Acute phase of myocardial infarction (avoid, if bradycardia, hypotension and left ventricular failure), first degree AV block.
Side effects Constipation, ankle oedema, dizziness, fatigue, flushing, headache, nausea, vomiting, angioedema, arthralgia, asystole.
Hepatic impairment Dose may need to be reduced; in cirrhosis, reduce dose by 20-50% of normal dose.
Renal impairment Use with caution.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.

12.2 Antiarrhythmic agents

ADENOSINE

Injection, 3 mg/mL (2 mL) — NRH/RRH/DH

Therapeutic category Antiarrhythmic.
Indications and dose **Rapid reversion to sinus rhythm of paroxysmal supraventricular tachycardias, including those associated with accessory conducting pathways** ADULT: Initially 6 mg *rapid IV injection*, administered into central or large peripheral vein and given over 2 seconds, followed by 12 mg after 1-2 minutes if required, then 12 mg after 1-2 minutes if required, increments should not be given if high level AV block develops at any particular dose; CHILD (1-11 months): Initially 150 mcg/kg *rapid IV injection*, then increased in steps of 50-100 mcg/kg, Q1-2 minutes (max. 500 mcg/kg/dose) if required, dose to be repeated until tachycardia terminated or maximum single dose given; CHILD (1-11 years): Initially 100 mcg/kg *rapid IV injection,* then increased in steps of 50-100 mcg/kg, Q1-2 minutes (max. 12 mg/dose) if required, dose to be repeated until tachycardia terminated or maximum single dose given; CHILD

(12-17 years): Initially 3 mg *rapid IV injection*, followed by 6 mg after 1-2 minutes if required, followed by 12 mg after 1-2 minutes if required.
Contraindications Asthma, chronic obstructive lung disease, decompensated heart failure, long QT syndrome, second- or third-degree AV block and sick sinus syndrome (unless pacemaker fitted), severe hypotension.
Cautions Atrial fibrillation or flutter with accessory pathways, autonomic dysfunction, bundle branch block, first-degree AV block, heart transplant, left main coronary artery stenosis, left to right shunt, pericardial effusion, pericarditis, QT-interval prolongation, recent myocardial infarction, severe heart failure, stenotic carotid artery disease with cerebrovascular insufficiency, stenotic valvular heart disease, uncorrected hypovolemia.
Side effects Angina (discontinue), apprehension, arrhythmia (discontinue if asystole or severe bradycardia occur), AV block, dizziness, dyspnea, flushing, headache, nausea, sinus pause, blurred vision, hyperventilation, metallic taste, palpitation, sweating, weakness.
Pregnancy category C
Breast-feeding Excretion in milk unknown, avoid.
IV fluid compatibility Sodium chloride 0.9%.
Note 3 mg dose ineffective in a number of patients, therefore higher initial dose may be necessary but for patients with heart transplant who are very sensitive to effects of adenosine should not receive higher initial dose.

ADRENALINE

Injection, 1 mg/mL (1 mL) (1:1000) NRH/RRH/DH/PHC

Therapeutic group Antiallergics (vasoconstrictor sympathomimetic) and medicines used in emergency treatment of acute anaphylaxis, antiarrhythmic.
Indications and dosage **Control of bradycardia in patients with arrhythmias after myocardial infarction, if there is a risk of asystole, or if the patient is unstable and has failed to respond to atropine** ADULT: 2-10 mcg/minute *IV infusion*, adjusted according to response. *For details, refer to page no. 23.*

AMIODARONE

Injection, 50 mg/mL (3 mL) NRH/RRH/DH
Tablet, 200 mg NRH/RRH/DH

Therapeutic group Antiarrhythmic. For details, refer to page no.
Indications and dose **Treatment of arrhythmias, particularly when other medicines are ineffective or contraindicated (including paroxysmal supraventricular, nodal and ventricular tachycardias, atrial fibrillation and flutter, ventricular fibrillation, and tachyarrhythmias associated with Wolff Parkinson-White syndrome), *by Orally*,** ADULT: 200 mg *PO,* Q8H x 1 week, then reduce to 200 mg, Q12H x 1 week, followed by maintenance dose, usually 200 mg/day or the minimum dose required to control arrhythmia; CHILD (1 month-11 years): Initially 5-10 mg/kg (max. 200 mg/dose) *PO,* Q12H x 7-10 days, then reduced to 5-10 mg/kg Q24H; max. 200 mg/day; ***by Injection***, ADULT: Initially 5 mg/kg *IV infusion*, to be given over 20-120 minutes with ECG monitoring, subsequent infusions given if necessary according to response; max. 1.2 g/day; CHILD: Initially 5-10 mg/kg *IV infusion*, dose given over 20 minutes to 2 hours, then 300 mcg/kg/hour, adjusted according to response; increased if necessary up to 1.5 mg/kg/hour; max. 1.2 g/day. **Ventricular fibrillation or pulseless ventricular tachycardia refractory to defibrillation (for cardiopulmonary resuscitation)** ADULT: Initially 300 mg *IV injection*, dose to be considered after administration of adrenaline, dose should be given diluted in 20mL Dextrose 5%, then 150mg if required, followed by (900 mg/24H); CHILD: 5 mg/kg (max. 300 mg/dose) *IV injection,* dose to be given over at least 3 minutes.
Contraindications Severe conduction disturbances and sinus node disease (unless pacemaker fitted), iodine sensitivity, sino-atrial heart block and sinus bradycardia (except in cardiac arrest), thyroid dysfunction; *With IV use* Bolus injection in cardiomyopathy and congestive heart failure, circulatory collapse, severe arterial hypotension, severe respiratory failure.
Cautions Acute porphyrias, conduction disturbances, elderly, heart failure, hypokalemia, severe bradycardia; *With IV use* Moderate and transient fall in blood pressure; severe hepatocellular toxicity.

Side effects Bradycardia, hyperthyroidism, hypothyroidism, jaundice, nausea, persistent slate grey skin discoloration, phototoxicity, pulmonary toxicity, raised serum transaminases, reversible corneal microdeposits, sleep disorders, taste disturbances, tremor, vomiting.
Hepatic impairment Avoid in severe impairment. Liver function tests required before treatment and then every 6 months.
Pregnancy category D
Breast-feeding Excreted in milk, use with caution.
IV fluid compatibility Dextrose 5%.
Counselling Patients should be advised to shield the skin from light during treatment and for several months after discontinuing amiodarone; a wide-spectrum sunscreen to protect against both long-wave ultraviolet and visible light should be used.

BISOPROLOL

Tablet, 5 mg NRH/RRH

Therapeutic group Medicine use for heart failure, Antianginal, antiarrhythmic and antihypertensive.
Indications and dose **Arrhythmias:** 2.5 mg once daily, titrate the dose as needed MAX: 10 mg per day. *For details, refer to page no. 82.*

CARVEDILOL

Tablet, 3.125 mg and 12.5 mg NRH/RRH

Therapeutic group Antiarrhythmic.
Indications and dose **Angina** ADULT: Initially 12.5 mg *PO,* Q12H x 2 days, then increased to 25 mg, Q12H. **Hypertension** ADULT: Initially 12.5 mg *PO,* Q24H x 2 days, then increased to 25 mg, Q24H; increased if necessary up to 50 mg/day, dose to be increased at intervals of at least 2 weeks as a single dose or in divided doses; ELDERLY: Initially 12.5 mg *PO,* Q24H. **Adjunct to diuretics, digoxin, or ACE inhibitors in symptomatic chronic heart failure** ADULT: Initially 3.125 mg *PO,* Q12H, then increased to 6.25 mg, Q12H, then increased to 12.5 mg, Q12H, then increased to 25 mg, Q12H, dose should be increased at intervals of at least 2 weeks up to the highest tolerated dose; Max. 25 mg, Q12H in patients with severe heart failure or body-weight less than 85kg; max. 50mg, Q12H in patients over 85 kg. *For details, refer to page no. 82.*

DIGOXIN

Injection, 250 mcg/mL (2 mL) NRH/RRH
Tablet, 250 mcg NRH/RRH/DH/PHC

Therapeutic group Antiarrhythmic and medicine used in heart failure.
Indications and dose **Rapid digitalization, for atrial fibrillation or flutter** ADULT: 0.75-1.5 mg *PO,* in divided doses; reduce dose in the elderly. **Maintenance, for atrial fibrillation or flutter** ADULT: Maintenance 125-250 mcg/day, dose according to renal function and initial loading dose, reduce dose in the elderly. **Heart failure (for patients in sinus rhythm)** ADULT: 62.5-125 mcg *PO,* Q4H; reduce dose in the elderly. **Emergency loading dose, for atrial fibrillation or flutter** ADULT: Loading dose 0.75-1 mg *IV infusion*, given over at least 2 hours, then PO; ***maintenance***, start on the following day, reduce dose in the elderly.
Note Adjust maintenance dose by estimating CrCl and measuring serum levels; Use lower end of dosing (0.125 mg/day) in patients with impaired renal function or low lean body mass. When switching from IV to oral route may need to increase dose by 20-33% to maintain the same plasma-digoxin concentration.
Contraindications Constrictive pericarditis, hypertrophic cardiomyopathy, intermittent complete heart block, myocarditis; second degree AV block, Supraventricular arrhythmias associated with accessory conducting pathways e.g. Wolff-Parkinson-White syndrome (although can be used in infancy), ventricular tachycardia or fibrillation.
Cautions Hypercalcemia, hypokalemia, hypomagnesaemia, hypoxia, recent myocardial infarction, severe respiratory disease, sick sinus syndrome, thyroid disease.
Side effects Arrhythmias, blurred vision, conduction disturbances, diarrhoea, dizziness, eosinophilia, nausea, rash, vomiting, yellow vision.

Renal impairment Reduce dose, monitor plasma-digoxin concentration in renal impairment
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.
Iv fluid compatibility Dextrose 5%, dextrose 10%, compound solution of sodium lactate, sodium chloride 0.9%.

DILTIAZEM

Injection, 5 mg/mL (10 mL) NRH

Therapeutic group Antiarrhythmic.
Indications and dose **Paroxysmal supraventricular tachycardia and Atrial fibrillation** 0.25 mg/kg (average adult dose, 20 mg) *IV bolus* over 2 minutes; after 15 minutes, 0.35 mg/kg of actual body weight over 2 min (average adult dose, 25 mg) direct IV if first dose tolerated but response inadequate; *Continuous infusion* 10 mg/hr, *IV initially*; increased to no more than 15 mg/hr x 24 hours.
Note Use weight-based dosing for lower body weight patients.
Contraindications Use in new-born, concomitant beta-blocker therapy. cardiogenic shock, ventricular tachycardia.
Cautions Hepatic and renal failure, heart failure or significantly impaired left ventricular function, bradycardia (avoid if severe), first degree AV block or prolong PR interval.
Side effects Oedema, headache, dizziness, AV block, peripheral oedema, bradyarrhythmia, headache, hypotension, nausea, vomiting, vasodilation, extrasystoles, flushing, medicine-induced gingival hyperplasia, myalgia, diarrhea, constipation, bronchitis, sinus congestion, dyspnea.
Hepatic impairment Reduce dose.
Renal impairment Start with a smaller dose.
Pregnancy category C
Breastfeeding Excreted in milk, avoid.
IV fluid compatibility Dextrose 5%, sodium chloride 0.9%.

ESMOLOL

Injection, 10 mg/mL (10 mL) NRH/RRH

Therapeutic group Antiarrhythmic agent.
Indications and dose **Intraoperative tachycardia and/or hypertension** I.V.: Initial bolus: 80 mg (1 mg/kg) over 30 seconds, followed by a 150 mcg/kg/minute infusion. Adjust infusion rate as needed to maintain desired heart rate and/or blood pressure, up to 300 mcg/kg/minute. **Supraventricular tachycardia or gradual control of postoperative tachycardia/hypertension:** I.V.: Loading dose: 500 mcg/kg over 1 minute; follow with a 50 mcg/kg/minute infusion for 4 minutes. **Supraventricular tachycardias (SVT):** Usual dosage range: 50-200 mcg/kg/minute with average dose of 100 mcg/kg/minute.
Note *Concentrations >10 mg/mL or infusion into small veins or through a butterfly catheter should be avoided (can cause thrombophlebitis). Infusions must be* ***administered with an infusion pump****.*
Contraindications sinus bradycardia, heart block greater than first degree, cardiogenic shock, uncompensated heart failure.
Cautions Bronchospastic disease, cerebrovascular insufficiency, CHF, DM, hyperthyroidism, liver disease, renal impairment, peripheral vascular disease. Avoid sudden discontinuation, can exacerbate angina and lead to myocardial infarction.
Side effects Asymptomatic and symptomatic hypotension, diaphoresis, peripheral ischemia.
Pregnancy category C
Compatibility Stable in dextrose 5% in .0.45% normal saline, dextrose 5% in 0.9% normal saline, dextrose 5%, compound sodium lactate solution.

METOPROLOL SUCCINATE

Tablet, 25 mg NRH/RRH/DH

Therapeutic group Antiarrhythmic.

Indications and dose **Arrhythmias** ADULT: Usual dose 50 mg *PO,* Q8-12H, then increased if necessary up to 300 mg/day in divided doses; CHILD (12-17 years): Usual dose 50 mg *PO,* Q8-12H, then increased if necessary up to 300 mg/day in divided doses. *For details, refer to page no. 83.*

PROPRANOLOL

Tablet, 40 mg NRH/RRH/DH

Therapeutic group Antiarrhythmic.
Indications and dose **Arrhythmias** ADULT: 10-40 mg *PO,* Q6-8H; CHILD: 250-500 mcg/kg *PO,* Q6-8H (max. 1 mg/kg, Q6H), maximum 160 mg/day. *For details, refer to page no. 84.*

VERAPAMIL

Tablet, 40 mg NRH/RRH

Therapeutic group Antiarrhythmic.
Indications and dose **Supraventricular arrhythmias** 40-120 mg *PO,* Q8H; CHILD (2-17 years): 40-120 mg *PO,* Q8-12H. *For details, refer to page no. 85.*

12.3 Antihypertensive agents

AMLODIPINE

Tablet, 5 mg NRH/RRH/DH

Therapeutic group Antihypertensive.
Indications and dose **Hypertension** ADULT: Initially 5 mg *PO,* Q24H, max. 10 mg/day; Child (1 month-11 years): Initially 100-200 mcg/kg *PO,* Q24H; increased if necessary up to 400 mcg/kg Q24H, adjusted at intervals of 1-2 weeks; max. 10 mg/day. *For details, refer to page no. 81.*

BISOPROLOL

Tablet, 5 mg NRH/RRH

Therapeutic group Medicine use for heart failure, antianginal, antiarrhythmic and antihypertensive.
Indications and dose **Congestive heart failure** ADULT: Initially 1.25 mg once daily for 1 week, then increased if tolerated to 2.5 mg once daily for 1 week. Can be increased in the order of 3.75 mg once daily for 1 week, 5 mg once daily for 4 weeks, 7.5 mg once daily for 4 weeks, and 10 mg once daily if tolerated according to patient conditions, maximum 10 mg per day. **Hypertension and Angina** ADULT: Initially 5 mg once daily. Titrate up to 10 mg or 20 mg once daily if necessary to achieve adequate response. **Arrhythmias:** 2.5 mg once daily, titrate the dose as needed MAX: 10 mg per day. *For details, refer to page no. 82.*

CARVEDILOL

Tablet, 3.125 mg and 12.5 mg NRH/RRH

Therapeutic group Antihypertensive.
Indications and dose **Hypertension** ADULT: Initially 12.5 mg *PO,* Q24H x 2 days, then increased to 25 mg, Q24H; increased if necessary up to 50 mg/day, dose to be increased at intervals of at least 2 weeks as a single dose or in divided doses; ELDERLY: Initially 12.5 mg *PO,* Q24H. *For details, refer to page no. 82.*

ENALAPRIL

Tablet, 5 mg NRH/RRH/DH

Therapeutic group Antihypertensive and medicine used in heart failure.
Indications and dose **Hypertension** ADULT: Initially 5 mg *PO,* Q4H; lower initial doses may be required when used in addition to diuretic or in renal impairment; ***maintenance*** 20 mg, Q24H; max. 40 mg/day; CHILD (1 month-11 years):

Initially 100 mcg/kg *PO,* Q24H, then increased if necessary up to 1 mg/kg/day in 1-2 divided doses; CHILD (12-17 years) (body weight up to 50 kg): Initially 2.5 mg *PO,* Q24H, ***maintenance*** 10-20 mg/day in 1-2 divided doses; CHILD (12-17 years)(body-weight 50 kg and above): Initially 2.5 mg *PO,* Q24H, ***maintenance*** 10-20 mg/day in 1-2 divided doses; max. 40 mg/day. **Heart failure** ADULT: Initially 2.5mg *PO,* Q24H, increased if tolerated to 10-20 mg, Q12H, dose increased gradually over 2-4 weeks; CHILD (1 month-11 years): Initially 100 mcg/kg *PO,* Q24H, then increased if necessary up to 1 mg/kg/day, Q24H in 1-2 divided doses; CHILD (12-17 years) (body-weight up to 50 kg): Initially 2.5mg *PO,* Q24H, ***maintenance*** 10-20mg/day in 1–2 divided doses; CHILD (12-17 years) (body-weight 50 kg and above): Initially 2.5mg *PO,* Q24H, ***maintenance*** 10-20 mg/kg in 1-2 divided doses; max. 40 mg/day. **Prevention of symptomatic heart failure in patients with asymptomatic left ventricular dysfunction** ADULT: Initially 2.5 mg *PO,* Q24H, increased if tolerated to 10-20 mg, Q12H, dose increased gradually over 2-4 weeks.
Contraindications Hypersensitivity to ACE inhibitors (including angioedema) and in known or suspected renal artery stenosis, pregnancy.
Cautions Patients receiving diuretics, renal impairment, peripheral vascular disease, discontinue STAT if the patient becomes pregnant.
Side effects Dizziness, hypotension, headache, chest pain, cough, rash.
Renal impairment CrCl <30 mL/min: Initiate 2.5 mg, titrate to response, not to exceed 40 mg; CrCl ≥30 mL/min: Initiate 5 mg/day, titrate to maximum of 40 mg; Dialysis: 2.5 mg PO on day of dialysis, adjust dose on no non-dialysis days according to BP.
Hepatic impairment Close monitoring of patients required.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.
Note *Profound first dose hypotension may occur when ACE inhibitors are introduced in patients with severe heart failure or those receiving high doses of diuretics, high dose vasodilator therapy, hypovolemic, impaired renal, aged 70 years or more.*

FUROSEMIDE

Injection, 10 mg/mL (2 mL) NRH/RRH/DH
Tablet, 40 mg NRH/RRH/DH

Therapeutic group Antihypertensive.
Indications and dose **Resistant hypertension** by *ORALLY,* ADULT: 40-80 mg/day; by *INJECTION,* ADULT: Initially 20–50 mg, IV injection or IV infusion, then increased in steps of 20 mg every 2 hours if required, doses greater than 50 mg given by IV infusion only; max. 1.5 g per day. *For details, refer to page no. 110.*

HYDRALAZINE

Injection, 20 mg/mL (1 mL) NRH/RRH/DH/PHC
Tablet, 25 mg NRH/RRH/DH

Therapeutic group Antihypertensive.
Indications and dose **Moderate to severe hypertension (adjunct)** ADULT: Initially 25 mg *PO,* Q12H, increased if necessary up to 50, Q12H. **Hypertensive emergencies (including during pregnancy); Hypertension with renal complications** ADULT: Initially 200-300 mcg/minute *IV infusion*; ***maintenance*** 50-150 mcg/minute; **OR** ADULT: 5-10 mg diluted with 10 mL sodium chloride 0.9%, *slow IV injection,* Q20-30 minutes. **Heart failure (with long acting nitrate)** ADULT: Initially 25 mg *PO,* Q8-12H; ***maintenance*** 50-75 mg, Q6H. **Resistant hypertension (adjunct)**: CHILD (1 month-11 years): 250-500 mcg/kg *PO,* Q8-12H, increased if necessary to 7.5 mg/kg/day; max. 200 mg/day; CHILD (12-17 years): 25 mg *PO,* Q12H, increased to 50-100 mg, Q12H; ****Slow IV injection***: CHILD (1 month-11 years): 100-500 micrograms/kg, dose repeated if necessary q4-6H; max. 3mg/kg/ day; max 60mg/day; CHILD (12-17 years): 5-10mg, dose repeated if necessary q4-6 hours; ***Continuous IV infusion*** CHILD (1 month-11 years): 12.5-50 micrograms/kg/hour; max. 3mg/kg/day; CHILD (12-17 years): 3-9mg/hour; max. 3mg/kg/day; **Continuous IV infusion is the preferred route in cardiac patients.*
Contraindications Severe tachycardia, high-output heart failure, myocardial Insufficiency due to mechanical obstruction, cor pulmonale, dissecting aortic aneurysm.

Cautions Cerebrovascular disease, coronary artery disease, occasionally blood pressure reduction too rapid even with low parenteral doses, pulmonary hypertension, discontinue slowly to avoid rapid rise in blood pressure.
Side effects Tachycardia, palpitations, flushing, hypotension, fluid retention, GI disturbances, headache, dizziness, systemic lupus erythematosus-like syndrome after long-term therapy with over 100mg daily.
Renal impairment Reduce dose if eGFR > 30 mL/min/1.72m^2.
Hepatic impairment Reduce dose.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.

HYDROCHLOROTHIAZIDE

Tablet, 25 mg NRH/RRH/DH/PHC

Therapeutic group Antihypertensive (Diuretics).
Indications and dose **Hypertension** ADULTS: 12.5-50 mg *PO,* Q24hr initially and increase to 50 mg daily if required*;* CHILD (<6 months): 1-3 mg/kg/day *PO,* Q12hr; not to exceed 37.5 mg/day; CHILD (6 months – years): 1-2 mg/kg/day *PO,* Q24hr or Q12hr; CHILD (2-12 years): 1-3 mg/kg/day. **Oedema** ADULT: 25-100mg *PO,* Q12-24hr; not to exceed 200 mg/day; CHILD (<6 months): 1-3 mg/kg/day *PO,* Q12hr; CHILD (6 months – years): 1-3 mg/kg/day *PO,* Q24hr or Q12hr; CHILD (2-12 years): 1-3 mg/kg/day. **Hypertension and Mild fluid retention in heart failure** 25 mg *PO,* Q12-24hr*;* Max. ADULT: 200 mg/day; CHILD (<6 months-2 years): 37.5 mg/day; CHILD (2-12 years): 3 mg/kg/day (100 mg/day).
Contraindications Severe renal or severe hepatic impairment, hyponatremia, hypercalcemia, refractory hypokalemia, symptomatic hyperuricemia, Addison's disease.
Cautions Gout, diabetes, fluid and electrolyte imbalance, hypercholesterolemia, systemic lupus erythematosus, hypercalcemia, hypotension, liver or renal disease, hypokalemia, parathyroid disease.
Side effects GI disturbances, water and electrolyte disturbances, hyperglycemia, hyperuricemia, dizziness, epigastric distress, fatigue, headache, hypotension, muscle weakness, rash, vertigo.
Renal impairment CrCl <10 mL/min: Avoid use; CrCl ≥10 mL/min: dose adjustment not necessary.
Pregnancy category B
Breast-feeding Excreted in milk, use with caution.
Counselling Take this medicine in the morning regularly as instructed.

LOSARTAN

Tablet, 25 mg NRH/RRH/DH/PHC

Therapeutic group Antihypertensive.
Indications and dose **Hypertension (including reduction of stroke risk in hypertension with left ventricular hypertrophy)** ADULT: 18-75 years: Initially 50 mg *PO,* Q24H for several weeks, then increased if necessary to 100 mg, Q24H; ADULT (76 years and over): Initially 25 mg *PO,* Q24H for several weeks, then increased if necessary to 100 mg, Q24H; CHILD (6-17 years) (body-weight 20-49 kg): Initially 700 mcg/kg *PO,* Q24H (max. 25 mg/dose), adjusted according to response to 50 mg/day; max. 50 mg/day; CHILD (6-17 years) (body-weight 50 kg and above): Initially 50 mg *PO,* Q, adjusted according to response to 1.4 mg/kg, Q24H; max. 100 mg/day. **Hypertension with intravascular volume depletion** ADULT: (18-75 years): Initially 25 mg *PO,* Q24H for several weeks, then increased if necessary up to 100 mg, Q24H; CHILD 6-17 years (body-weight 50 kg and above): Initially 25 mg *PO,* Q24H; adjusted according to response to 1.4 mg/kg, Q24H. **Chronic heart failure when ACE inhibitors are unsuitable or contra-indicated** ADULT: Initially 12.5 mg *PO,* Q24H, increased if tolerated to up to 150 mg, Q24H, doses to be increased at weekly intervals; max. 100 mg/day. **Diabetic nephropathy in type 2 diabetes mellitus** ADULT (18-75 years): Initially 50 mg *PO,* Q24H for several weeks, then increased if necessary to 100 mg, Q24H; ADULT (76 years and over): Initially 25mg *PO,* Q24H for several weeks, then increased if necessary to 100 mg, Q24H.
Cautions Angioedema, volume-depletion, severe congestive heart failure (CHF), hepatic or renal impairment.
Side effects Fatigue, hypoglycemia, anaemia, urinary tract infection, chest pain, weakness, diarrhoea, upper respiratory tract infection, hypotension, dizziness, cellulitis, gastritis, nausea.
Hepatic impairment Dose reduction in mild to moderate impairment. Avoid in severe impairment.

Pregnancy category D
Breast-feeding Excretion in milk unknown, avoid.
Counselling Dizziness or light-headedness may occur after the first dose of this medicine; do not drive or operate machinery.

MAGNESIUM SULPHATE

Injection, 50% (2 mL) NRH/RRH/DH

Therapeutic group Antihypertensive.
Indications and dose **Treatment of seizures and prevention of recurrent seizures in eclampsia,** by *IV injection*, initially 4 g over 5-15 minutes followed either *by IV infusion,* 1 g/hour for at least 24 hours after the last seizure or delivery (whichever occurs later). **Prevention of seizures in pre-eclampsia,** *by IV injection*, initially 4 g over 5-15 minutes followed by *IV infusion,* 1 g/hour for 24 hours*;* if seizure occurs, give an additional dose *by IV injection* of 2g. **Mild hypomagnesaemia,** deep IM injection, 1 g every 6 hourly for 4 doses. **Severe hypomagnesaemia,** by IV infusion, 5 g IV over 3 hours.
Note *for IV injection, concentration of magnesium sulphate should not exceed 20% (dilute 1 part of magnesium sulphate injection, 50%, with at least 1.5 parts of water for injections); for IM injection, mix magnesium sulphate injection, 50%, with 1 mL of lignocaine injection 2%. Monitor renal function, blood pressure, respiratory rate and deep tendon reflex.*
Contraindications Myocardial damage, heart block, diabetic coma, hypermagnesemia, hypercalcemia.
Cautions Digitalized patients, myasthenia gravis and other neuromuscular diseases.
Side effects Respiratory depression, oliguria, neuromuscular depression and muscle weakness.
Renal impairment Do not exceed 20 g in 48 hours. Increased risk of toxicity.
Pregnancy Category D
Breastfeeding Compatible, infant risk is minimal.

METHYLDOPA

Tablet, 250 mg NRH/RRH/DH/PHC

Therapeutic group Antihypertensive.
Indications and dose **Hypertension** ADULT: Initially 250 mg *PO,* Q8-12H, dose should be increased gradually at intervals of at least 2 days; max. 3 g/day; ELDERLY: Initially 125 mg *PO,* Q12H, dose should be increased gradually; max. 2 g/day.
Note *Methyldopa is used in hypertension in pregnancy, where other medicines are contraindicated.*
Contraindications Acute porphyria, depression, pheochromocytoma, active liver disease.
Cautions CHF, dialysis patients, oedema, hemolytic anaemia, hypotension, severe bilateral CVD, history of liver disease, avoid abrupt withdrawal, risk of decreased libido and impotence in men.
Side effects Angina, bradycardia, orthostatic hypotension, depression, dizziness, lethargy, sedation, rash, gynecomastia, impotence, dry mouth, nausea, vomiting, hemolytic anaemia, thrombocytopenia, liver toxicity, arthralgia, autoimmune disease.
Renal impairment CrCl >50 mL/min: Q8hr; CrCl 10-50 mL/min: q8-12H; CrCl <10 mL/min: q12-24hr.
Hepatic impairment Avoid in acute liver disease.
Pregnancy category B
Counselling May cause drowsiness, do not drive or operate machinery.

METOPROLOL SUCCINATE

Tablet, 25 mg NRH/RRH

Therapeutic group Antihypertensive.
Indications and dose **Hypertension** 25-100 mg/day *PO,* STAT or Q12H; dose increased every week as needed up to 400 mg, Q24H; CHILD (≥ 6 Years): 1 mg/kg *PO,* Q24H (max. 50 mg/dose/day; 2 mg/kg; 200 mg/day).
For details, refer to page no. 83.

NIFEDIPINE

Tablet (Sustained Release), 20 mg NRH/RRH/DH

Therapeutic group Antihypertensive.
Indications and dose **Hypertension** 20 mg *PO,* Q12H, increased up to max. of 40 mg, Q12H.
For details, refer to page no. 83.

NIMODIPINE

Tablet, 30 mg NRH/RRH

Therapeutic group Antihypertensive.
Indications and dose **Subarachnoid haemorrhage** 60 mg PO, Q4 hours for 21 days, start therapy within 96 hours after subarachnoid haemorrhage.
Contraindications Acute porphyria, unstable angina, within 1 month of myocardial infarction.
Cautions Cerebral oedema, hypotension, severely raised intracranial pressure, congestive heart failure, Reflex tachycardia, hepatic impairment, cirrhosis.
Side effect Flushing, gastro-intestinal disorders, headache, nausea, sweating and thrombocytopenia, variation in heart rate.
Renal Impairment Monitor renal function closely.
Hepatic Impairment Reduce dosage to 30 mg every 4 hours in patients with liver failure.
Pregnancy category C
Breast feeding Excreted in breast milk, avoid.

PROPRANOLOL

Tablet, 40 mg NRH/RRH/DH

Therapeutic group Antihypertensive.
Indications and dose **Hypertension** ADULT: Initially 80 mg *PO,* Q12H, dose should be increased at weekly intervals as required; ***maintenance*** 160-320 mg/day; CHILD (1 month-11 years): Initially 0.25-1 mg/kg *PO,* Q8H, then increased to 5 mg/kg/day in divided doses, dose increased at weekly intervals; CHILD (12-17 years): Initially 80 mg *PO,* Q12H, then increased if necessary up to 160-320 mg/day, dose increased at weekly intervals. *For details, refer to page no. 84.*

SODIUM NITROPRUSSIDE

Powder for injection, 500 mg NRH/RRH

Therapeutic group Antihypertensive.
Indications and dose **Management of hypertensive crisis; congestive heart failure; controlled hypotension to reduce bleeding during surgery** by IV infusion, ADULT: Initial: 0.3-0.5 mcg/kg/minute; increase in increments of 0.5 mcg/kg/minute, titrating to the desired hemodynamic effect or the appearance of headache or nausea; max dose: 10 mcg/kg/minute; CHILD: 0.3 mcg/kg/minute; increase in increments of 0.5 mcg/kg/minute, titrating to the desired hemodynamic effect or the appearance of headache or nausea; max dose: 8 mcg/kg/minute.
Note: *Not suitable for direct injection. Requires dilution prior to infusion. Administration requires the use of an infusion pump.*
Side effects Excessive hypotensive response, palpitation, substernal distress, disorientation, psychosis, headache, restlessness, thyroid suppression, nausea, vomiting, weakness, muscle spasm, tinnitus, hypoxia, diaphoresis, thiocyanate toxicity.
Cautions Head trauma, hyponatremia, hypothyroidism, severe renal and hepatic impairment, elderly.
Contraindications Compensatory hypertension (aortic coarctation, arteriovenous shunting), high output failure, congenital optic atrophy.
Renal impairment GFR < 30 mL/min: limit infusion rate to less than 3 mcg/kg/min.
Hepatic impairment Use with caution, avoid prolonged use.

Pregnancy category C
Counselling Solutions are highly sensitive to light. Solutions should be wrapped with aluminium foil or other opaque material to protect from light.
Compatibility Stable in compound sodium lactate, dextrose 5% and sodium chloride 0.9%.

VERAPAMIL

Tablet, 40 mg NRH/RRH

Therapeutic group Antihypertensive.
Indications and dose **Hypertension** ADULT: 240-480 mg/day *PO,* Q8-12H; CHILD (2-17 years): 40-120 mg *PO,* Q8-12H. *For details, refer to page no. 85.*

12.4 Medicines used in heart failure

ADRENALINE

Injection, 1 mg/mL (1 mL) NRH/RRH/DH/PHC

Therapeutic group Vasoconstrictor sympathomimetic.
Indications and dose **Anaphylactic shock, asthma and cardiac arrest, severe angioedema anaphylaxis**: *By IM injection,* as given below:

Age	Volume
< 1-year	0.05mL
2 years	0.2mL
3-4 years	0.3mL
5 years	0.4mL
6-12 years	0.5mL
ADULT	0.5-1.0mL

Doses may be repeated every 10 minutes, according to blood pressure and pulse, until improvement occurs (may be repeated several times). **Asthma** *by IM injection,* ADULT: 0.1-0.5 mg at 15–20 minutes intervals as required; CHILD, 0.01mg/kg SC, repeated after 4 hours if required to a maximum of 0.5mg. **Cardiac arrest** by IV injection, ADULT: 0.1 – 0.5 mcg/kg/min; CHILD, 0.1 – 1 mcg/kg/min IV and titrate to response. *For details, refer to page no. 23.*

BISOPROLOL

Tablet, 5 mg NRH/RRH

Therapeutic group Medicine use for heart failure, antianginal, antiarrhythmic and antihypertensive.
Indications and dose **Congestive heart failure** ADULT: Initially 1.25 mg once daily for 1 week, then increased if tolerated to 2.5 mg once daily for 1 week. Can be increased in the order of 3.75 mg once daily for 1 week, 5 mg once daily for 4 weeks, 7.5 mg once daily for 4 weeks, and 10 mg once daily if tolerated according to patient conditions, maximum 10 mg per day. *For details, refer to page no. 82.*

CARVEDILOL

Tablet, 3.125 mg and 12.5 mg NRH/RRH

Therapeutic group Antianginal.
Indications and dose **Adjunct to diuretics, digoxin, or ACE inhibitors in symptomatic chronic heart failure** ADULT: Initially 3.125 mg *PO,* Q12hr, then increased to 6.2 mg, Q12hr, then increased to 12.5 mg, Q12hr, then increased to 25mg, Q12hr, dose should be increased at intervals of at least 2 weeks up to the highest tolerated dose; Max. 25 mg, Q12hr in patients with severe heart failure or body-weight less than 85 kg; max. 50 mg, Q12hr in patients over 85 kg. *For details, refer to page no. 82.*

DIGOXIN

Injection, 250 mcg/mL (2 mL) NRH/RRH
Tablet, 250 mcg NRH/RRH/DH/PHC

Therapeutic group Antiarrhythmic and medicines used in heart failure.
Indications and dose **Heart failure (for patients in sinus rhythm)** ADULT: 62.5-125 mcg *PO,* Q4H; reduce dose in the elderly. *For details, refer to page no. 87.*

DOPAMINE

Injection, 40 mg/mL (5 mL) NRH/RRH/DH

Therapeutic group Medicine used in heart failure.
Indications and dose **Cardiogenic shock in infarction or cardiac surgery, congestive heart failure, septic shock**, ADULT: Initial 2-5 mcg/kg/min *IV infusion,* increase in 5-10 mcg/kg/min (max. 50 mcg/kg/min); CHILD: Initially 5 mcg/kg/min (max. 20 mcg/kg/min).
Contraindications Pheochromocytoma, tachyarrhythmia.
Cautions Hypovolemia, hyperthyroidism, ventricular arrhythmias.
Side effects Chest pain, dyspnea, headache, hypotension, nausea, palpitation, tachycardia, vasoconstriction, vomiting.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.
IV fluid compatibility Dextrose 5%, dextrose 5% in sodium chloride 0.9%, compound sodium lactate solution.

ENALAPRIL

Tablet, 5 mg NRH/RRH/DH

Therapeutic group Medicine used in heart failure.
Indications and dose **Heart failure** ADULT: Initially 2.5 mg *PO,* Q24hr, increased if tolerated to 10-20 mg, Q12hr, dose increased gradually over 2-4 weeks; CHILD (1 month-11 years): Initially 100 mcg/kg *PO,* Q24hr, then increased if necessary up to 1 mg/kg/day, Q24hr in 1-2 divided doses; CHILD (12-17 years) (body-weight up to 50 kg): Initially 2.5mg *PO,* Q24hr, ***maintenance*** 10-20 mg/day in 1–2 divided doses; CHILD (12-17 years) (body-weight 50 kg and above): Initially 2.5 mg *PO,* Q24hr, ***maintenance*** 10-20 mg/kg in 1-2 divided doses; max. 40 mg/day.
For details, refer to page no. 89.

FUROSEMIDE

Injection, 10 mg/mL (2 mL) NRH/RRH/DH
Tablet, 40 mg NRH/RRH/DH

Therapeutic group Medicine used in heart failure.
Indications and dose **Oedema associated with chronic heart failure, liver cirrhosis and renal diseases, including nephrotic syndrome** ADULT: Initially 40 mg *PO,* Q24hr, dose to be taken in the morning, then maintenance 20-40 mg; CHILD (1 month-11 years): 0.5-2 mg/kg *PO, Q8-12hr*, alternatively 0.5-2 mg/kg, Q24hr, if corrected gestational age of under 31 weeks, higher doses may be required in resistant oedema (max. 80mg/day; max. 12 mg/kg/day); CHILD (12-17 years): 20-40 mg *PO,* Q24hr daily; increased to 80-120 mg, Q24hr, in resistant oedema; ***IM or slow IV injection or IV infusion*** Initially 20-50 mg *IM or slow IV injection or IV infusion*, then increased in steps of 20 mg, Q2hr if required, doses greater than 50 mg given by *IV infusion*; max. 1.5 g/day; ***Slow IV injection*** CHILD (1 month-11 years): 0.5-1 mg/kg *slow IV injection*, Q8hr as required (max. 40 mg, Q8hr; max. 6 mg/kg/day); CHILD (12-17 years):

20-40 mg *PO,* Q8hr as required, higher doses may be required in resistant cases; ***Continuous IV infusion*** CHILD: 0.1-2 mg/kg/hour. *For details, refer to page no. 110.*

HYDROCHLOROTHIAZIDE

Tablet, 25 mg NRH/RRH/DH/PHC

Therapeutic group Diuretic.
Indications and dose **Hypertension and Mild fluid retention in heart failure** 25 mg *PO,* Q12-24hr*;* Max. ADULT: 200 mg/day; CHILD (<6 months-2 years): 37.5 mg/day; CHILD (2-12 years): 3 mg/kg/day (100 mg/day).
For details, refer to page no. 111.

LOSARTAN

Tablet, 25 mg NRH/RRH/DH/PHC

Therapeutic group Medicine used in heart failure.
Indications and dose **Chronic heart failure when ACE inhibitors are unsuitable or contra-indicated** ADULT: Initially 12.5 mg *PO,* Q24H, increased if tolerated to up to 150 mg, Q24H, doses to be increased at weekly intervals; max. 100 mg/day. *For details, refer to page no. 91.*

METOPROLOL SUCCINATE

Tablet, 25 mg NRH/RRH

Therapeutic group Medicine used in heart failure.
Indications and dose **Heart failure** 25 mg *PO,* Q24hr x 2 weeks in patients with NYHA Class II heart failure and 12.5 mg *PO,* Q24hr in patients with more severe heart failure. Double the dose every two weeks to up to 200 mg.
For details, refer to page no. 83.

SPIRONOLACTONE

Tablet, 25 mg NRH/RRH/DH

Therapeutic group Medicine used in heart failure.
Indications and dose **Oedema; Ascites in cirrhosis of the liver** ADULT: 100-400 mg *PO,* Q24hr, adjusted according to response. **Malignant ascites** ADULT: Initially 100-200 mg *PO,* Q24hr, then increased if necessary to 400 mg Q24hr, maintenance dose adjusted according to response. **Nephrotic syndrome** ADULT: 100-200 mg *PO,* Q24hr. **Oedema in congestive heart failure** ADULT: Initially 100 mg *PO,* Q24hr, alternatively initially 25-200 mg/kg *PO*, dose may be taken as a single dose or divided doses, maintenance dose adjusted according to response. **Moderate to severe heart failure (adjunct)** ADULT: Initially 25 mg *PO,* Q24hr, then adjusted according to response to 50 mg, Q24hr. **Resistant hypertension (adjunct)** ADULT: 25 mg *PO,* Q24hr. **Primary hyperaldosteronism in patients awaiting surgery** ADULT: 100-400 mg *PO,* Q24hr, may be used for long-term maintenance if surgery inappropriate, use lowest effective dose; CHILD (1 month-11 years): Initially 1-3 mg/kg *PO,* Q12-24hr; increased if necessary up to 9 mg/kg/day, in resistant ascites; CHILD (12-17 years): Initially 50-100 mg/day, Q12-24hr; increased if necessary up to 9 mg/kg/day, in resistant ascites; max. 400 mg/day.
Contraindications Hyperkalemia, anuria, Addison's disease.
Cautions Elderly patients, acute porphyria.
Side effects Acute renal failure, agranulocytosis, alopecia, breast pain, changes in libido, dizziness, drowsiness, electrolyte disturbances, GI disturbances, gynaecomastia, hepatotoxicity, hyperkalaemia (discontinue), hypertrichosis, hyperuricemia, hyponatraemia, leg cramps, leukopenia, malaise, menstrual disturbances, rash, Stevens-Johnson syndrome, thrombocytopenia.
Renal impairment CrCl >50 mL/min: 25 mg/Q24hr; CrCl 30-50 mL/min: 25 mg/Q 48 Hr
Pregnancy category C
Breast-feeding Metabolite excreted in milk, use with caution.
Note For hypertension, doses >75 mg/day may not provide additional reductions in blood pressure.

12.5 Antithrombotic medicines

12.5.1 Antiplatelet medicines

ASPIRIN

Tablet (enteric coated), 75 mg — NRH/RRH/DH/PHC
Tablet, (soluble) 300 mg — NRH/RRH/DH

Therapeutic group Antiplatelet.
Indications and dose **Cardiovascular disease (secondary prevention)** ADULT: 75 mg *PO,* Q24hr; CHILD (1 month-11 years): 1-5 mg/kg *PO,* Q24hr (max. 75 mg/dose); CHILD (12-17 years): 75 mg *PO,* q24hr. **Management of unstable angina and non-ST-segment elevation myocardial infarction (NSTEMI); Management of ST-segment elevation myocardial infarction (STEMI)** ADULT: 325 mg, chewed or dispersed in water. **Suspected transient ischemic attack** ADULT: 300 mg *PO,* Q24hr until diagnosis established. **Transient ischemic attack; Ischemic stroke not associated with atrial fibrillation** ADULT: 75 mg *PO,* Q24hr; **Acute ischemic stroke** ADULT: 325 mg *PO,* Q24hr x 14 days, to be initiated 24 hours after thrombolysis or as soon as possible within 48 hours of symptom onset in patients not receiving thrombolysis. **Atrial fibrillation following a disabling ischemic stroke (before being considered for anticoagulant treatment)** ADULT: 325 mg *PO,* Q24hr x 14 days. **Following disabling ischemic stroke in patients receiving anticoagulation for a prosthetic heart valve and who are at significant risk of hemorrhagic transformation** ADULT: 325 mg *PO,* Q24hr, anticoagulant treatment stopped for 7 days and to be substituted with aspirin. **Following coronary by-pass surgery** ADULT: 75-325 mg *PO,* Q24hr.
Contraindications Active peptic ulceration, bleeding disorders, children under 16 years (risk of Reye's syndrome), haemophilia, previous peptic ulceration, severe cardiac failure.
Cautions Allergic disease, anaemia, asthma, dehydration, elderly, G6PD deficiency, preferably avoid during fever or viral infection in children, previous peptic ulceration, thyrotoxicosis, uncontrolled hypertension.
Side effects Blood disorders, bronchospasm, confusion, GI haemorrhage, GI irritation, haemorrhage including subconjunctival haemorrhage, increased bleeding time, skin reactions in hypersensitive patients, tinnitus.
Overdose The main features of salicylate poisoning are hyperventilation, tinnitus, deafness, vasodilatation, and sweating, coma is uncommon but indicates very severe poisoning.
Hepatic impairment Avoid in severe impairment.
Renal impairment Use with caution, avoid in severe impairment.
Pregnancy category C
Breastfeeding Excreted in milk, use with caution.
Counselling Take after or with meals.

CLOPIDOGREL

Tablet, 75 mg — NRH/RRH/DH

Therapeutic group Antiplatelet.
Indications and dose **Prevention of atherothrombotic events in percutaneous coronary intervention (adjunct with aspirin) in patients not already on clopidogrel** ADULT: Loading dose 300 mg *PO*, prior to the procedure; OR loading dose 600 mg *PO*, higher dose may produce a greater and more rapid inhibition of platelet aggregation. **Transient ischemic attack for patients with aspirin hypersensitivity, or those intolerant of aspirin; Acute ischemic stroke for patients with aspirin hypersensitivity, or those intolerant of aspirin** ADULT: 75 mg *PO,* Q24hr. **Prevention of atherothrombotic events in peripheral arterial disease or within 35 days of myocardial infarction, or within 6 months of ischemic stroke** ADULT: 75 mg *PO,* Q24hr **Prevention of atherothrombotic events in acute coronary syndrome without ST-segment elevation (given with aspirin)** ADULT: Initially 300 mg *PO*, then 75 mg Q24hr for up to 12 months. **Prevention of atherothrombotic events in acute myocardial infarction with ST-segment elevation (given with aspirin)** ADULT (18-75 years): Initially 300 mg *PO*, then 75 mg for at least 4 weeks; ADULT (76 years and over): 75 mg *PO,* Q24hr for at least 4 weeks. **Prevention of atherothrombotic and thromboembolic events in patients with atrial fibrillation and at least one risk factor for a vascular event (with aspirin) and for whom warfarin is unsuitable** ADULT: 75 mg *PO,* Q24hr.

Contraindications Active bleeding.
Cautions Discontinue 7 days before elective surgery if antiplatelet effect is not desirable, patients at risk of increased bleeding from trauma, surgery, or other pathological conditions, atrial fibrillation, allergic to aspirin.
Side effects Abdominal pain, bleeding disorders (including GI and intracranial), diarrhoea, dyspepsia, constipation, decreased platelets, dizziness, duodenal ulcers, eosinophilia, flatulence, gastric ulcer, gastritis, headache, leukopenia, nausea, paraesthesia, pruritus, rash, vomiting.
Pregnancy category D
Breast-feeding Excretion in milk unknown, avoid.
Hepatic impairment Use with caution (risk of bleeding). Avoid in severe impairment.
Renal impairment Use with caution.

12.5.2 Thrombolytic medicines

ALTEPLASE

Powder for injection, 50 mg NRH/RRH

Therapeutic group Thrombolytic agent.
Indications and dose **ST Elevation Myocardial Infarction (STEMI),** If patients report to health facility within 6 hours of symptom onset, *by IV injection*, ADULT, body weight up to 65 kg: 15 mg IV bolus over 1-2 mins followed by 0.75 mg/kg after 30 mins, then 0.5 mg/kg infused over 60 mins, max total dose of 100 mg over 90 mins. Body weight > 65 kg: 15 mg IV bolus over 1-2 mins, followed IV 50 mg, over 30 minutes then 35 mg over 60 minutes, max. dose of 100 mg administered over 90 minutes. If patients report to a health facility after 6-12 hours of symptom onset, IV injection, ADULT, 10 mg followed by 50 mg over 60 minutes then 10 mg for 4 infusions, each 10 mg infusion given over 30 minutes, max. total 100 mg over 3 hours, 1.5 mg/kg in patients less than 65 kg. **Acute ischemic stroke** ADULT, 18-79 years, initially IV 90 mg within 4.5 hours of symptom onset, followed by 10% of initial dose administered within 60minutes. **Pulmonary embolism** ADULT: 10 mg over 1-2 minutes, followed by 90 mg, over 2 hours, max. 1.5 mg/kg in patients less than 65 kg.
Contraindications History of stroke in patients with diabetes, hyperglycemia, hypoglycemia, severe stroke, stroke in the last 3 months, convulsion accompanying stroke, recent head trauma.
Caution: recent major surgery, cerebrovascular disease, hypertension, acute pericarditis, hemostatic defects, severe hepatic and renal dysfunction, avoid IM injection, elderly, pregnancy.
Side effects Stroke, intracranial bleeding, gastrointestinal haemorrhage.
Pregnancy category C
IV compatibility Stable in sodium chloride, water for injection.

STREPTOKINASE

Powder for injection, 1.5 million IU NRH/RRH/DH

Therapeutic group Thrombolytic.
Indications and dose **Acute myocardial infarction** ADULT: 1,500,000 units *IV infusion*, to be initiated within 12 hours of symptom onset, dose to be given over 60 minutes. **Deep-vein thrombosis; Pulmonary embolism; Acute arterial thromboembolism; Central retinal venous or arterial thrombosis** ADULT: 250,000 units *IV infusion* given over 30 minutes, then 100,000 units, Q1hr for up to 12-72 hours, duration is adjusted according to condition with monitoring of clotting parameters. **Intravascular thrombosis** CHILD (1 month-11 years): Initially 2500-4000 units/kg *IV infusion* given over 30 minutes, followed by 500-1000 units/kg/hr *continuous IV infusion* for up to 3 days until reperfusion occurs; CHILD (12-17 years): Initially 250,000 units *IV infusion*, given over 30 minutes, followed by 100,000 units/hour *continuous IV infusion* for up to 3 days until reperfusion occurs.
Contraindications Severe uncontrolled hypertension, active internal bleeding, recent intracranial or intra-spinal surgery or trauma, intracranial neoplasm, aneurysm, known bleeding diathesis, recent history of cerebrovascular accident, acute pancreatitis.

Cautions History of streptococcal infection (within 12 months), previous streptokinase administration (within 12 months), recent major surgery, cerebrovascular disease, recent GI or genitourinary bleeding, pregnancy, diabetic hemorrhagic retinopathy, atrial fibrillation, mitral valve defect.
Side effects Fever, hypotension, haemorrhage at injection site, ecchymosis, gastrointestinal bleeding, epistaxis, cardiac dysrhythmia, intracranial haemorrhage, visual acuity, acute respiratory distress syndrome.
Pregnancy Category C
Breast-feeding Excretion in milk unknown. Milk should be discarded during the first 24 hours following thrombolytic therapy.
Note *Streptokinase should not be used again beyond 4 days of first administration.*

SODIUM TETRADECYL SULPHATE

Injection, 15 mg/mL (2 mL) NRH

Therapeutic Group Sclerosing agent.
Indications and dose **Sclerotherapy of reticular veins and spider veins in legs and varicose veins**, by intravenous injection, ADULT: Test dose: 0.5 mL given several hours prior to administration of larger dose; 0.5-2 mL (preferred maximum: 1 mL) in each vein, maximum 10 mL per treatment session.
Contraindications incompetency of collateral deep veins in the legs, incompetency of the valves of the greater and lesser saphenous veins before ligation, thrombophlebitis, tuberculosis, hyperthyroidism, acute infections, prolonged recumbency, cardiac insufficiency, diabetes, arterial disease, varicosities caused by pelvic neoplasia.
Cautions Extravasation may cause necrosis of tissues, history of migraine (use smaller volumes), venous insufficiency with lymphoedema (pain and inflammation may worsen).
Side effects Pain, ulcer and urticaria at injection site, nausea, vomiting, headache, skin necrosis, deep vein thrombosis.
Pregnancy C
Breastfeeding Excretion in breast milk unknown, use caution.

12.6 Hemostatic

TRANEXAMIC ACID

Injection, 50 mg/mL (5mL) NRH/RRH
Capsule, 250 mg NRH

Therapeutic group Antifibrinolytic agent.
Indications and dose **Treatment and prophylaxis of haemorrhage associated with excessive fibrinolysis; To control bleeding during neurosurgical operations** ADULT: 1-1.5 g *PO*, Q8-12H, alternatively 15-25 mg/kg *PO,* Q8-12H; 0.5-1 g *Slow IV injection*, Q8-12H administered at a rate not exceeding 100 mg/minute; dose followed by 25-50 mg/kg *continuous IV infusion*, dose given over 24 hours.
Contraindications Active intravascular clotting, history of convulsion, thromboembolic disease.
Cautions Irregular menstrual bleeding, massive hematuria, patients receiving OCP.
Side effects Nausea, vomiting, diarrhoea, infrequently hypotension and thrombosis.
Renal impairment Dose reduction required in impairment.
Pregnancy category B
Breast-feeding Excreted in milk unknown, use with caution.
IV fluid compatibility Dextrose 5%, sodium chloride 0.9%.

12.7 Lipid lowering agents

ATORVASTATIN

Tablet, 10 mg NRH/RRH/DH

Therapeutic group Lipid lowering agent.
Indications and dose **Primary hypercholesterolemia in patients who have not responded adequately to diet and other appropriate measures; Combined hyperlipidemia in patients who have not responded adequately to diet**

and other appropriate measures ADULT: Usual dose 10 mg *PO,* Q24hr; increased if necessary up to 80 mg, Q24hr, dose to be increased at intervals of at least 4 weeks. **Heterozygous familial hypercholesterolemia in patients who have not responded adequately to diet and other appropriate measures; Homozygous familial hypercholesterolemia in patients who have not responded adequately to diet and other appropriate measures** ADULT: Initially 10 mg *PO,* Q24hr, then increased to 40 mg, Q24hr, dose to be increased at intervals of at least 4 weeks; max. 80 mg, Q24hr. **Primary prevention of cardiovascular events in patients at high risk of a first cardiovascular event** ADULT: 20 mg *PO,* Q24hr, dose can be increased if necessary. **Secondary prevention of cardiovascular events** ADULT: 80 mg *PO,* Q24hr.
Contraindications Active liver disease.
Cautions Hemorrhagic stroke.
Side effects Back pain, epistaxis, hyperglycemia, nasopharyngitis, pharyngolaryngeal pain, anorexia, blurred vision, chest pain, hypoglycemia, malaise, neck pain, peripheral oedema, pyrexia, tinnitus, weight gain.
Pregnancy category X
Breast-feeding Excreted in breast milk, avoid.
Counselling Advice patient to report promptly unexplained muscle pain, tenderness, and weakness.

FENOFIBRATE

Tablet, 160 mg NRH/RRH/DH

Therapeutic group Lipid-lowering agent.
Indications and dose **Hypercholesterolemia, Primary hypercholesterolemia or mixed dyslipidemia; adjunct to diet** ADULT: initial, 160 mg PO once daily with a meal; MAX 160 mg/day; **Hypertriglyceridemia (Severe), Adjunct to diet** ADULT: 160 mg orally once daily with a meal, adjust if necessary following repeat lipid determinations at 4- to 8-week intervals; MAX 160 mg/day.
Contraindications Gallbladder disease, pancreatitis.
Cautions Correct hypothyroidism before initiating treatment.
Side effects Abdominal distension; anorexia, diarrhoea, nausea, alopecia, cholestasis, dizziness, erectile dysfunction, headache, myotoxicity (with myasthenia, myalgia, or very rarely rhabdomyolysis) - special risk in renal impairment; pancreatitis; photosensitivity reactions; pruritus; pulmonary embolism; rash, renal failure, urticaria.
Hepatic impairment Avoid.
Renal impairment Reduce dose in moderate to severe impairment.
Pregnancy category C
Breast-feeding Excretion in milk unknown, avoid.

12.8 Peripheral vasodilator

PENTOXIFYLLINE

Tablet, 400 mg NRH

Therapeutic group Peripheral vasodilator.
Indications and dose **Peripheral vascular disease; Venous leg ulcers** ADULT: 400mg PO, Q8-12hr with meals; minimum 8 weeks for optimum effects.
Contraindications Cerebral haemorrhage, extensive retinal haemorrhage, acute myocardial infarction, lactation, porphyria.
Side effects GI disturbances, dizziness, headache, rarely flushing, tachycardia, hypersensitivity including rash, pruritus, bronchospasm, angina, hypotension.
Hepatic impairment Reduce dose in severe impairment.
Renal impairment CrCl <30 mL/min: decrease dose to 400 mg/day.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.
Counselling Take this medicine with meals so that it will not upset your stomach.

12. 9 Vasopressor agents

ADRENALINE

Injection, 1 mg/mL (1 mL) NRH/RRH/DH/PHC

Therapeutic group Vasopressor (sympathomimetic).
Indications and dose **Anaphylaxis**, By IM injection, as given below:

Age	Volume
< 1 - year	0.05 mL
2 years	0.2 mL
3 - 4 years	0.3 mL
5 years	0.4 mL
6 - 12 years	0.5 mL
ADULT	0.5 - 1.0 mL

Doses may be repeated every 10 minutes, according to blood pressure and pulse, until improvement occurs (may be repeated several times); **Asthma,** By IM injection, ADULT: 0.1-0.5 mg, IM, Q15-20 minute intervals as required; CHILD: 0.01 mg/kg, SC, Q4H if required to a maximum of 0.5 mg; **Cardiac arrest,** ADULT: 0.1-0.5 mcg/kg/min, IV; CHILD: 0.1-1 mcg/kg/min, IV and titrate to response. *For details, refer to page no. 23.*

DOBUTAMINE

Injection 50 mg/mL (20 mL) NRH/RRH

Therapeutic group Vasopressor (sympathomimetic).
Indications and dose **Decreased cardiac output**, ADULT: initial dose 0.5 – 1 mcg/kg/min IV infusion, then 2 – 20 mcg/kg/min: not to exceed 40 mcg/kg/min. **Heart failure**, ADULT: initial dose 0.5 to 1 mcg/kg/min IV; Maintenance dose 2 to 40 mcg/kg/min IV; CHILD, 2 to 20 mcg/kg/min.
Note: Dilute with dextrose 5% or 0.9% normal saline solutions to a concentration of 0.5-1 mg/mL and give by an infusion pump; give higher concentration (max. 5 mg/mL) through central venous catheter.
Contraindications Pheochromocytoma, patients with stable heart failure.
Cautions Acute Heart Failure (AHF), myocardial infarction, arrhythmias, atrial fibrillation, hyperthyroidism, severe hypotension bronchial asthma who are hypersensitive to sulphites.
Side effect Psychosis, fever, headache, chest pain, tachycardia, arrhythmias, dyspnea, AV block, hypokalemia.
Pregnancy category B
Breast feeding excretion in breast milk unknown.
IV fluid compatibility Incompatible with bicarbonates and other strong alkaline solutions

DOPAMINE

Injection, 40 mg/mL (5 mL) NRH/RRH/DH

Therapeutic group Vasopressor.
Indications and dose **Cardiogenic shock in infarction or cardiac surgery; congestive heart failure; septic shock**; ADULT: Initial 2-5 mcg/kg/min IV infusion, increase in 5-10 mcg/kg/min; MAX. dose 50 mcg/kg/min. CHILD: Initially 5 mcg/kg/min MAX. 20 mcg/kg/min.
Contraindications Pheochromocytoma, tachyarrhythmia.
Cautions Hypovolemia, hyperthyroidism, ventricular arrhythmias.
Side effects Chest pain, dyspnea, headache, hypotension, nausea, palpitation, tachycardia, vasoconstriction, vomiting.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.
IV fluid compatibility Dextrose 5%, dextrose 5% in sodium chloride 0.9%, compound solution of sodium lactate.

EPHEDRINE

Injection, 3 mg/mL (10 mL) NRH/RRH/DH

Therapeutic group Vasopressor.
Indications and dose **Reversal of hypotension from spinal or epidural anaesthesia,** ADULT: 3-6 mg every 3-4 minutes by slow IV injection; Max. per dose 9 mg; adjusted according to response, MAX. 30 mg per course; CHILD (1-11 years): 500-750 mcg/kg every 3-4 minutes, adjusted according to response, maximum 30 mg per course; CHILD (12-17 years): 3-7.5 mg every 3-4 minutes; Max. per dose 9 mg, adjusted according to response, MAX 30 mg per course.
Cautions Diabetes mellitus, elderly, hypertension, Hyperthyroidism, ischemic heart disease, prostatic hypertrophy (risk of acute urinary retention); susceptibility to angle-closure glaucoma.
Side effects Anginal pain, anorexia. Anxiety, arrhythmias, changes in blood-glucose concentration, confusion; difficulty in micturition; dizziness, dyspnea, flushing, headache, hypersalivation, insomnia, nausea, psychoses, restlessness, sweating, tachycardia, tremor, urine retention, vasoconstriction with hypertension; vasodilation with hypotension, vomiting.
Renal impairment Use with caution.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.

LABETALOL

Injection, 5 mg/mL (20 mL) NRH/RRH

Therapeutic group Vasopressor.
Indications and dose **Acute severe hypertension in pregnancy** ADULT,10 to 20 mg IV, then 20 to 80 mg every 10 to 30 minutes to a MAX cumulative dosage of 300 mg; OR 1 to 2 mg/min IV infusion; initiate within 30 to 60 minutes. **Severe intrapartum or postpartum hypertension** ADULT, Initial, 20 mg slow IV injection (over more than 2 minutes). Target lowering to range of 140 to 150/90 to 100 mmHg. If SBP or DBP threshold is still exceeded after 10 minutes, give 40 mg slow IV injection, then if a threshold is still exceeded after a further 10 minutes, give 80 mg slow IV injection. If threshold remains exceeded after a further 10 minutes, switch to hydralazine 10 mg IV over more than 2 minutes. **Acute ischemic stroke: Pretreatment** ADULT, 10 to 20 mg IV over 1 to 2 minutes, may repeat x 1 dose to achieve blood pressure (BP) less than 185/110 mm Hg prior to alteplase; if BP exceeds 180/105 mm Hg in first 24 hrs after alteplase treatment, administer 10 mg IV followed by a continuous infusion of 2 to 8 mg/min. **Hypertensive Emergency** ADULT Initial, 20 mg (0.25 mg/kg for an 80 kg patient) by slow IV injection over 2 minutes; additional doses of 40 or 80 mg may be given at 10-minute intervals until desired blood pressure (BP) is achieved or up to a total of 300 mg. Individualise dosage to severity of disease and degree of response *OR* initial, 2 mg/minute as an IV infusion; adjust infusion rate to BP response and individualise dosage to severity of disease and degree of response. Usual total dosage, 50 to 200 mg; a total dosage of up to 300 mg may be required. CHILD, (*1 year and above*) Bolus: 0.2 to 1 mg/kg/dose IV bolus up to 40 mg/dose *OR* 0.25 to 3 mg/kg/hour IV infusion.

Contraindications Severe bradycardia, heart block greater than first degree, cardiogenic shock, bronchial asthma, decompensated cardiac failure, conditions associated with severe and prolonged hypotension.
Cautions Liver damage.
Side effects Lichenoid rash, difficulty in micturition, epigastric pain, liver damage, nausea, postural hypotension, vomiting, weakness.
Hepatic impairment Avoid; severe hepatocellular injury reported.
Renal Impairment Dose reduction may be required.
Pregnancy category C
Breastfeeding Small amount excreted in milk, use with caution.
IV fluid compatibility Dextrose 5%, Dextrose 5% sodium chloride 0.9%, compound solution of sodium lactate, sodium chloride 0.9%.

NORADRENALINE

Injection 1mg /mL (1 mL) NRH/RRH/DH

Therapeutic group Vasopressor.
Indications and dose **Acute hypotension**, ADULT: 8-12 mcg/min by IV infusion, titrate to effect. Maintenance dose 2-4 mcg/min; CHILD: 0.05 – 0.1 mcg/kg, titrate to effect, MAX. 1 – 2 mcg/kg/min. **Cardiac arrest** ADULT, initial 8-12mcg/min by IV infusion, titrate to effect, Maintenance dose 2-4 mcg /min; CHILD; initial 0.05 – 0.1 mcg/kg, titrate to effect, max. 1 - 2 mcg/kg/min. **Sepsis and septic shock,** ADULT: 0.01-3 mcg/kg/min by IV infusion; CHILD: 0.05 – 0.1 mcg/kg by IV, titrate to effect, MAX. 1-2 mcg/kg/min.
Note *To be administered by using an infusion pump.*
Contraindications Hypertension, severe hyperthyroidism, Hypotension due to low volume deficit, Peripheral vascular thrombosis.
Cautions Coronary disease, coronary vascular thrombosis, diabetes, elderly, extravasation at injection site may cause necrosis, hypercapnia, hyperthyroidism, hypoxia, mesenteric vascular thrombosis, peripheral vascular thrombosis, Prinzmetal's variant angina, glaucoma, uncorrected hypovolaemia.
Side effects Angle-closure glaucoma, anorexia, anxiety, arrhythmias, bradycardia, confusion, dyspnoea. Headache, hypertension, hypoxia, insomnia, nausea, palpitation, peripheral ischaemia, psychosis, tachycardia, tremor, urinary retention, vomiting, weakness.
IV fluid compatibility Compatible with dextrose 5% in 0.9% normal saline, dextrose 5%, compound sodium lactate solution, normal saline.
Pregnancy category C
Breastfeeding Not known if excreted in breast milk, avoid use.

PHENYLEPHRINE

Injection, 10 mg/mL (1 mL) NRH/RRH

Therapeutic group Vasopressor.
Indications and dosage **Mild to moderate hypotension** ADULT, IV injection 0.1- 0.5 mg in every 15 minutes, not to exceed 0.5 mg/dose. SC/IM 2-5 mg every 1-2 hour if necessary, maintenance 1-10 mg. CHILD ≥ 2years, SC/IM injection 0.1 mg/kg in every 1-2 hour if necessary, maximum 5 mg/dose. **Severe hypotension or shock** ADULT, 0.1-0.5 mg/dose by IV bolus every 5-10minutes if necessary, not to exceed 0.5 mg. IV infusion , 0.1 to 0.18 mg/ minute, titrate to desired response, alternatively, 0.0005 mg/kg/min, titrate to desired response. CHILD ≥ 2years,IV injection, 0.005 - 0.02 mg/kg once, then 0.0001 – 0.0005 mg/kg/min, not to exceed 0.003-0.005 mg/kg/min.
Contraindications Severe hypertension, closed angle glaucoma, severe hyperthyroidism, ventricular tachycardia.
Caution Cerebrovascular insufficiency, hypertension, cardiovascular disorder; prostatic hypertrophy.
Side effects Hypertension, anxiety, headache, rebound congestion, bradycardia, palpitation, metabolic acidosis, decreased urine output.
Pregnancy category C
Breast-feeding Excreted in breast milk, however safe.

VASOPRESSIN

Injection, 20 IU/mL (1 mL) NRH/RRH/DH

Therapeutic group Vasopressor (Antidiuretic hormone).
Indications and dose **Pituitary diabetes insipidus** ADULT, 5–10 units every 8-12 hourly by IM/SC injection. CHILD, 2.5 -10 units every 8-12 hourly. **Esophageal variceal bleeding**: ADULT, 20 units IV injection to be administered over 15 minutes. CHILD, 0.3 units/kg (not to exceed 20 units). **Septic shock** ADULT, 0.01-0.04 unit/min IV infusion.
Contraindications Chronic nephritis, cardiac insufficiency.
Cautions Asthma, epilepsy, heart failure, hypertension and migraine.
Side effects Abdominal cramps, belching, desire to defecate, anginal attacks, peripheral ischemia, myocardial ischemia, constriction of coronary arteries, fluid retention, headache, nausea, pallor, sweating, tremor, vertigo, vomiting, Gangrene(rare).
Pregnancy category C
Breast-feeding unknown whether the medicine is distributed in breast milk, use with caution.

13. DERMATOLOGICAL MEDICINES (TOPICAL)

13.1 Antifungal medicines

MICONAZOLE

Cream 2% (15 g) NRH/RRH/DH/PHC

Therapeutic group Antifungal.
Indications and dose **Susceptible fungal infection of skin and mucous membrane** ADULT and CHILD, Apply Q12hr daily continuing for 10 days after lesions have healed; **Fungal nail infections** ADULT and CHILD Apply 12-24hr.
Cautions For topical use only, avoid contact with eyes.
Side effects Occasional irritation, burning, allergic dermatitis and maceration.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.
Counselling Treatment should be prolonged for 10 days after all lesions have disappeared to prevent relapse.

13.2 Anti-infective medicines

NITROFURAZONE

Cream, 0.2% (500 g) NRH/RRH/DH/PHC

Therapeutic group Antibacterial (topical).
Indications and dose **Superficial skin infections; Superficial burns** Topical application, Q6-8hr after cleaning the affected area.
Cautions Sensitization may occur if treatment exceeds 5 days.
Note *Regular soap and water washing, followed by exposure or dry dressing, will usually be adequate treatment for superficial infections.*

SILVER SULFADIAZINE

Cream, 1% (25 g) NRH/RRH/DH/PHC

Therapeutic group Antibacterial (topical).
Indications and dose **Skin infections, particularly gram-negative infection such as pseudomonas infection; Second- and third-degree burns; Infected leg ulcers; Pressure sores** Topical application, apply thin layer of ointment over infected or burn areas q12hr.
Contraindications Sulfa allergy, G6PD deficiency, premature infants or neonates <2 months of age.

Cautions If applied at large areas for long duration, risk of blood disorders and skin discoloration,hepatic and renal impairment, pregnancy and breastfeeding.
Side effects prolonged use leads to Itching, rash, erythema multiforme, discoloration of skin and photosensitivity.
Pregnancy category C; X (near term).
Breast-feeding Excretion in milk unknown, use with caution.
Counselling In burns, apply with sterile applicator, in leg ulcers apply at least 3 times a week.

13.3 Antiviral medicines

ACYCLOVIR

Eye Ointment, 3% (5 g) NRH/RRH

Therapeutic group Antiviral.
Indications and dose **Herpes simplex infection (local treatment)** ADULT and CHILD, apply to the skin 5 times a day for 5-10 days, to be applied to lesions approximately every 4 hours, starting at first sign of attack. **To the eye** ADULT and CHILD, Apply 1 centimetre 5 times a day continue for at least 3 days after complete healing.
Cautions Avoid cream coming in to contact with eyes and mucous membranes, not recommended for recurrent infections.
Side effects Drying of the skin, erythema, itching of the skin, transient burning, transient stinging, local inflammation, local irritation, superficial punctate keratopathy.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.

13.4 Anti-inflammatory and antipruritic medicines

BETAMETHASONE VALERATE

Cream, 0.1% (15 g) NRH/RRH

Therapeutic group Anti-inflammatory and antipruritic medicines (potent corticosteroid).
Indications and dose **Severe inflammatory skin disorders such as eczema unresponsive to less potent steroids; Psoriasis** ADULT and CHILD: topical application, apply thinly over affected areas 1-2 times daily for 1-2 weeks only
Contraindications Underlying infections present, ophthalmic use.
Cautions Avoid prolonged use in infants and children and on the face; Do not use this medication near the eyes if you have glaucoma; Use of more than 100 g per week of 0.1% preparation is likely to cause adrenal suppression.
Side effects Skin atrophy, dry skin, erythema folliculitis, acneiform lesion, burning, irritation, pigmentation changes, allergic dermatitis.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.
Counselling Advise patient not to use bandages, wraps, or other occlusive dressing over the treatment area; Discontinue use once psoriasis is controlled; Use beyond 2 weeks is not recommended.

CLOBETASOL PROPIONATE

Cream, 0.05% w/w (15 g) NRH/RRH

Therapeutic group Anti-inflammatory and antipruritic medicines (very potent corticosteroid).
Indications and dose **Short-term treatment only of severe resistant inflammatory skin disorders such as recalcitrant eczemas unresponsive to less potent corticosteroids; Psoriasis** ADULT, apply thinly to the skin, Q12-24hr x 4 weeks; MAX. 50g/week; CHILD, apply thinly to the skin, Q12-24hr x 4 weeks; **Moderate scalp psoriasis** ADULT: Apply thinly then rinsed off after 15 minutes; Q24hr x 4 weeks, frequency of application should be reduced after clinical improvement.
Contraindications Viral, fungal, tubercular skin lesions, ophthalmic use.

Cautions not more than 50g of preparation should be applied per week; discontinue use if irritation occurs; pregnancy and lactation; avoid contact with eyes.
Side effects skin atrophy, telangiectasia, burning, irritation, hypopigmentation, dry skin.
Pregnancy category C (use on smallest area of the skin and for shortest duration possible).
Breast-feeding Excretion in milk unknown; Use with caution (use on smallest area of the skin and for shortest duration possible).
Counselling Advise patients not to use bandages, wraps, or other occlusive dressing over the treatment area, discontinue use once psoriasis is controlled. Use beyond 2 weeks is not recommended. Wash hands after each application.

FLUTICASONE PROPIONATE

Cream, 0.05% (15 g) NRH/RRH/DH

Therapeutic group Anti-inflammatory and antipruritic.
Indications and dose **Inflammatory skin disorder like allergic reactions, eczema, psoriasis and severe atopic dermatitis in children not responding to 1% hydrocortisone and other topical corticosteroids cannot be used** ADULT and CHILD, Topical application, apply thinly over the affected area, Q12-24hr; reducing the frequency as the condition improves.
Contraindications: Rosacea, acne vulgaris, perioral dermatitis; primary cutaneous viral infections (e.g.: herpes simplex, chickenpox); perianal and genital pruritus; ulceration of the skin; atrophy of the skin; juvenile dermatosis; dermatoses in infants under 1 year of age, including dermatitis and napkin eruptions.
Side effects Pruritus, dryness, skin irritation, eczema, telangiectasia, numbness of fingers, burning, folliculitis, acneiform lesions, urticaria.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.

HYDROCORTISONE

Cream, 1% (15 g) NRH/RRH/DH/PHC

Therapeutic group Anti-inflammatory and antipruritic.
Indications and dose **Mild inflammatory skin disorders** ADULT and CHILD *Topical application*, apply thinly for 2-3 times daily, reducing the frequency as the condition improves; **Nappy rash** CHILD, apply as required for no more than 1 week, discontinued as soon as the inflammation subsides.
Contraindications Underlying infections, ophthalmic use, treatment of diaper dermatitis.
Cautions Chronic topical therapy, diabetes, cardiovascular disease, hepatic impairment, myocardial infarction, myasthenia gravis, osteoporosis, ocular disease, renal impairment or thyroid disease.
Side effects Skin atrophy, striae, acneiform lesion, perioral dermatitis, folliculitis, itching, pigmentation changes, HAP suppression.
Pregnancy category C (should not be used extensively, in large amounts, or for prolonged periods of time).
Breast-feeding Excretion in milk unknown, use with caution.
Note *Hydrocortisone has the few side effects of all topical steroid preparations, only if the lesion is unresponsive patients should be advised to use a stronger preparation.*

TRIAMCINOLONE ACETONIDE

Cream, 0.1%, (15 g) NRH/RRH/DH

Therapeutic group Anti-inflammatory and antipruritic (potent corticosteroid).
Indications and dose **Inflammatory dermatoses responsive to steroids** ADULT and CHILD *Topical application,* apply thinly over the affected area, Q8-12hr, reducing the frequency as the condition improves.
Contraindications Underlying fungal, bacterial, or viral infection, ophthalmic use**.**
Cautions Avoid large amounts or prolonged usage, occlusive dressings increase the risk of systemic absorption, do not use in patients with decreased skin circulation.

Side effects Skin atrophy, striae, acneiform lesion, pigmentation changes, HPA suppression.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.
Counselling Advise patients not to use bandages, wraps, or other occlusive dressing over the treatment area.

TRIAMCINOLONE ACETONIDE

Paste, 0.1% (5 g) NRH/RRH/DH

Therapeutic group Anti-inflammatory medicines used in treatment of oral ulcer (dental paste). *For details, refer to page no. 162.*

TACROLIMUS

Ointment, 0.1% (15 g) NRH

Therapeutic group Anti-inflammatory and antipruritic.
Indications and dose **Moderate to severe atopic dermatitis/eczema** (flares) second Line therapy ADULT and CHILD > 15 years: 0.1% ointment, apply thinly twice daily until lesion clears, reduce frequency to once daily, if condition improves. **Vitiligo** (off-label use) ADULT and CHILD > 15 years: 0.1% ointment apply thinly twice daily for 2-6 months.
Contraindications Children below 2 years of age, hypersensitivity, immunodeficiency, generalised erythroderma, congenital epidermal barrier defects, infection at the treatment site.
Cautions UV light, avoid excessive exposure to sunlight. Do not use with occlusive dressings.
Side effects Burning sensations, pruritus, skin erythema, flu-like symptoms, and headache.
Pregnancy category C
Breast-feeding Use with caution.
Counselling Apply a thin layer to affected skin, rub in gently and completely.

13.5 Scabicides and pediculicides

PERMETHRIN

Cream, 5% (60 g) NRH/RRH/DH/PHC

Therapeutic group Scabicides and pediculicide.
Indications and dose **Scabies** ADULT and CHILD >2 months, apply 5% cream to the entire body including face, neck, scalp, and ears; leave on for 8-14 hours then wash off. Repeat in 7 days if live mites reappear. **Crusted scabies** ADULT, Apply 5% cream to entire body from the neck down, then wash off after 8 to 14 hours; repeat daily for 7 days then twice weekly until cure; give in combination with ivermectin 200 mcg/kg orally on days 1, 2, 8, 9, and 15; consider additional ivermectin on days 22 and 29 for severe cases. CHILD <2 months, Safety and efficacy not established, Not recommended.
Contraindications Hypersensitivity to permethrin, children < 2 months.
Cautions Children aged 2 months -2 years; medical supervision required.
Side effects Erythema, pruritus, rash, stinging of skin and scalp irritation.
Pregnancy category B
Breast-feeding Use with caution.
Counselling Advise patients to avoid contact with body orifices and open wounds during application. Instruct patients to report if pruritus persists beyond 4 weeks.

14. DIAGNOSTIC AGENTS

14.1 Ophthalmic agents

FLUORESCEIN

Strips, 4% (100 strips/pkt) NRH/RRH/DH

Therapeutic group Diagnostic agent (ophthalmic).
Indications and dose **Eye examination (staining of anterior segment of the eye during eye examinations)** ADULT and CHILD, Moisten by applying 1-2 drops sterile water or other ophthalmic solution; ***Application*** While patient looks down, stroke applicator tip across bulbar conjunctiva for fornix; then have patient blink several time.
Contraindications Hypersensitivity to mercury-containing compounds.
Cautions History of allergies or asthma.
Side effects Skin discoloration.
Pregnancy category C
Breast-feeding Excreted in milk, compatible.
Note *Remove contact lens before use to avoid staining, after exam, flush eye with saline eye drops and wait at least 1 hr before reinserting contact lenses.*

TROPICAMIDE

Eye drop, 1% (5 mL) NRH/RRH

Therapeutic group Diagnostic agent (ophthalmic).
Indications and dose **Refractive procedure** ADULT and CHILD, instil 1-2 drops 1% soln. in eyes(s); repeat in 5 min, perform exam within 30 minutes of second instillation; **Fundus examination** ADULT and CHILD, Instil 1-2 drops 0.5% in the eye(s), 15-20 min prior to exam.
Contraindications Angle-closure glaucoma.
Cautions Hypertension, hyperthyroidism, diabetes.
Side effects Increased intraocular pressure, transient stinging, dry mouth, blurred vision, photophobia, headache, allergic reactions.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.
Counselling Do not drive or operate machinery for 1-2 hrs after mydriasis.

14.2 Radiocontrast media

BARIUM SULPHATE

Oral suspension, 95% w/v NRH/RRH/DH

Therapeutic group Radio-contrast media.
Indications and dose Radiography of GI tract as a suspension or paste by mouth or by enema.
Contraindications intestinal obstruction, intestinal perforation, or conditions with risk of perforation, high risk of aspiration.
Cautions Patient with bronchial asthma, cardiac disease, colostomy, constipation, cystic fibrosis, hypertension.
Side effects Cardiorespiratory arrest, edema, impaction of intestine, small bowel obstruction.

GADODIAMIDE

Injection, 0.5 mmol/mL (10 mL) NRH

Therapeutic group Radiocontrast media.
Indications and dose **CNS Imaging (MRI)** ADULT, 0.2 mL/kg (0.1 mmol/kg) as a *bolus IV injection*; CHILD (2-16 years), 0.2 mL/kg (0.1 mmol/kg) as a *bolus IV injection*; **Vascular Imaging (MRI): Imaging of kidney** ADULT, 0.1 mL/kg (0.05 mmol/kg) as an *IV bolus injection*; CHILD (2-16 years), 0.1 mL/kg (0.05 mmol/kg) administered as an *IV bolus injection;* **Imaging of intrathoracic (noncardiac), intra-abdominal, an pelvic cavities** ADULT, 0.2 mL/kg (0.1 mmol/kg) administered as a *bolus IV injection*; CHILD (2-16 years), 0.2 mL/kg (0.1 mmol/kg) administered as a bolus IV injection.
Note*:* Flush IV line with 5mL of sodium chloride 0.9% to ensure dose is completely administered; Complete the imaging procedure within 1 hour of administration.
Contraindications Acute kidney disease or chronic and severe renal impairment (GFR <30 mL/min); CHILD >2 years

Cautions Anaemia, hepatic and renal impairment; Not for intrathecal use.
Side effects Injection site reaction, vasodilation, dizziness, headache, nausea, anaphylactic reactions, nephrogenic systemic fibrosis.
Renal impairment Dose adjustment required.
Pregnancy category C
Breast-feeding Excretion in breast milk unknown, use with caution.

IODIXANOL

Injection, 320 mg/mL (100 mL) NRH/RRH/DH

Therapeutic group Radiocontrast media.
Indications and dose ***Intra-arterial (arteriography):*** **Carotid arteries** ADULT and CHILD (>12 years), 10-14 mL (not to exceed 175 mL; 80 g); **Vertebral arteries** ADULT and CHILD (>12 years), 10-12 mL(not to exceed 175 mL; 80 g); **Right coronary artery** ADULT and CHILD (>12 years), 3-8 mL(not to exceed 200 mL; 80 g); **Left coronary artery** ADULT and CHILD (>12 years), 3-10 mL (not to exceed 200 mL; 80 g); **Left ventricle** ADULT and CHILD (>12 years), 20-45 mL(not to exceed 200 mL; 80 g); **Aortography** ADULT and CHILD (>12 years), 30-70 mL(not to exceed 250 mL; 80 g); **Major aorta branch** ADULT and CHILD (>12 years), 10-70 mL(not to exceed 250 mL; 80 g); **Peripheral arteries** ADULT and CHILD (>12 years), 15-30mL(not to exceed 250 mL; 80 g); **Aortofermoral runoffs** ADULT and CHILD (>12 years), 20-90 mL (not to exceed 250 mL; 80 g); **Renal arteries** ADULT and CHILD (>12 years), 8-18 mL (not to exceed 250 mL; max. 80 g); ***Intra-arterial digital subtraction angiography (IA-DSA)*** **Carotid or vertebral arteries** ADULT and CHILD (>12 years), 5-8 mL (not to exceed 175 mL; 80 g); **Aortography** ADULT and CHILD (>12 years), 10-50 mL (not to exceed 250 mL; 80 g); **Major aorta branch** ADULT and CHILD (>12 years), 2-10 mL (not to exceed 250 mL; 80 g), **Aortofemoral runoffs** ADULT and CHILD (>12 years), 6-15 mL (not to exceed 250 mL; 80 g); **Peripheral arteries** ADULT and CHILD (>12 years), 3-15 mL (not to exceed 250 mL; 80 g); ***IV Administration*** **CECT of head or body** ADULT and CHILD (>12 years), 75-150 mL *bolus IV*, then 100-150 mL *infusion* not to exceed 150 mL; **Excretory urography** ADULT and CHILD (>12 years), 1 mL/kg, not to exceed 100 mL; **Venography** ADULT and CHILD (>12 years), 50-150 mL per lower extremity (not to exceed 250 mL; 80 g);
CHILD (1-12 years) for all studies, 1-2 mL/kg; not to exceed 4 mL/kg.
Contraindications Intrathecal use; In children with prolonged fasting and use of laxative before administration.
Cautions Maintain adequate hydration, renal/hepatic impairment, cardiovascular disease, multiple myeloma, pheochromocytoma, sickle cell disease, elderly patients, thyroid dysfunction.
Side effects Discomfort at injection site, angina pectoris, chest pain, headache, migraine, vertigo, paraesthesia, pruritus, skin rash, erythema, dysgeusia.
Pregnancy category B
Breast-feeding Poorly excreted in milk, interrupt Breast-feeding and milk for 10 hr after administration.

IOHEXOL

Injection, 300 mg (50 mL) NRH/RRH
Injection, 350 mg (100 mL) NRH/RRH

Therapeutic group Radiocontrast media.
Indications and dose **Myelography, urography, arthrography and for visualisation of GI tract and body cavities** Route and dose depends on the procedure; administered only by radiologist.
Contraindications Significant bacterial infection; Do not immediately repeat myelography.
Cautions Severe renal impairment, combined renal/hepatic disease, severe thyrotoxicosis, multiple myeloma, anuria, pheochromocytoma, congestive heart failure, severe arterial/venous disease; dehydration (correct fluid and electrolyte balance before administration), allergies.
Side effects Nausea, vomiting, metallic taste, flushing, sensation of heat, weakness, headache, coughing, rhinitis, angina pectoris, cardiac arrest, thromboembolic disorder, nephrotoxicity.
Renal impairment Use with caution/dose need to be adjusted.
Pregnancy category B
Breast-feeding Excreted in small amounts in milk, use with caution.

Counselling Advice patient to maintain adequate hydration after injection is administered.

SODIUM AMIDOTRIAZOATE + MEGLUMIN AMIDOTRIAZOATE

Solutions, 10:60 (150 mL) NRH

Therapeutic group Radiocontrast media.
Indications and dose **Urography, venography, operative cholangiography, splenoportography, arthrography, discography; computer assisted axial tomography** ADULT and CHILD, route and dosage depend on procedure and preparation used (consult manufacturer's literature); **Radiographic exam of GI tract segments** ADULT, 30-90 mL PO, CHILD (<5 years), 30 mL PO (dilute 1:1, if <10 kg OR if debilitated, dilute 1:3), CHILD (5-10 years) 60 mL PO (dilute 1:1, if <10 kg OR if debilitated, dilute 1:3) **Tomography** ADULT 25-77 mL in 1000 mL tap water PO, 15-30 minutes prior to imaging.
Contraindications Hypersensitivity to iodine-containing compounds.
Cautions Electrolyte imbalance, history of iodine hypersensitivity, esophagotracheal fistula.
Side effects Nausea, vomiting, diarrhoea, metallic taste, flushing, sensations of heat, weakness, dizziness, headache, coughing, rhinitis, sweating, sneezing, lacrimation, visual disturbances, pruritus, salivary gland enlargement, pallor, cardiac disorders, hemodynamic disturbances and hypotension, disseminated intravascular coagulation, fibrinolysis and depression of blood coagulation factors.
Pregnancy category B
Breast-feeding Excreted in milk, use with caution.
Note *Administration, only by radiologists, according to manufacturer's literature.*

15. DIURETICS

FUROSEMIDE

Injection, 10 mg/mL (2 mL) NRH/RRH/DH
Tablet, 40 mg NRH/RRH/DH

Therapeutic group Diuretics (Loop).
Indications and dose **Oedema** ADULT, Initially 40 mg PO, Q24hr; **maintenance** 20-40 mg, Q24hr; **IM or IV injection or IV infusion** ADULT, Initially 20-50 mg, then increased in steps of 20 mg, Q2hr if required; CHILD and INFANT, 1-2 mg/kg IM or IV injection or PO, Q24hr initially; increased by 1-2 mg/kg PO, Q6-8hr or 1 mg/kg IM/IV injection, Q2hr; individual dose not to exceed 6 mg/kg; **Resistant oedema** ADULT: 80-120 mg PO, Q24hr ; Initially 20-50 mg IM or IV injection or IV infusion, then increased in steps of 20 mg, Q2hr if required; **Resistant hypertension** ADULT, 40-80 mg PO, Q24hr; Initially 20-50 mg IM or IV injection or IV infusion, then increased in steps of 20 mg, Q2hr if required; Doses greater than 50 mg given by IV infusion only; MAX. 1.5 g/day; CHILD (1-17 years), 0.5-2 mg/kg PO Q24hr or Q12hr; individual dose not to exceed 6 mg/kg/dose; **Oliguria** CHILD (12-17 years), Initially 250 mg PO, Q24hr, then increased in steps of 250 mg, Q4-6hr (MAX. dose 2 g) if required; **IV infusion** CHILD (1 month-11 years), 2-5 mg/kg, Q6hr; MAX. 1 g/day; CHILD (12-17 years), Initially 250 mg, administered over 1 hr; increased to 500 mg administered over 2 hrs, if satisfactory urine output not obtained; then increased to 1 g administered over 4 hrs, if satisfactory response not obtained within subsequent hour; If no response obtained dialysis probably required; effective dose of up to 1 g given at a maximum rate of 4 mg/minute can be repeated Q24hrs.
Contraindications Anuria, renal failure due to nephrotoxic or hepatotoxic medicines, severe hypokalemia, severe hyponatremia.
Cautions Children with obstruction of urinary outflow, diabetes, gout; comatose and pre comatose states associated with liver cirrhosis, hypotension, hypovolemia.
Side effects Hyperuricemia, hypokalemia, acute urinary retention, blood disorders, bone-marrow depression, electrolyte disturbances, hepatic encephalopathy, hyperglycemia, hypochloremia, hypomagnesaemia hyponatraemia, increased calcium excretion, leukopenia, metabolic alkalosis, mild GI disturbances, pancreatitis, postural hypotension, rash.
Hepatic impairment Use with caution when used in high dose.
Renal impairment 1-3 g/day in acute impairment.

Pregnancy Category C
Breastfeeding Excreted in milk, use with caution.
Counselling Take this medicine regularly in the morning, add potassium chloride tablets on prolonged treatment.

HYDROCHLOROTHIAZIDE

Tablet, 25 mg NRH/RRH/DH/PHC

Therapeutic group Diuretic.
Indications and dose **Hypertension** ADULTS, 12.5-50 mg PO, Q24hr initially and increase to 50 mg daily if required; CHILD (<6 months), 1-3 mg/kg/day PO, Q12hr; not to exceed 37.5 mg/day; CHILD (6 months – years): 1-2 mg/kg/day PO, Q24hr or Q12hr; CHILD (2-12 years): 1-3 mg/kg/day; **Oedema** ADULT, 25-100 mg PO, Q12-24hr; not to exceed 200 mg/day; CHILD (<6 months), 1-3 mg/kg/day PO, Q12hr; CHILD (6 months – years): 1-3 mg/kg/day PO, Q24hr or Q12hr; CHILD (2-12 years): 1-3 mg/kg/day; **Hypertension and Mild fluid retention in heart failure** 25mg PO, Q12-24hr; MAX. ADULT, 200 mg/day; CHILD (<6 months-2 years) 37.5 mg/day; CHILD (2-12 years), 3 mg/kg/day (100 mg/day).
Contraindications Severe renal or severe hepatic impairment; hyponatremia, hypercalcemia, refractory hypokalemia, symptomatic hyperuricemia, Addison disease.
Cautions Gout, diabetes, fluid and electrolyte imbalance, hypercholesterolemia, systemic lupus erythematosus, hypercalcemia, hypotension, liver or renal disease, hypokalemia, parathyroid disease.
Side effects GI disturbances, water and electrolyte disturbances, hyperglycemia, hyperuricemia, dizziness, epigastric distress, fatigue, headache, hypotension, muscle weakness, rash, vertigo.
Renal impairment CrCl <10 mL/min: Avoid use; CrCl ≥10 mL/min, dose adjustment not necessary.
Pregnancy category B
Breast-feeding Excreted in milk, use with caution.
Counselling Take this medicine in the morning regularly as instructed.

MANNITOL

Injection, 20% (350 mL) NRH/RRH

Therapeutic group Diuretic (Osmotic).
Indications and dose **Forced diuresis in impending renal failure** ADULT, 1 mL/kg IV infusion over 5 minutes and repeated after 2-3 hours; if no response, reassess the patient; if urine flow does increase, 250-500 mL over 5 minutes. **Emergency reduction of intracranial pressure, cerebral oedema, and intraocular pressure** ADULT and CHILD (12 years and above), 0.25-2 g/kg IV infusion administered over 30-60 minutes, if necessary, dose may be repeated 1-2 times after 4-8 hours; CHILD (1 month-11 years), 0.25-1.5 g/kg IV infusion administered over 30–60 minutes, if necessary, may be repeated 1-2 times after 4-8 hours.
Contraindications Established anuria from severe renal disease; congestive cardiac failure; severe dehydration; active intracranial bleeding; pulmonary oedema.
Cautions Do not give simultaneously with blood.
Side effects Fluid and electrolyte imbalance associated with fluid retention or fluid depletion; occasional idiosyncratic reactions, hypotension, thrombophlebitis; arrhythmia, blurred vision, chest pain, chills, convulsions, cramp, dehydration, dizziness, dry mouth, fever, focal osmotic nephrosis, headache.
Renal impairment Use with caution in severe impairment.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.
Note If crystals are found in the bottle, warm gently to dissolve before use.

SPIRONOLACTONE

Tablet, 25 mg NRH/RRH/DH

Therapeutic group Diuretic (potassium sparing).

Indications and dose **Oedema; Ascites in cirrhosis of the liver** ADULT, 100-400 mg PO, Q24hr, adjusted according to response; **Malignant ascites** ADULT, Initially 100-200 mg PO, Q24hr, then increased if necessary to 400 mg Q24hr, maintenance dose adjusted according to response; **Nephrotic syndrome** ADULT, 100-200 mg PO, Q24hr; **Oedema in congestive heart failure** ADULT, Initially 100 mg PO, Q24hr, alternatively initially 25-200 mg/kg PO, dose may be taken as a single dose or divided doses, maintenance dose adjusted according to response; **Moderate to severe heart failure (adjunct)** ADULT, Initially 25 mg PO, Q24hr, then adjusted according to response to 50 mg, Q24hr; **Resistant hypertension (adjunct)** ADULT, 25mg PO, Q24hr; **Primary hyperaldosteronism in patients awaiting surgery** ADULT,100-400mg PO, Q24hr, may be used for long-term maintenance if surgery inappropriate, use lowest effective dose; CHILD (1 month-11 years), Initially 1-3 mg/kg PO, Q12-24hr; increased if necessary up to 9 mg/kg/day, in resistant ascites; CHILD (12-17 years), Initially 50-100 mg/day, Q12-24hr; increased if necessary up to 9 mg/kg/day, in resistant ascites; MAX. 400 mg/day.
Contraindications Hyperkalemia, anuria, Addison's disease.
Cautions Elderly patients, acute porphyria.
Side effects Acute renal failure, agranulocytosis, alopecia, breast pain, changes in libido, dizziness, drowsiness, electrolyte disturbances, GI disturbances, gynecomastia, hepatotoxicity, hyperkalemia (discontinue), hypertrichosis, hyperuricemia, hyponatremia, leg cramps, leukopenia, malaise, menstrual disturbances, rash, Stevens-Johnson syndrome, thrombocytopenia.
Renal impairment CrCl >50 mL/min: 25 mg/Q24hr; CrCl 30-50 mL/min: 25 mg/Q 48 Hr.
Pregnancy category C
Breast-feeding Metabolite excreted in milk, use with caution.
Note For hypertension, doses >75 mg/day may not provide additional reductions in blood pressure.

VASOPRESSIN

Injection, 20 IU/mL (1 mL) NRH/RRH/DH

Therapeutic Group Vasopressor (Antidiuretic hormone).
Indications and Dose **Pituitary diabetes insipidus**, by IM/SC inj. ADULT 5–10 units every 8-12 hour; CHILD 2.5 -10 units every 8-12 hours. *For details, refer to page no. 104.*

16. GASTROINTESTINAL MEDICINES

16.1 Antacids

ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE

Tablet, 250 mg + 400 mg NRH/RRH/DH/PHC

Therapeutic group Antacid.
Indications and Dose **Dyspepsia and gastro-oesophageal reflux disease** ADULT, 1-2 tablets chewed, Q6-8 hr; CHILD (6-12 years), 10mL PO, Q6-8hr.
Contraindications Hypophosphatemia, undiagnosed GI or rectal bleeding, appendicitis, porphyria.
Cautions Impaired renal function and renal dialysis, hepatic impairment, constipation, dehydration, fluid restriction, GI disorders associated with decreased bowel motility or obstruction.
Side effects Constipation, intestinal obstruction (with large doses), hypophosphatemia with increased bone resorption, hypercalciuria, and increased risk of osteomalacia (more common in patients on a low phosphate diet or on prolonged therapy), hyperalbuminemia resulting in osteomalacia, encephalopathy, dementia, and microcytic anaemia (in chronic renal failure treated with aluminium hydroxide as phosphate binding agent).
Hepatic impairment Avoid in severe impairment.
Renal impairment Avoid in severe impairment.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.
Counselling Do not take other medicines within 2-4 hours of aluminium hydroxide preparations. May be taken with water to reduce constipating effects.

16.2 Antiemetic medicines

DEXAMETHASONE

Injection, 4 mg/mL (2mL) NRH/RRH/DH/PHC
Tablet, 4 mg NRH/RRH

Therapeutic group Antiemetic (corticosteroid).
Indications and Dose **Chemotherapy-Induced Nausea & Vomiting:** 8-12 mg PO/IV alone or in combination with other antiemetics before chemotherapy, then 8 mg PO/IV Q24hr for 1-3 days after chemotherapy (days 2-4), titrate according to the response. *For details, refer to page no. 24.*

METOCLOPRAMIDE

Injection, 5 mg/mL (2 mL) NRH/RRH/DH/PHC
Tablet, 10 mg NRH/RRH/DH/PHC

Therapeutic group Antiemetic.
Indications and Dose **Symptomatic treatment of nausea and vomiting including that associated with acute migraine; Delayed (but not acute) chemotherapy-induced nausea and vomiting; Radiotherapy-induced nausea and vomiting; Prevention of postoperative nausea and vomiting** ADULT (body-weight up to 60 kg), Up to 500 mcg/kg slow IV injection, Q8hr, administered over at least 3 minutes; ADULT (body-weight 60 kg and above), 10mg slow IV injection, Q8hr administered over at least 3 minutes; **Second-line option for treatment of established postoperative nausea and vomiting; Prevention of delayed chemotherapy-induced nausea and vomiting** CHILD, 100-150 mcg/kg slow IV injection, Q8hr (MAX.10 mg/dose), administered over at least 3 minutes; **Hiccup in palliative care** ADULT, 10 mg PO, Q6-8hr; **Nausea and vomiting in palliative care** ADULT, 10 mg PO, Q8hr; ***SC infusion*** ADULT, 30-100 mg SC infusion, Q24hr; *MAX. 500 mcg/kg/day; Metoclopramide should only be prescribed for short term use (up to 5 days).*
Contraindications 3-4 days after GI surgery, GI haemorrhage, obstruction and perforation, pheochromocytoma.
Cautions Asthma, atopic allergy, bradycardia, cardiac conduction disturbances, children, elderly, epilepsy, may mask underlying disorders such as cerebral irritation, Parkinson's disease, uncorrected electrolyte imbalance, young adults (15-19 years old), hypertension.
Side effects Extrapyramidal effects (especially in children and young adults (15-19 years old)), galactorrhea, gynecomastia, hyperprolactinemia, menstrual changes; depression, methemoglobinemia (more severe in G6PD deficiency), neuroleptic malignant syndrome.
Hepatic impairment Reduce dose.
Renal impairment Avoid or use small doses in severe impairment, increased risk of extrapyramidal reactions.
Pregnancy category B
Breast-feeding Excreted in milk, avoid.
IV fluid compatibility Sodium chloride 0.9%.

ONDANSETRON

Injection, 2 mg/mL (4 mL) NRH/RRH
Tablet, 4 mg NRH/RRH

Therapeutic group Antiemetic.
Indications and Dose **Moderately emetogenic chemotherapy or radiotherapy** ADULT, Initially 8 mg PO, 1-2 hours before treatment, then 8 mg, Q12hr x 5 days; **Initially by IM injection, or slow IV injection** ADULT, Initially 8 mg IM or IV injection, immediately before treatment, then 8 mg PO, Q12hr x 5 days; ELDERLY, 8 mg IM or IV injection administered immediately before treatment, IV infusion to be given over at least 15 minutes, then 8 mg PO, Q12hr x 5 days; **Severely emetogenic chemotherapy** ADULT, 24 mg PO, 1-2 hours before treatment, then 8 mg, Q12hr x 5 days; **Initially by IM injection, or slow IV injection** ADULT, Initially 8 mg IM or IV injection, immediately before treatment, followed by 1 mg/hour continuous IV infusion for up to 24 hours, then 8 mg PO, Q12hr x 5 days; **Prevention and treatment of chemotherapy and radiotherapy-induced nausea and vomiting: Initial dose** CHILD (6 months - 17 years), 150 mcg/kg IV infusion (MAX. 8 mg/dose), immediately before chemotherapy, then 150 mcg/kg, Q4hr for

2 further doses then orally; MAX. 32 mg/day; **Prevention and treatment of chemotherapy and radiotherapy induced nausea and vomiting (follow on dose based on body weight)** (dose started 12 hours after IV administration) CHILD (6 months - 17 years), Body weight up to 10.1kg*:* 2 mg PO, Q12hr x 5 days; MAX. 32 mg/day; Body weight 10.1-40 kg: 4 mg PO, Q12hr x 5 days; MAX. 32 mg/day; Body weight 41 kg and above: 8 mg PO, Q12hr x 5 days; MAX. 32 mg/day; **Prevention of postoperative nausea and vomiting** ADULT, 16 mg PO, 1 hour before anesthesia; CHILD, 100 mcg/kg slow IV injection (MAX. 4 mg/dose) STAT given over at least 30 seconds before, during, or after induction of anesthesia; **Treatment of postoperative nausea and vomiting** ADULT, 4 mg IM injection, or slow IV injection, STAT; CHILD, 100 mcg/kg slow IV Injection (MAX. 4 mg/dose) STAT given over at least 30 seconds.
Contraindications Congenital long QT syndrome.
Cautions Severe hepatic impairment, adenotonsillar surgery, subacute intestinal obstruction, susceptibility to QT-interval prolongation (including electrolyte disturbances).
Side effects Constipation, flushing, headache, injection site-reactions; arrhythmias, bradycardia, chest pain, hiccups, hypotension, movement disorders, seizures.
Pregnancy category B
Breast-feeding Excretion in milk unknown, use with caution.
Hepatic impairment MAX 8 mg/day in moderate or severe impairment.

PROMETHAZINE

Injection, 25 mg/mL (2 mL) NRH/RRH/DH/PHC
Tablet, 10 mg NRH/RRH/DH/PHC

Therapeutic group Antiemetic.
Indications and Dose **Nausea, Vomiting, Vertigo, Labyrinthine disorders and Motion sickness** ADULT, 20-25 mg PO, CHILD (2-4 years), 5mg PO, CHILD (5-9 years): 10mg PO; CHILD (10-17 years), 20-25 mg PO; *For motion sickness, the dose should be taken at bedtime on night before travel, repeat following morning if necessary*.
For details, refer to page no. 25.

16.3 Antifoaming agent

SIMETHICONE

Oral drop, 100 mg/mL (30 mL) NRH/RRH/DH

Therapeutic group Anti-flatulence.
Indications and dose **Postoperative gas pain or for use in endoscopic examination** ADULT and CHILD more > 12 years, PO 40-360 mg after meals and at bedtime, as needed. Infants and Children <2 years or <11 kg, 20 mg 4 times/day, as needed. Children >2 years or >11 kg, 40 mg 4 times/day, as needed.
Contraindications Hypersensitivity to simethicone or any component of the formulation.
Cautions Can cause false negative guaiac tests.
Side Effects Diarrhoea, nausea, regurgitation, vomiting.
Pregnancy Category C.
Breastfeeding Not absorbed systemically, not expected to be excreted in breast milk.
Counselling Advise patients that medicine will work best when used after meals and at bedtime.

16.4 Anti-hemorrhoidal

ANTI-HAEMORRHOIDAL

Ointment with applicator, (15 g) NRH/RRH/DH/PHC

Therapeutic group Anti-hemorrhoid.
Indications and Dose **Symptomatic relief of first-degree haemorrhoids and *pruritus ani*** Apply *to* rectum, Q12hr and apply after a bowel movement; not more than 7 days.
Contraindications Systemic fungal infections.

Cautions Local anaesthetic components can be absorbed through the rectal mucosa; local anaesthetic components may cause hypersensitivity.
Counselling Apply the ointment as instructed, externally to the anus or rectum using the nozzle.

16.5 Antispasmodic

ATROPINE SULPHATE

Injection,1 mg/mL (1 mL) NRH/RRH/DH/PHC

Therapeutic group antispasmodic Antispasmodic (antimuscarinic).
Indications and Dose **Spasmolytic**: by IM injection, 1 mg with appropriate analgesia. *For details, refer to page no. 14.*

DICYCLOMINE

Injection, 10 mg/mL (2 mL) NRH/RRH/DH
Tablet, 10 mg NRH/RRH/DH/PHC

Therapeutic group Antispasmodic.
Indications and dose **Symptomatic relief of GI disorders characterised by smooth muscle spasm** ADULT, 10-20 mg PO, Q8hr; MAX. 80 mg/day, CHILD (6-23 months), 5-10 mg PO, Q6-8hr, dose to be taken 15 minutes before feeds; CHILD (2-11 years): 10 mg PO, Q8hr; CHILD (12-17 years): 10-20mg PO, Q8hr; MAX. 60 mg/day; **IM injection** ADULT: 20 mg IM, Q4-6hr as required; CHILD (over 2 years): 10 mg, Q6hr.
Contraindications Closed-angle glaucoma, GI obstruction, children below 6 months of age, urinary retention, intestinal atony, myasthenia gravis, unstable CVS, reflux esophagitis, IV use.
Cautions Hepatic or renal impairment, benign prostatic hyperplasia, autonomic neuropathy, infants, elderly, pregnancy, congestive heart failure.
Side effects Dizziness, xerostomia, blurred vision, somnolence, nervousness, and weakness.
Pregnancy-category B
Breast-feeding Excreted in milk, avoid.
Counselling Take 30 minutes before a meal.
Note *IM should not be used more than 1-2 days, replace IM with PO as soon as possible.*

16.6 Antiulcer medicines and medicines used in variceal bleeding

OMEPRAZOLE

Capsule, 20 mg NRH/RRH/DH
Injection, 40 mg/mL NRH/RRH

Therapeutic group Antiulcer.
Indications and dose **Helicobacter pylori eradication in combination with clarithromycin and metronidazole** ADULT: 20 mg PO, Q12hr; CHILD (12-17 years): 40 mg PO, Q24hr; **Gastric ulcer** ADULT: 20 mg PO, Q24hr x 8 weeks; **Duodenal ulcer** ADULT: 20 mg PO, Q24hr x 4 weeks; **Prophylaxis in patients with a history of NSAIM-associated duodenal, gastric, gastroduodenal lesions and dyspeptic symptoms who require continued NSAIM treatment** ADULT: 20 mg PO, Q24hr; **Zollinger-Ellison syndrome** ADULT: Initially 60 mg PO or IV injection or IV infusion, Q24hr; up to 120 mg/day (if dose>80 mg (PO) and >60 mg (IV), divide it); CHILD (2-17 years): 10-20 mg PO, Q24hr; **Gastro-esophageal reflux disease** ADULT: 20 mg PO, Q24hr x 4 weeks, continued for a further 4-8 weeks if not fully healed; CHILD (2-17 years): 10-20 mg PO, Q24hr; **Acid-related dyspepsia** ADULT: 20 mg PO, Q24hr x 2-4 weeks according to response; CHILD (2-17 years): 10-20 mg PO, Q24hr ; **IV injection or IV infusion (for all conditions)** ADULT: 40 mg, Q24hr; CHILD (1 month-11 years): Initially 0.5 mg/kg, Q24hr (MAX. 20 mg/dose), increased if necessary to 2 mg/kg, Q24hr (MAX. 40 mg/dose); CHILD (12-17 years): 40 mg, Q24hr.
Note *IV injections to be given over 5 minutes and infusion over 20-30 minutes.*
Cautions Liver disease.
Side effects Headache, abdominal pain, GI disturbance (diarrhoea, nausea, vomiting, constipation), dizziness, rash, cough.

Hepatic impairment Dose reduction in severe impairment.
Renal impairment Dose adjustment not necessary.
Pregnancy category C
Breast-feeding May be excreted in milk, avoid.
Counselling The medicine should be taken before food.

RANITIDINE

Injection, 25 mg/mL (2 mL) NRH/RRH/DH
Tablet, 150 mg NRH/RRH/DH/PHC

Therapeutic group Antiulcer.
Indications and dose **Benign gastric ulcer; Duodenal ulcer** ADULT and CHILD (over 12 years): 150 mg PO, Q12hr x 4-8 weeks; CHILD (3-11 years): 2-4 mg/kg PO, Q12hr (MAX. 150 mg/dose); **Chronic episodic dyspepsia** ADULT: 150 mg PO, Q12hr x 6 weeks; **Prophylaxis of NSAIM-associated gastric and duodenal ulcer** ADULT: 300 mg PO, Q24hr; **Gastro-esophageal reflux disease** ADULT: 150 mg PO, Q12hr x 8 weeks or if necessary 12 weeks; 50mg IM or IV injection, Q6-8hr; **Prophylaxis of acid aspiration in obstetrics** ADULT: 150 mg PO given at onset of labour, then 150 mg, Q6hr; **Prophylaxis of acid aspiration in surgical procedures** ADULT: 50 mg IM or IV injection given 45-60 minutes before induction of anaesthesia; OR 150mg PO given 2 hours before induction of anaesthesia and also when possible on the preceding evening; **Stress ulceration** ADULT: 50 mg slow IV injection, Q8hr, then 150mg PO, Q12hr; CHILD (12-17 years): 50 mg IV injection, Q8hr, then 150mg PO, Q12hr; **Reflux esophagitis and other conditions where gastric acid reduction is beneficial** ADULT and CHILD (12-17 years): 150mg PO, Q12hr, then increased if necessary to 300 mg, Q12hr x 12 weeks in moderate to severe gastro-esophageal reflux disease; , CHILD (6 months-11 years): 2-4 mg/kg PO, Q12hr; **Conditions where reduction of gastric acidity is beneficial and oral route not available** ADULT: 50mg IM or slow IV injection, Q6-8hr.
Note For IV injection, dose to be diluted to 20mL and given over at least 2 minutes.
Cautions Signs and symptoms of gastric cancer (in adults)**,** renal and hepatic impairment, acute porphyria.
Side effects Headache, abdominal pain, agitation, reversible confusion states, nausea and vomiting, diarrhoea.
Hepatic impairment Dose adjustment not necessary.
Renal impairment CrCl < 50 mL/min: 50mg IV or IM, Q18-24 hr or 150mg PO, Q24hr.
Pregnancy category B
Breast-feeding Excreted in milk, use with caution.

OCTREOTIDE

Injection 50 mcg/mL (1 mL) NRH/RRH

Therapeutic group Somatostatin analogue.
Indications and dose **Oesophageal varices bleeding**, By IV injection, ADULT: IV bolus 25-50 mcg followed by continuous IV infusion of 25-50 mcg/hour. **Acromegaly**, By SC/IV injection, ADULT: initially 50 mcg 3 times a day. Titrate to achieve growth hormone levels <5 ng/mL, usual effective dose 100-200 mcg 3 times/day.
Complications following pancreatic surgery, By SC inj. ADULT: 100 mcg 3 times daily for 7 consecutive days, starting on the day of surgery at least 1 hour before laparotomy.
Cautions Cholelithiasis, pancreatitis, hypothyroidism, cardiovascular diseases, diabetes and excessive fluid loss.
Side Effects Colitis, pancreatitis, alopecia, arrhythmia, bradycardia, dehydration, dizziness, dyspnoea, headache, hepatitis, rash.
Hepatic impairment Adjustment of maintenance dose may be necessary in patients with liver cirrhosis.
Pregnancy Category B
Breastfeeding Excretion in breast milk unknown, use with caution.
IV fluid compatibility Stable in dextrose 5%, sodium chloride 0.9%.

VASOPRESSIN

Injection, 20 IU/mL (1mL) NRH/RRH/DH

Therapeutic group Vasopressor (Antidiuretic hormone).
Indications and dose **Esophageal variceal bleeding**: IV inj. ADULT: 20 units to be administered over 15 minutes; CHILD: 0.3 units/kg (not to exceed 20 units), **Septic shock**: ADULT: 0.01-0.04 unit/min IV infusion.
For details, refer to page no. 104.

16.7 Laxatives

GLYCERINE

Suppositories (4 g) NRH/RRH/DH

Therapeutic group Laxative.
Indications and dose **Constipation** ADULT: 4 g as required; CHILD (1-11 months): 1 g as required; CHILD (1-11 years): 2 g as required; CHILD (12-17 years): 4 g as required.
Contraindications Intestinal obstruction.
Cautions Moisten suppositories with water before insertion.

LACTULOSE

Solution, 10 mg/15 mL (100 mL) NRH/RRH/DH

Therapeutic group Laxative.
Indications and dose **Constipation** ADULT: Initially 15-20 mL PO, Q12hr, adjusted according to response; CHILD (1-11 months): 2.5 mL PO, Q12hr, adjusted according to response; CHILD (1-4 years): 2.5-10mL PO, Q12hr, adjusted according to response; CHILD (5-17 years): 5-20 mL PO, Q12hr, adjusted according to response; **Hepatic encephalopathy (portal systemic encephalopathy)** ADULT: Adjusted according to response to 30-50 mL PO, Q8hr, subsequently adjusted to produce 2-3 soft stools per day; CHILD (12-17 years): Adjusted according to response to 30-50mL PO, Q8hr, subsequently adjusted to produce 2–3 soft stools per day.
Contraindications Galactosaemia, intestinal obstruction.
Cautions Lactose intolerance, diabetes, electrolytes abnormalities.
Side effects Dehydration, diarrhoea, excessive bowel activity, nausea and vomiting, abdominal cramps and distension.
Pregnancy category B
Breast-feeding Excretion in milk unknown, use with caution.
Note *Lactulose may take up to 48 hours to act.*

SENNA

Tablet, 15 mg NRH/RRH/DH/PHC

Therapeutic group Laxative.
Indications and dose **Constipation** ADULT and CHILD (6-17 years): 15-30 mg PO, Q24hr usually taken at night; initial dose should be low then gradually increased; **Bowel preparation** ADULT: 130 mg PO between 2;00 and 4:00 PM in afternoon of day before procedure.
Contraindications GI obstruction; appendicitis, faecal impaction, GI or rectal bleeding, children under 6 years of age.
Cautions Should not be used more than 7 days, undiagnosed abdominal pains, nausea, vomiting.
Side effects Abdominal spasm, diarrhoea, electrolyte imbalance, excessive bowel activity, nausea, discoloration of urine.
Pregnancy category C
Breast-feeding Not excreted in milk, compatible.
Note *Senna tablet is not recommended for children under 6 years of age.*

16.8 Medicines used in diarrhoea

16.8.1 Oral Rehydration

ORAL REHYDRATION SALT (ORS)

Powder for reconstitution (1 g) NRH/RRH/DH/PHC

Therapeutic group Medicine used in diarrhoea.
Indications and dose **Prevention and treatment of dehydration**, according to fluid loss, usually 200-400 mL solution after every loose motion; **Moderate dehydration**: by oral administration, INFANT (up to 4 months): 200-400 mL; INFANT (4 months -12 months): 400-700 mL; CHILD (12 months up to 2 years): 700-900 mL; CHILD (2 years-5 years): 900-1400 mL; **Severe dehydration**, *By IV injection*, 100mL/kg compound solution of sodium lactate (or, sodium chloride 0.9%), divided as follows: INFANT (<12 months): 30mL/kg in the 1st hour and 70mL/kg from the 5th hour; CHILD (12 months-5 years): 30mL/kg in the first ½ hour and 70mL/kg from 2 ½ hours; repeat once if radial pulse is still very weak or not detectable; reassess the child every 1-2 hours; if hydration status is not improving, give the IV drip more rapidly; also administer ORS (about 5mL/kg/hour) as soon as the child can drink; usually after 3-4 hours (infants) and 1-2 hours (children); reassess an infant after 6 hours and a child after 3 hours.
Cautions Renal impairment; always assess dehydration; ask about blood in the stool; check for pyrexia and severe malnutrition.
Counselling Advice patient or caregiver to dissolve 1 packet in a litre of boiled and cooled water and take small sips throughout the day; if you cannot consume the solution in 24 hour discard it and prepare a fresh one.

16.8.2 Medicines for diarrhoea

CODEINE PHOSPHATE

Tablet, 15 mg NRH/RRH/DH

Therapeutic group Anti-diarrheal.
Indications and dose **Acute diarrhoea,** ADULT: 30 mg PO, 3-4 times a day; usual dose 15-60 mg, 3-4 times a day; CHILD (12-17 years): 30 mg, 3-4 times a day; usual dose 15-60 mg, 3-4 times a day. *For details, refer to page no. 20.*
Note *Do not use codeine in children under 12 years and breast-feeding mothers. Codeine is not recommended for adolescents (12-18 years) who have problems with breathing*.

ZINC SULPHATE

Tablet, 20 mg NRH/RRH/DH/PHC

Therapeutic group Antidiarrhoeal.
Indications and dose **Adjunct to oral rehydration therapy in acute diarrhoea**, *By oral administration,* INFANT (under 6 months): 10 mg daily for 10-14 days; CHILD (6 months-5 years): 20 mg daily for 10-14 days.
Cautions Acute renal failure (may accumulate).
Side effects Abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation, gastritis, irritability, headache, lethargy.
Note *Zinc sulphate tablets may be dispersed in breast milk, in ORS, or in water on a small spoon. Older children may chew the tablets or swallow them with water.*

17. MEDICINES FOR ENDOCRINE DISORDERS

17.1 Adrenal hormones & synthetic substitutes

DEFLAZACORT

Tablet 1 mg and 6 mg NRH/RRH

Therapeutic group Adrenal hormones and synthetic substitutes.

Indications and dose **Duchenne muscular dystrophy and inflammatory conditions**, ADULT and CHILD (≥2 years): 0.9 mg/kg PO once daily with or without food, round up to nearest possible tablet strength. May decrease dose by 25% to 33% in patients who experience intolerable adverse effects.
Contraindications Hypersensitivity to deflazacort or any component of its products, live or live attenuated vaccines is not recommended concurrently.
Cautions Heart failure, hypertension and renal insufficiency patients, gastrointestinal disorders, Cushing syndrome, risk of thromboembolism, risk of infection, hyperglycemia (monitor recommended).
Side effects Rash, Cushingoid appearance, abdominal pain, respiratory infection, hirsutism, weight gain, rhinitis, arrhythmia, hot flush.
Hepatic impairment No dose adjustment.
Renal impairment No dose adjustment.
Pregnancy category X
Breast-feeding Weigh potential benefit vs risk.

DEXAMETHASONE

Injection, 4 mg/mL (2 mL) NRH/RHR/DH/P
Tablet 4 mg NRH/RRH

Therapeutic group corticosteroid. *For details, refer to page no. 24*

METHYLPREDNISOLONE

Powder for injection, 500 mg NRH/RRH

Therapeutic group Adrenal hormones and synthetic substitutes (corticosteroid).
Indications and dose **Suppression of inflammatory and allergic disorders; Cerebral oedema associated with malignancy** ADULT: Initially 10-500 mg IM or slow IV injection or IV infusion; CHILD: 0.5-1.7 mg/kg/day IM or slow Iv injection or IV infusion, Q6H-Q12H, divide doses depending on condition and response; **Treatment of graft rejection reactions** ADULT: Up to 1 g/day IV infusion, up to 3 days; CHILD: 10-20 mg/kg IV injection, Q24H x 3 days; **Severe erythema multiforme; Lupus nephritis; Systemic onset juvenile idiopathic arthritis** CHILD: 10-30 mg/kg IV injection Q24H.
Contraindications Hypersensitivity to corticosteroids, systemic fungal infections, concurrent administration of live vaccines, intrathecal administration, serious infections, use in premature infants.
Cautions Cirrhosis, hypertension, ocular herpes simplex, diverticulum, myasthenia gravis, peptic ulcer disease, ulcerative colitis, psychotic tendencies, pregnancy, diabetes, cardiovascular disorder, renal insufficiency, ocular disease, head injury.
Side Effects Acne, adrenal suppression, arthralgia, bladder dysfunction, cardiomegaly, Cushing syndrome, delayed wound healing, diabetes, fat embolism, hyperglycemia, indigestion, insomnia, osteoporosis, syncope, tachycardia, vertigo.
Hepatic impairment Use with caution.
Renal impairment Use with caution, fluid retention may occur.
Pregnancy category C
Breast-feeding Excreted in breast milk; Use with caution.
IV fluid compatibility Compatible with dextrose 5%, dextrose 5% sodium chloride 0.9%, sodium chloride 0.9%.

PREDNISOLONE

Tablet 5 mg and 20 mg NRH/RRH/DH

Therapeutic group antiallergics, adrenal hormones and synthetic substitutes (corticosteroids).
For details, refer to page no. 25.

TRIAMCINOLONE ACETONIDE

Injection, 40 mg/mL (1 mL) NRH/RRH/DH

Therapeutic group Adrenal hormones and synthetic substitutes (corticosteroid).
Indications and dose **Severe inflammatory skin disorders such as eczema unresponsive to less potent corticosteroids; psoriasis,** By deep IM injection, ADULT, 2.5-60 mg/day; CHILD (6-12 years), 0.03 – 0.2 mg/kg; by intralesional injection, 2-3 mg; maximum 30 mg in multiple injections; doses are repeated every 1-2 weeks according to response; **Local inflammation of joints (especially in RA) and soft tissues,** By intra-articular injection, 2.5-40 mg according to joint size, to a maximum of 80 mg in multiple injections.
Contraindications local/systemic fungal infections, septic arthritis, herpes simplex, hypersensitivity, peptic ulcer, osteoporosis (long term use), history of glucocorticoid induced myopathy.
Cautions repeated infections may lead to Cushingoid's syndrome, or to local necrosis and muscle wasting; in tendonitis, the injection should be into the synovial sheath, not into the tendon itself. Not recommended for children below 6 years.
Side effects Cushing's syndrome, growth retardation in children, osteoporosis, vertebral compression, glaucoma, hyperglycemia, nocturia, obesity, facial rounding, increased fragility of skin and behavioural changes.
Hepatic impairment Use with caution.
Renal impairment Use with caution, fluid retention may occur.
Pregnancy category C
Breast-feeding Excretion in breast milk unknown, use with caution.

17.2 Estrogens

METHYLERGOMETRINE

Injection, 200 mcg/mL (1 mL) NRH/RRH/DH/PHC
Tablet, 0.125 mg NRH/RRH/DH/PHC

Therapeutic group Oxytocic.
Indications and dose **Third stage of labor; post-partum hemorrhage; sub-involution of the uterus; incomplete abortion** ADULT, PO 1-2 tablets 3 times daily, MAX 3 days; by IM injection, **labor:** 0.2 mg when anterior shoulder is delivered or immediately after birth; **PPH**: by IV injection, 0.25-0.5 mg when anterior shoulder is delivered or immediately after birth.
Contraindications Antepartum haemorrhage, first and second stage of labour, impaired pulmonary, hepatic or renal function, severe hypertension, sepsis.
Cautions Pre-eclampsia and eclampsia, cardiac disease, sepsis, also exclude multiple pregnancy.
Side effects Nausea, vomiting, transient hypertension, vasoconstriction.
Note *To control bleeding in incomplete abortion, oxytocin should be used as well; the uterus in early pregnancy responds better to the combination than to either medicine alone.*

CONJUGATED OESTROGEN

Tablet, 0.625 mg NRH/RRH

Therapeutic group Conjugated estrogen.
Indications and dose **Treatment of postmenopausal symptoms,** by oral administration, 0.3–1.25 mg daily continuously; with cyclical progestogen for 12–14 days of each cycle. **Osteoporosis prophylaxis,** by oral administration, Adult, 0.625–1.25 mg daily continuously; with cyclical progestogen for 12–14 days of each cycle.
Contraindications Breast carcinoma, liver disease, thromboembolic disorders, vaginal bleeding of unknown cause, suspected oestrogen dependent neoplasia, active thrombophlebitis.
Cautions Migraine, epilepsy, asthma, renal and cardiac disease, recurrent and chronic mastitis, may cause retention of salt and water, abnormal mammograms; to discontinue if cancer progression or hypercalcemia occurs, uterine fibromyomata.
Side effects Nausea, vomiting, breakthrough bleeding, breast tenderness, breast enlargement.
Hepatic impairment Avoid in active liver disease.
Pregnancy category X
Breast-feeding Avoid until weaning or for 6 months after birth.

ETHINYLOESTRADIOL

Tablet, 50 mcg — NRH/RRH/DH/PHC

Therapeutic group Estrogen.
Indications and dose **Menstrual disorders,** ADULT: 20–50 mcg PO daily from day 5 to 25 of each cycle, to be given with progestogen, added either throughout the cycle or from day 15 to 25. **Female hypogonadism,** 10–50 mcg daily usually on a cyclical basis, initial oestrogen therapy should be followed by combined oestrogen and progestogen therapy.
Note *For primary amenorrhea, the combined oral contraceptive may be more convenient in establishing cyclical bleeding.*
Contraindications Oestrogen-dependent cancer, history of thromboembolism, hepatic impairment, endometriosis and undiagnosed vaginal bleeding.
Cautions Oestrogen predisposes to thromboembolism and, in prolonged courses, to endometrial cancer; care is needed in diabetes, epilepsy, migraine, cardiac or renal disease.
Side effects Nausea, vomiting, headache, breast tenderness and weight gain may occur; changes in libido, depression, and amenorrhea occur occasionally; thromboembolism is more common than in the normal population.
Hepatic impairment Avoid.
Pregnancy category X
Breast-feeding Avoid until weaning or for 6 months after birth.

17.3 Progestogens

MEDROXYPROGESTERONE ACETATE

Tablet, 10 mg — NRH/RRH/DH

Therapeutic group Progestogen.
Indications and dose **Dysfunctional uterine bleeding, Secondary amenorrhea,** ADULTS, 2.5-10 mg PO daily for 5-10 days beginning 16th-21st day of cycle, repeated for 2 cycles in dysfunctional uterine bleeding (3 cycles in secondary amenorrhea); **Mild to moderate endometriosis,** 10 mg 3 times daily for 90 consecutive days, beginning on the 1st day of cycle.
Contraindications Undiagnosed vaginal bleeding, active liver disease, breast or genital tract carcinoma, porphyria, severe arterial disease.
Cautions Diabetes, hypertension, cardiac and renal failure.
Side effects Acne, urticaria, fluid retention, weight changes, GI disturbances, changes in libido, breast discomfort, premenstrual symptoms, irregular menstrual cycles; also, depression, insomnia, somnolence, alopecia, hirsutism, anaphylactoid-like reaction and rarely jaundice.
Hepatic impairment Avoid in severe impairment.
Renal impairment Use with caution.
Pregnancy category X
Breast-feeding Excreted in breast milk, safe.

17.4 Medicine for diabetes

17.4.1 Insulins

HUMAN INSULIN

Injection Isophane, 40 IU/mL (10 mL) — NRH/RRH/DH
Mixtard, (neutral + isophane) 30:70 IU (10 mL) — NRH/RRH/DH
Soluble, 40 IU/mL (10 mL) — NRH/RRH/DH

Therapeutic group Antidiabetic agent.
Indications and dose **Diabetes mellitus type 1,** SOLUBLE INSULIN, by SC injections, initially 0.2 – 0.4 units/kg/day every 8 hourly, maintenance dose 0.5-1 unit/kg/day adjusted according to patient's requirements; ISOPHANE

INSULIN, by SC injection, 0.5 - 1 unit/kg/day in divided doses (two thirds of dose to be administered in the morning and one third in the evening); MIXTARD INSULIN, by SC injection, 0.5-0.7 units/kg/day. **Diabetes mellitus type 2:** SOLUBLE INSULIN, by SC injection, 10 units/day initially once or twice daily adjusted according to patients requirements; ISOPHANE INSULIN, by SC injection, 0.2 units/kg/day in divided doses (two thirds of dose to be administered in the morning and one third in the evening); MIXTARD INSULIN, by SC injection, 0.5-1 units/kg/day in divided doses(two thirds of dose to be administered in the morning and one third in the evening); **Diabetes ketoacidosis,** SOLUBLE INSULIN, By IV injection, 0.1 units/kg/hr. IV bolus, then 0.1 mg/kg/hr continuous IV infusion.
Contraindications Hypoglycaemia.
Cautions Diarrhoea, nausea/vomiting, malabsorption, hypo- or hyperthyroidism, fever, trauma, infection, surgery, concomitant use of beta blockers.
Side effect Fat hypertrophy at injection site, local reactions at injection site, transient oedema, hypoglycemia, weight gain.
Hepatic impairment Insulin requirements may be decreased in patients with hepatic impairment.
Renal impairment Insulin requirements may decrease in patients with renal impairment and therefore dose reduction may be necessary.
Pregnancy category B
Breast-feeding Compatible.
Counselling The injection site should be rotated to prevent lipodystrophy. Patients should be educated on symptoms of hypoglycaemia and its management.

17.4.2 Oral hypoglycemic agents

GLIPIZIDE

Tablet, 5 mg NRH/RRH/DH

Therapeutic group Oral antidiabetic agent (sulfonylureas).
Indications and dose **Diabetes mellitus type 2,** ADULT: initially 2.5-5 mg PO daily, adjusted in increments of 2.5 - 5 mg according to response; allow several days between titration MAX.40 mg/day (doses >15mg should be divided).
Contraindications Hypersensitivity to sulfonamides, type 1 diabetes, diabetic ketoacidosis.
Cautions Elderly, debilitated patients, adrenal insufficiency, stress due to infection, fever, trauma or surgery, concomitant use of beta blockers.
Side effects Dizziness, drowsiness, headache, tremor, hypoglycemia, photosensitivity.
Hepatic impairment Avoid.
Renal impairment Avoid.
Pregnancy category C
Breast-feeding Avoid.
Counselling Preferably take shortly before breakfast or lunch; Patients should be educated on symptoms of hypoglycemia and its management.

METFORMIN

Tablet, 500 mg NRH/RRH/DH/PHC

Therapeutic group Oral antidiabetic agents (biguanides).
Indications and dose **Diabetes mellitus type 2,** ADULT, initially 500 mg PO once daily for at least 1 week, then 500 mg twice daily for at least 1 week, and then 500 mg thrice daily titrated up to maximum of 2550 mg per day; doses to be preferably taken with or after meals; **polycystic ovary syndrome,** ADULT, Initially 500 mg once daily for 1 week, , then 500 mg twice daily for 1 week, then 1.5–1.7 g daily in 2–3 divided doses; doses to be preferably taken with or after meals.
Contraindications Ketoacidosis, use of general anaesthesia, chronic heart failure, severe renal impairment (GFR<30mL/min).
Cautions Serious infections, trauma, surgery, heavy alcohol use, elderly.
Side effects Anorexia, nausea, vomiting, diarrhoea, occasionally metallic taste, urticaria, malabsorption of vitamin B_{12}.

Hepatic impairment Risk of lactic acidosis, avoid.
Renal impairment Avoid in severe impairment.
Pregnancy category D
Breast-feeding Avoid.

PIOGLITAZONE

Tablet, 15 mg NRH/RRH/DH

Therapeutic group Oral antidiabetic agent.
Indications and dose **Diabetes mellitus type 2 (alone or combined with metformin or a sulphonylurea):** ADULTS, initially 15-30 mg once daily, increased to 45 mg once daily according to response; In elderly patients, initiate with lowest possible dose and increase gradually.
Note *Monitor liver function before treatment, then every 2 months for 12 months and periodically thereafter.*
Contraindications Hepatic impairment, history of heart failure, history of bladder cancer, hematuria.
Cautions Cardiovascular disease, in combination with insulin, elderly, women, risk factors for bladder cancer, acute porphyria.
Side effects GI disturbances, weight gain, oedema, anaemia, headache, visual disturbances, dizziness, arthralgia, hypoesthesia, hematuria, impotence, less commonly hypoglycemia, fatigue, insomnia, vertigo, sweating, altered blood lipids, proteinuria, liver dysfunction.
Hepatic impairment Avoid.
Pregnancy Category C
Breastfeeding Excreted in breast milk, avoid.

VILDAGLIPTIN

Tablet, 50 mg NRH/RRH

Therapeutic group Oral antidiabetic agents (DPP IV inhibitors).
Indications and dose **Uncontrolled Type 2 diabetes mellitus as dual or triple therapy in combination with other oral antidiabetics, or insulin**. ADULT, 50 mg twice daily. **Type 2 diabetes mellitus in combination with sulfonylurea (if metformin inappropriate)**: ADULT: 50 mg daily, to be taken in the morning.
Contraindications Ketoacidosis.
Cautions Angioedema, severe heart failure.
Side effects Asthenia, dizziness, headache, nausea, peripheral oedema, tremor, arthralgia, constipation, hypoglycemia, hepatic dysfunction.
Hepatic impairment Avoid.
Renal impairment Reduce dose to 50 mg once daily if eGFR less than 50 mL/minute/1.73m^2.
Pregnancy Avoid - toxicity in animal studies.
Breast-feeding Avoid - present in milk in animal studies.
Counselling Patients should be advised to seek prompt medical attention if symptoms of liver toxicity such as nausea, vomiting, abdominal pain, fatigue, and dark urine develop.

17.5 Medicines affecting bone metabolism

ALENDRONATE

Tablet, 70 mg NRH/RRH

Therapeutic group Medicine affecting bone metabolism.
Indications and dose **Postmenopausal osteoporosis** ADULT (female): 10 mg daily or 70 mg once weekly. Prophylaxis 35 mg orally once weekly or 5 mg orally once daily. **Osteoporosis in men**: 10 mg daily or 70 mg once weekly. **Osteoporosis due to corticosteroid**: 5 mg orally once daily or 70 mg weekly; **Postmenopausal women not receiving estrogen replacement therapy**: 10 mg orally once daily or 70 mg weekly. **Osteoporosis due to corticosteroid (**Prophylaxis): 5 mg or 10 mg orally once daily or 35 mg orally once weekly (off-label dosage)**. Cystic**

fibrosis of the lung (Osteopenia): 70 mg orally once weekly (off-label dosage)**. Paget's disease**: 40 mg orally once daily for 6 months; may consider retreatment after a 6-month post-treatment evaluation if relapse is evident based on increase in serum alkaline phosphatase or if serum alkaline phosphatase failed to normalise. **Juvenile idiopathic generalised osteoporosis** (5 years or older, 20 kg or less) 5 mg orally once daily (off-label dosage). (5 years or older, greater than 20 kg) 10 mg orally once daily (off-label dosage).
Contraindications Abnormalities of oesophagus, hypocalcemia. Patients who are unable to sit or stand upright for at least 30 minutes.
Cautions Active gastro-intestinal bleeding. Atypical femoral fractures, duodenitis, dysphagia. Gastritis history (within 1 year) of ulcers. surgery of the upper gastro-intestinal tract. symptomatic esophageal diseases, ulcers. upper gastrointestinal disorders and breastfeeding. Esophageal irritation such as dysphagia, new or worsening heartburn, pain on swallowing or retrosternal pain.
Side effects Transient hypocalcemia and hypophosphatemia, abdominal pain, heartburn, nausea, constipation, diarrhoea, flatulence, and esophagitis. Esophagitis, esophageal ulcers, esophageal stricture and esophageal erosions. Myalgia, joint pain, headache, dizziness, peripheral edema, back pain, and weakness.
Renal impairment No dosage adjustment necessary if CrCl 35 to 60 mL/min. Avoid if CrCl is less than 35 mL/min.
Hepatic impairment No dosage adjustments necessary.
Pregnancy category C
Breast-feeding Excretion in breast milk is unknown, use with caution.
Counselling Tablets should be swallowed whole and should be taken with plenty of water upright on an empty stomach at least 30 minutes before breakfast (or another oral medicine); Patients should stand or sit upright for at least 30 minutes after administration.
Note *Patient should receive supplemental calcium and vitamin D if dietary intake is adequate.*

17.6 Thyroid hormones and antithyroid medicines

CARBIMAZOLE

Tablet, 5 mg NRH/RRH/DH

Therapeutic group Antithyroid medicine.
Indications and dose **Hyperthyroidism,** ADULT and CHILD 12 years and above, 15-40 mg PO daily in divided doses until the patient is euthyroid, usually 4-8 weeks; then gradually reduce to a maintenance dose of 5-15 mg daily; CHILD 1 month-11 years, 0.75 mg/kg daily until patient is euthyroid, usually after 4–8 weeks, then gradually reduce to a maintenance dose of 30-60% of the initial dose.
Contraindications Severe blood disorders.
Cautions Liver disorders.
Side effects Nausea, mild GI disturbances, headache, rashes and pruritus, arthralgia, rarely myopathy, alopecia, bone marrow suppression, jaundice.
Hepatic impairment Avoid in severe impairment.
Renal impairment Use with caution.
Pregnancy category C
Breast-feeding Amount in milk may be sufficient to affect neonatal thyroid function therefore the lowest effective dose should be used.
Counselling Warn patient to report immediately if sore throat, mouth ulcers, bruising, fever, malaise, or non-specific illness develops; blood test should be advised at regular intervals.

THYROXINE

Tablet, 25 mcg and 100 mcg NRH/RRH/DH

Therapeutic group Thyroid hormone.
Indications and dose **Hypothyroidism,** ADULT 18 – 49 years, initially 50–100 mcg PO once daily; adjusted in steps of 25–50 mcg every 3 - 4 weeks, according to response; maintenance 100–200 mcg once daily. ADULTS 50 years and older, initially 25 mcg PO once daily; adjusted in steps of 25 mcg every 4 weeks, adjusted according to response;

maintenance 50–200 mcg once daily; CHILD, 10 mcg/kg PO up to maximum of 50 mcg guided by clinical response, growth assessment and laboratory response.
Contraindications Thyrotoxicosis.
Cautions Cardiovascular diseases, diabetes, elderly, hypertension.
Side effects Arrhythmia, angina, tachycardia, skeletal muscle cramps, headache, restlessness, excitability, flushing, sweating, diarrhoea and excessive weight loss.
Pregnancy category A
Breast-feeding Excreted in breast milk, however safe.
Counselling Dose should be taken preferably at least 30 minutes before breakfast, avoid caffeine-containing liquids, or other medication.

18. IMMUNOLOGICALS

18.1 Sera and immunoglobulins

ANTI-SNAKE VENOM SERUM

Powder for injection (10 g) NRH/RRH/DH/PHC

Therapeutic group Specific (Antitoxin). *For details, refer to page no. 27.*

EQUINE RABIES IMMUNOGLOBULIN (ERIG)

Injection, 300 IU/mL NRH/RRH/DH

Therapeutic group Immunoglobulin.
Indications and dose **Post-exposure treatment against rabies infection**, By local infiltration, or by infiltration or by I.M. injection, 40 IU/kg body weight (MAX: 3000 IU) in and around all cleansed wounds and if there is any remaining, it should be given intramuscularly (IM) on the antero-lateral region or deltoid region (away from the site of vaccine administration). It is not required if more than 7 days have elapsed after the first dose of anti-rabies vaccine, or more than 1 day after the second dose of vaccine.
For details and in immunocompromised patients refer to National Guideline for Management of Rabies 2nd Edition, 2014.
Cautions No live vaccine (OPV, MR, BCG) should be administered for the next three months after the administration of the ERIG.
Side effects Arthralgia, chills, fatigue, fever, headache, hypersensitivity, hypotension, influenza like illness, malaise, nausea, skin reactions, tachycardia.
Counselling Advised to keep patient under observation for 10-15 minutes after administration of ERIG for AEFI. **ERIG should not be given intravenously.**
Pregnancy category Pregnancy is not a contraindication for RIG and anti-rabies vaccination when indicated.

TETANUS IMMUNOGLOBULIN

Injection, 500 IU NRH/RRH/DH

Therapeutic group Sera and immunoglobulin.
Indications and dose **Passive immunisation against tetanus in high-risk cases prophylaxis** By IM injection, 1500 units; **Established tetanus**: By IM or IV injection, at least 10,000 units in association with sedative and other medicines.
Contraindications known hypersensitivity to horse serum.
Cautions Anaphylaxis or lesser evidence of sensitivity may occur; adrenaline should always be available, possibly in association with corticosteroids and antihistamines.
Side effects Serum sickness, with fever, vomiting, diarrhoea, bronchospasm and urticaria may often occur 7-10 days after the injection.

18.2 Vaccines

BACILLUS CALMETTE-GUERIN (BCG)

Freeze dried powder for injection, (1 mL) NRH/RRH/DH/PHC

Therapeutic group Vaccine.
Indications and dose **Routine prevention of tuberculosis** At birth or at first contact 0.05 mL Intradermal, right upper arm.
Contraindications Known HIV infection.
Cautions Correct intradermal technique is needed to reduce the risk of ulceration or abscess formation; use a fresh needle and syringe for every child and discard the vial at the end of the session.
Side effects A papule or small ulcer appears within 6 weeks, and normally heals within 6 weeks.
For details refer to the latest EPI Services Manual for health workers 5th edition 2020.

DIPHTHERIA PERTUSSIS TETANUS (DPT)

Suspension for injection (0.5mL**)** NRH/RRH/DH/PH

Therapeutic group Vaccine.
Indications and dose **Prevention of diphtheria, tetanus, and pertussis** Booster at 24 months 0.5 mL Intramuscular (IM) antero-lateral aspect of left mid-thigh.
For details refer to EPI Services Manual for health workers 5th Edition 2020.

DPT- Hep B- Hib (PENTAVALENT)

Injection, (0.5 mL) NRH/RRH/DH/PHC

Therapeutic group Vaccine.
Indications and dose **Prevention of diphtheria, tetanus, pertussis, hepatitis B and haemophilus influenza B** 0.5 mL Intramuscular (IM) antero-lateral aspect of left mid-thigh at 6, 10 and 14th weeks.
Contraindications Known hypersensitivity to any component of the vaccine, or a severe reaction to a previous dose of the combination vaccine or any of its constituents is an absolute Contraindications to subsequent doses of the combination vaccine or the specific vaccine known to have provoked an adverse reaction.
Caution Careful injection technique will reduce the risk of thigh abscess; use a fresh needle and syringe for every child and discard the vial at the end of the session.
Side effects Mild local or systemic reactions are common, temporary swelling, tenderness and redness at the site of injection, fever, vomiting, diarrhoea.
For details refer to EPI Services Manual for health workers 5th Edition 2020.

HEPATITIS B VACCINE

Injection (10 mL) NRH/RRH/DH/PHC

Therapeutic group Vaccine.
Indications and dose **Active immunisation against hepatitis B virus infection**, By IM injection into deltoid muscle, ADULT, 3 doses of 1mL (20 mcg) at an interval of 0,1,6; CHILD, 3 doses of 0.5 mL (20 mcg) at an interval of 0, 1, 6; **Chronic hemodialysis patients**: 4 doses of 2 mL (40 mcg), at an interval of 0, 1, 2, 6 Note the vaccine is used in individuals at high risk of contracting hepatitis B.
Contraindications Known hypersensitivity to the components of the vaccine, severe febrile infections.
Caution Should not be administered in the gluteal region or intradermally.
Side effects Mild local or systemic reactions are common, temporary swelling, tenderness, and redness at the site of injection, fever, vomiting, diarrhoea.

HUMAN PAPILLOMA VACCINE

Injection (0.5 mL) NRH/RRH/DH/PHC

Therapeutic group Vaccine.
Indications and dose **Human papillomavirus type 6, 11, & 16 associated cervical cancer prophylaxis** *GIRLS and BOYS < 15 years old; CLASS SIX GIRLS and BOYS; OUT of SCHOOL GIRLS and BOYS at 12 year old*: 0.5 mL Intramuscular (IM) left upper arm, at 0 and 6 months; *15 years and above*: 0.5 mL Intramuscular (IM) left upper arm, at 0, 2 and 6 months.
For details refer to EPI Services Manual for health workers 5th Edition 2020.

MUMPS MEASLES RUBELLA VACCINE

Powder for Injection (0.5 mL) NRH/RRH/DH/PHC

Therapeutic group Vaccine.
Indications and dose **Prevention of measles, mumps, and rubella** 0.5 mL Subcutaneous-left upper arm at 9 and 24th months.
Contraindications Allergy to eggs, immune deficiency disorders.
Cautions Acute febrile illness, mild febrile illness, malnutrition and diarrhoea are no reason for delaying vaccination. Use a fresh needle and syringe for every child, and discard the vial at the end of the session.
Side effects A mild measles like rash and fever may occur about 1 week after the injection. Convulsions and encephalitis are rare complications.
For details refer to EPI Services Manual for health workers 5th Edition 2020.

PNEUMOCOCCAL CONJUGATE 13 VACCINE

Injection (0.5 mL) NRH/RRH/DH/PHC

Therapeutic group Vaccine.
Indications and dose **Prevention of pneumococcal diseases:** 0.5 mL Antero-lateral aspect of left mid-thigh at 6 and 10th weeks and 9th months.
For details refer to EPI Services Manual for health workers 5th Edition 2020.

INACTIVATED POLIO VACCINE (IPV)

Injection (0.5 mL) NRH/RRH/DH/PHC

Therapeutic group Vaccine.
Indications and dose **Prevention of poliomyelitis**: 0.5 mL Antero-lateral aspect of left mid-thigh at 14th weeks and 8th months.
For details refer to EPI Services Manual for health workers 5th Edition 2020.

ORAL POLIO VACCINE (BOPV) LIVE ATTENUATED

Oral drops, (10 doses) NRH/RRH/DH/PHC

Therapeutic group Vaccine.
Indications and dose **Prevention of poliomyelitis** 2 drops PO at 0 at birth (within 0-14 days as "zero dose"), 6, 10 and 14 weeks.
For details refer to EPI Services Manual for health workers 5th Edition 2020.

PURIFIED VERO-CELL RABIES VACCINE (PVRV)

Injection (0.5 mL) NRH/RRH/DH/PHC

Therapeutic group Vaccine.
Indications and dose **Pre-exposure prophylaxis** by *Intradermal (ID) injection,* 0.1 mL, one site on day 0, 7, 21 and 28; by *intramuscular (IM) injection*, 0.5 mL, one site on day 0, 7, 21 and 28. **Pre-exposure prophylaxis (*using PVRV*):** by *Intradermal injection,* 0.1 mL, one site at deltoid on day 0, 7 and 28; by *intramuscular injection*, 0.5 mL, one site at deltoid on day 0, 7 and 28. **Booster dose:** One site 0.1 mL ID or 0.5 mL IM at 1 year and every 3 years for high

risk groups. **Post-exposure prophylaxis:** 0.1 mL ID or 0.5 mL IM at Day 0 and 3 with no RIGS in individuals who have received full pre-exposure regimens and booster doses. **Post-exposure vaccination:** *Thai Red Cross Regimen–2-2-2-0-2*, one dose each (0.1 mL)ID is given at 2 sites, on both arms (over deltoids) on day 0, 3, 7 and 28. *Essen Protocol IM Regimen,* 0.5 mL IM on day 0,3,7,14 and 28; for adults and children aged ≥2 years, the vaccine should always be administered in the deltoid area of the arm; for children aged <2 years, the antero-lateral area of the thigh is recommended.
Note Rabies vaccine should not be administered in the gluteal area, as the induction of an adequate immune response may be less reliable.
For details refer to National Guidelines for management of rabies 2nd edition 2014.
Contraindications Known hypersensitivity to the components of the vaccine.
Side effects Injection site pain, soreness, swelling, erythema, itching, burning, nausea, abdominal pain, diarrhoea, headache, fatigue, fever, chills, muscle ache, dizziness, malaise.
Pregnancy category C
Breast-feeding Compatible with breastfeeding.
Counselling Patients must be advised not to rub the site of injection after administration of vaccine.

TETANUS DIPHTHERIA (Td)

Injection, 5 mL NRH/RRH/DH/PHC

Therapeutic group Vaccine.
Indications and dose **Prevention of tetanus and diphtheria** 0.5 mL Intramuscular left upper arm, Td 1 at PP Class student Td 2 at Class seven students; *Out of school* 0.5 mL at age of 6 years and 13 years old. **Booster dose:** 0.5 mL IM every 10 years or after 5 years in the case of a severe or dirty wound or burn (patients that have completed primary immunisation).
Note *Td is only for children 7 years and older, adolescents, and adults. DTaP (Diphtheria, Petanus, and acellular Pertussis) vaccine is preferred for primary immunisation in children aged <7 years.*
Cautions Acute febrile illness, but mild illness is not a reason for delaying vaccination.
Side effects Redness or swelling where the shot was given, mild fever, headache.
For details refer to EPI Services Manual for health workers 5th Edition 2020.

19. MUSCLE RELAXANTS (PERIPHERALLY-ACTING) AND CHOLINESTERASE INHIBITORS

ATRACURIUM BESYLATE

Injection, 10 mg/mL (2.5 mL) NRH/RRH/DH

Therapeutic group Muscle relaxant (non-depolarizing).
Indications and dose **Muscle relaxation (short to intermediate duration) for surgery and intubation,** initially 300–600 mcg/kg, then (by IV injection) 100–200 mcg/kg as required; **Neuromuscular blockade during intensive care,** initially by IV injection. ADULT, initially 300–600 mcg/kg (initial dose is optional) then (by intravenous infusion) 270–1770 mcg/kg/hour.
Note *To avoid excessive dosage in obese patients, dose should be calculated based on ideal body weight.*
Contraindications Neuromuscular disease, lack of ventilator support.
Cautions Allergic cross-reactivity between neuromuscular blocking agents has been reported; caution is advised in cases of hypersensitivity to these medicines. Their activity is prolonged in patients with myasthenia gravis and in hypothermia, therefore lower doses are required; resistance may develop in patients with burns who may require increased doses.
Side effects Skin flushing, hypotension, tachycardia, bronchospasm and rarely, anaphylactic reactions; most aminosteroid muscle relaxants produce minimal histamine release.
Hepatic impairment No dose adjustment necessary.
Renal impairment No dose adjustment necessary.
Pregnancy Category C

Breast-feeding Excretion in breast milk unknown, use with caution.

BACLOFEN

Tablet, 10 mg NRH/RRH/DH

Therapeutic group Muscle relaxant (centrally acting).
Indications and dose **Muscle spasticity of cerebral and spinal origin,** ADULT 5-10 mg PO TID daily, increase by 5 mg/dose every 3 days as required (MAX. 80 mg/day); CHILD 8–17 years: Initially 0.3 mg/kg/day in 4 divided doses, increased gradually at weekly intervals until satisfactory response (MAX. 60 mg/day), CHILD, 1 month–7 years: Initially 0.3 mg/kg daily in 4 divided doses, increased gradually at weekly intervals until satisfactory response (MAX.40 mg/day). Review treatment if no benefit within 6 weeks of achieving maximum dose.
Contraindications Active peptic ulceration.
Side effects Transient drowsiness, dizziness, weakness, fatigue.
Cautions Reduce dose in impaired renal function, avoid abrupt withdrawal (hallucinations and seizures may occur), pregnancy.
Hepatic impairment Use with caution.
Renal impairment Risk of toxicity, use smaller doses (e.g., 5 mg daily by mouth) and if necessary, increase dosage interval.
Pregnancy category C
Breast-feeding Excreted in breast milk, amount probably too small to be harmful.
Counselling Avoid taking with alcohol and other CNS depressants.

NEOSTIGMINE

Injection, 0.5 mg/mL (1 mL) NRH/RRH/DH

Therapeutic group Muscle relaxant.
Indications and dose **Counteract the effect of non-depolarizing muscle relaxants,** ADULTS, IV injection 0.03 -0.07 mg/kg body weight (MAX. 5mg), repeated if necessary, after or with glycopyrronium or atropine, to be given over 1 minute; **Treatment of myasthenia gravis,** by IV/IM/SC injection, ADULTS, 1-2.5 mg, dose repeated at suitable intervals throughout the day (usual total daily dose 5–20 mg).
Contraindications mechanical obstruction of the intestinal or urinary tract.
Cautions Adequate ventilation must be maintained and complete recovery must be ensured before the patient is transferred to the ward.
Side effects Nausea and vomiting, increased salivation, diarrhoea, abdominal cramps, cardiac dysrhythmias, syncope and hypotension; progressive paralysis may occur; management is by artificial ventilation and IV atropine.
Renal impairment May need dose reduction.
Pregnancy category C
Breast-feeding Excretion in breast milk unknown, use caution.

SUXAMETHONIUM

Injection, 50 mg/mL (2 mL) NRH/RRH/DH

Therapeutic group Muscle relaxant (Depolarizing).
Indications and dose **Neuromuscular blockade during surgery and intubation,** ADULT, IV injection 1-1.5 mg/kg body weight.
Contraindications Hyperkalemia, patients with burns, neuropathic or bed ridden patients, known malignant hyperpyrexia, known atypical plasma pseudo-cholinesterase enzymes.
Cautions Patients with cardiac, respiratory or neuromuscular disease; raised intraocular pressure, severe sepsis.
Side effects Repeated dosing may lead to a paradoxical prolonged non-depolarizing effect, partial and temporary reversal with neostigmine may be possible, but ventilation must be controlled and monitored until spontaneous breathing is fully re-established, and patients may experience muscular pain following recovery from anaesthesia.
Hepatic impairment Prolonged apnea may occur in severe liver disease because of reduced hepatic synthesis.

Pregnancy category C
Breast-feeding May be resumed once the mother recovers from a neuromuscular block.

VECURONIUM

Injection, 4 mg/mL (2 mL) NRH/RRH

Therapeutic group Non-depolarizing muscle relaxant (amino steroid).
Indications and dose **Neuromuscular blockade (intermediate duration) during surgery and intubation:** ADULTS, IV injection 0.08 - 0.1 mg/kg initially; maintenance 0.02 – 0.03 mg/kg, adjusted according to response (MAX. 0.1 mg/kg).
Note *To avoid excessive dosage in obese patients, dose should be calculated on the basis of ideal body weight.*
Contraindications Neuromuscular disease, lack of ventilator support.
Cautions Allergic cross-reactivity between neuromuscular blocking agents has been reported; caution is advised in cases of hypersensitivity to these medicines. Their activity is prolonged in patients with myasthenia gravis and in hypothermia, therefore lower doses are required. Resistance may develop in patients with burns who may require increased doses; low plasma cholinesterase activity in these patients requires dose titration for mivacurium.
Side effects Duration is prolonged in hypothermia, hypothyroidism, and myasthenia gravis and in conjunction with aminoglycosides. The effect is slightly prolonged in renal and liver diseases.
Hepatic impairment Use with caution in severe impairment.
Renal impairment Use with caution.
Pregnancy category C
Breast-feeding Excretion in breast milk unknown, use with caution.

20. OPHTHALMOLOGICAL PREPARATIONS

20.1 Anti-infective agents

ACYCLOVIR

Eye ointment, 3% (5 g) NRH/RRH

Therapeutic group Antiviral.
Indications and dose **Ophthalmic herpes simplex infections.** Dose, apply 5 times daily and continue for at least 4 days after complete healing.
Contraindications Known hypersensitivity.
Side effects Transient burning pain in the eye may be felt.
Counselling Do not use it after 1 month of opening; do not share the ointment with another patient.

CHLORAMPHENICOL

Eye ointment, 1% (250 mg) NRH/RRH/DH/PHC
Eye drop, 0.4% (5 mL) NRH/RRH/DH/PHC

Therapeutic group Antibacterial.
Indications and dose **Bacterial infection**, Ocular instillation,1-2 drops 2 hourly; reduce once infection is controlled; Continue for 48 hours after the eye is white; Eye ointment, apply 3-4 times daily.
Contraindications Hypersensitivity.
Side effects Transient burning pain in the eye, aplastic anaemia.
Counselling Eye ointment**:** use a clean blade to cut off the tip of the capsule, and squeeze the ointment into your eye; Eye drop: Advise not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.

CIPROFLOXACIN

Eye drop, 0.3 % (5 mL) NRH/RRH/DH/PHC

Therapeutic group Antibacterial.
Indications and dose **Superficial bacterial infections; chronic otitis media in patients with perforation of the tympanic membrane; pseudomonas infection of the otitis externa,** by ocular/aural instillation, **superficial bacterial infection**: Apply 1-2 drops (Ear: 3-5 drops) 2 hourly; reduce once infection is controlled; continue for 48 hours after the eye is white; **corneal ulcer**: day 1 apply every 15 minutes for 6 hours, then 30 minutes, day 3 apply every hour, days 3-14 apply every 4 hours (Max. duration of treatment 21 days).
Contraindications Hypersensitivity.
Cautions Not recommended for children under 1 year.
Side effects Local sensitivity, taste disturbances, nausea and visual disturbances.
Counselling Advise not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.

MOXIFLOXACIN

Eye drop, 0.5% (5 mL) NRH/RRH

Therapeutic group Antibacterial (fluoroquinolone).
Indications and dose **Bacterial conjunctivitis and corneal ulcers not responding to ciprofloxacin,** by ocular instillation, 1 to 2 drops every 8 hours into affected eye(s), for 1 week.
Contraindications Hypersensitivity to quinolones.
Side effects Eye discomfort and pain; pharyngitis and rhinitis.
Counselling Advise not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.

NATAMYCIN

Eye drop, 5% (5 mL) NRH/RRH

Therapeutic group Ophthalmic anti-infective agents (anti-fungal).
Indications and dose **Fungal Blepharitis and conjunctivitis** ADULT: Instil 1 drop in affected eye(s) 4-6 times per day. **Fungal keratitis** ADULT: Instil 1 drop in affected eye(s) every 1-2 hours for 3-4 days, then 1 drop 6-8 times daily; continue for 14-21 days until infection eradicated. CHILD: safety and efficacy not established.
Contraindications Hypersensitivity to natamycin or any component of the product.
Cautions In keratitis, consider alternative treatment if no improvement in 7-10 days of therapy, corneal abrasion.
Side effects Eye irritation and blurred vision.
Pregnancy category C
Counselling Advise not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.

NEOSPORIN (Neomycin + polymyxin + bacitracin)

Eye ointment, 5 g NRH/RRH

Therapeutic group Antibacterial.
Indications and dose **Bacterial infection,** apply 3-4 times daily.
Contraindications Known sensitivity to any of the components.
Counselling Do not use it after 1 month of opening; do not share the ointment with another patient.

TETRACYCLINE

Eye ointment, 1% NRH/RRH/DH/PHC

Therapeutic group Antibacterial.
Indications and dose **Prevention of chlamydial and gonococcal neonatal conjunctivitis**, one single application immediately after birth.
Contraindications Hypersensitivity to tetracycline group of antibiotics.
Side Effects Transient blurring of vision.

TOBRAMYCIN

Eye drop, 0.3% (5 mL) NRH/RRH

Therapeutic group Antibacterial (aminoglycoside).
Indications and dose **External infections of the eye and its adnexa caused by susceptible bacteria** by ocular instillation, ADULT and CHILD over 1 year, 1 drop twice daily for 1 week; in severe infection, 1 drop four times daily on the first day, then twice daily for 5 to 7 days.
Contraindications Hypersensitivity.
Cautions Hypersensitivity, pregnancy; breastfeeding, if tobramycin is administered topically in conjunction with systemic aminoglycoside therapy, serum aminoglycoside concentration should be monitored.
Side effects Localised ocular toxicity and hypersensitivity including increased lacrimation, itching and oedema of the eyelid and conjunctival erythema.
Counselling Advise not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.

20.2 Anti-inflammatory agents

KETOROLAC

Eye drop, 0.4% (5 mL) NRH/RRH/DH

Therapeutic group Anti-inflammatory Agent.
Indications and dose **Prophylaxis and reduction of inflammation and associated symptoms following ocular surgery and to relieve ocular itching associated with allergic conjunctivitis** by ocular instillation, 1 drop to the affected eye three to four times daily.
Contraindications Hypersensitivity to Aspirin and NSAIMs.
Cautions Post cataract surgery, chronic use of ketorolac eye drop.
Side effects Transient ocular burning or stinging, conjunctival hyperaemia, corneal oedema, iritis, ocular inflammation, pain and pressure, superficial keratitis and infection.
Pregnancy category C
Counselling Advise not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.

PREDNISOLONE ACETATE

Eye drop, 1% (5 mL) NRH/RRH

Therapeutic group Anti-inflammatory agents (corticosteroids).
Indications and dose **Ophthalmic inflammatory conditions** Instil 1-2 drops of 1% solution 2 - 4 times daily, May reduce frequency but do not discontinue prematurely.
Contraindications Fungal, mycobacterial, viral infections.

Cautions Cataract surgery and glaucoma.
Side effects Raised intraocular pressure, optic nerve and pathway injury.
Counselling Advise not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.

20.3 Mast cell stabilisers

SODIUM CROMOGLYCATE

Eye drop, 2% (20 mL) NRH/RRH

Therapeutic group Mast cell stabilisers.
Indications and dose **Allergic conjunctivitis** By ocular instillation, 1 to 2 drops 4-6 times daily.
Contraindications Patients with known hypersensitivity to any of the ingredients in the formulation.
Side effects Transient burning and stinging.
Counselling Advise not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.

20.4 Miotics and antiglaucoma medicines

ACETAZOLAMIDE

Tablet, 250 mg NRH/RRH/DH

Therapeutic group Antiglaucoma medicine and diuretic.
Indications and dose **Open angle glaucoma, secondary glaucoma, hydrocephalus** ADULT, PO 250–750 mg/day in divided doses; CHILD, 8-30 mg/kg daily, MAX. of 750 mg; **Mountain sickness**: prophylactic: 125 to 250 mg twice daily starting 1 or 2 days before and continuing for 3 days once the highest altitude is reached; treatment: 250 mg twice a day for about 3 days.
Contraindications Hypersensitivity to acetazolamide, sulfonamides, hepatic disease, hypokalemia, hyponatremia, cirrhosis, hyperchloremic acidosis, severe renal disease or dysfunction, severe pulmonary obstruction, long-term use in non-congestive angle-closure glaucoma.
Cautions Pregnancy; May cause neonatal thrombocytopenia, diabetes, breastfeeding; Not for prolonged use.
Side effects Diuresis: paraesthesia, hypokalemia, loss of appetite, drowsiness and depression may occur, especially in the elderly; nausea, vomiting, diarrhoea, taste disturbance.
Renal impairment CrCl 10-50 mL/minute: Administer every 12 hours. CrCl <10 mL/minute: Avoid use (ineffective).
Hepatic impairment Use with caution in patients with hepatic dysfunction; in cirrhosis, avoid electrolyte and acid/base imbalances that might lead to hepatic encephalopathy.
Pregnancy category C
Breast-feeding Amount too small to be harmful.
Counselling May cause drowsiness, do not drive, or operate machinery.

BRIMONIDINE

Eye drop, 0.2 % (5 mL) NRH

Therapeutic group Antiglaucoma medicine.
Indications and dose **Raised intraocular pressure in open-angle glaucoma or ocular hypertension in patients whom beta-blockers are inappropriate; adjunctive therapy when intraocular pressure is being inadequately controlled by other anti-glaucoma therapy** by ocular instillation,1 drop 2 times daily.

Cautions Severe cardiovascular disease; cerebral coronary insufficiency, Raynaud's syndrome, postural hypotension, depression, hepatic or renal impairment; pregnancy, breast feeding.
Side effects Ocular reactions include hyperemia, burning, stinging, burning, blurring, pruritus, allergy, and conjunctival follicles; occasionally corneal erosion and staining, photophobia, eyelid inflammation, conjunctivitis; headache, dry mouth, taste alteration, fatigue, dizziness, drowsiness.
Counselling Advise not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.

DORZOLAMIDE

Eye drop, 2% (5 mL) NRH/RRH/DH

Therapeutic group Antiglaucoma.
Indications and dose **Glaucoma** by ocular instillation, 1 drop to the affected eye 3-4 times a day.
Contraindications Hyperchloremic acidosis, severe renal impairment with CrCl <30 mL/min.
Caution Chronic corneal defects, history of intraocular surgery, history of renal calculi, low endothelial cell count, systemic absorption follows topical application.
Side effects Asthenia, bitter taste, blurred vision, conjunctivitis, eyelid inflammation, headache, lacrimation, nausea, ocular irritation, superficial punctate keratitis.
Counselling Advise not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.

LATANOPROST

Eye drop, 0.005% (2.5 mL) NRH

Therapeutic group Miotic and antiglaucoma medicine.
Indications and dose **Elevated Intraocular Pressure (Open-angle glaucoma or ocular hypertension**) ADULT: Instil 1 drop in affected eye(s) once daily, in the evening MAX. once daily. CHILD: Safety and efficacy not established.
Contraindications Hypersensitivity to latanoprost, benzalkonium chloride, or other components of product. Herpetic keratitis with prostaglandin analogs.
Cautions Angle closure glaucoma, aphakia and patients with known risk factors for macular edema, macular edema, including cystoid macular edema, active intraocular inflammation (e.g., iritis, uveitis).
Side effects Eye discoloration, eye discomfort, eye inflammation, blurred vision, rash, dry eye, upper respiratory infection.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.
Counselling Advise patients about the possible change in eye colour. Advise not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.

TIMOLOL MALEATE

Eye drop 0.5 % (5 mL) NRH/RRH/DH

Therapeutic group Anti-glaucoma medicine (miotics).
Indications and dose **Intraocular pressure in primary open-angle glaucoma,** By ocular instillation,1 drop 2 times daily.
Contraindications Systemic absorption may follow topical application therefore eye drops containing a beta-blocker are contra-indicated in patients with bradycardia, heart block, or uncompensated heart failure, asthma.

Side effects Ocular stinging, burning, pain, itching, erythema, dry eyes and allergic reactions including anaphylaxis and blepharitis.
Counselling Advise not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.

20.5 Mydriatics

ATROPINE

Eye ointment, 1% (5 g) NRH/RRH/DH

Therapeutic group Mydriatics and cycloplegic.
Indications and dose **Refraction procedures in young children; anterior uveitis,** Apply a small amount into the conjunctival sac once or twice a day.
Contraindications Narrow angle glaucoma.
Cautions Infant and elder patients; the action of the medicine may persist for up to 7 days after stopping treatment.
Side effects Blurred vision, stinging, eye irritation, photophobia.
Counselling May cause drowsiness do not drive or operate machinery.

CYCLOPENTOLATE

Eye drop, 0.5% (5 mL) NRH/RRH

Therapeutic group Mydriatic and cycloplegic (antimuscarinic).
Indications and dose **Refraction procedures in young children, Uveitis** by ocular instillation, **diagnostic procedures**: 1-2 drops repeated after every 5 to 15 minutes; **Treatment of uveitis**; CHILDREN 3 months - 17 years, 1-2 drops up to four times daily.
Contraindications Narrow-angle glaucoma or anatomical narrow angles.
Cautions Premature and small infants, driving or hazardous activities, children with spastic paralysis or brain damage, Down's syndrome, elderly, may interfere with anti-glaucoma action of carbachol or pilocarpine, predisposition to angle-closure glaucoma, young children.
Side effects Blurred vision, burning sensation in the eye, photophobia.
Counselling Advice not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.

HOMATROPINE

Eye drop, 2% (5 mL) NRH/RRH

Therapeutic group Mydriatic.
Indications and dose **Mydriasis induction** ADULT, 1-2 drops of 2% solution, repeat in 5 to 10 mins if needed; **Uveitis** 1-2 drops of 2% solution, every 3 to 4 hours.
Contraindications Primary or narrow angle glaucoma.
Cautions Infants and young children, Down syndrome patient, keratoconus and elderly patient.
Side effects Follicular conjunctivitis, vascular congestion, edema, xerostomia, burning, irritation, stinging, blurred vision, exudate, eczematoid dermatitis.
Counselling Advise not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.
Note *Paralysis of accommodation will continue for up to 12 hours.*

TROPICAMIDE

Eye drops, 1% (5 mL) NRH/RRH

Therapeutic group Mydriatics and cycloplegics (antimuscarinics).
Indications and dose **Fundus examination I**nstil1-2 drops 0.5% in the eye(s), 15-20 min prior to exam. **Refractive procedures:** 1-2 drops 1% solution in eyes(s), repeat in 5 min, perform exam within 30 min of second instillation.
Contraindications Angle-closure glaucoma.
Cautions Children and elderly, hypertension, hyperthyroidism, diabetes.
Side effects Transient stinging, raised intraocular pressure, blurred vision.
Counselling Advise not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.

20.6 Miscellaneous

HYDROXYPROPYL METHYLCELLULOSE

Injection (prefilled), 2% NRH/RRH

Therapeutic group Surgical aid (Ophthalmic).
Indications and dose **Ophthalmic surgical aid in anterior segment surgical procedures, including cataract extraction and intraocular lens implantation,** by INTRAOCULAR injection, 2% injection to be injected carefully into the anterior chamber by using a 20 gauge or smaller cannula. Additional doses may be injected during surgery to fully maintain the chamber and to replace any fluid lost during the surgical procedure.
Cautions Glaucoma.
Side effects Transient increase in intraocular pressure, corneal oedema, hypopyon, iritis.

CARBOXYMETHYLCELLULOSE

Eye drop 1% (5 mL) NRH/RRH/DH

Therapeutic group Ophthalmic preparations/lubricant.
Indications and dose **Dry eye and tear deficiency** ADULT: Instil 1-2 drops 3-4 hourly as required. CHILD: Apply as required.
Contraindications Corneal abrasion, ocular infection, ocular trauma, visual disturbance. Contact lenses.
Cautions Hypersensitivity to ingredients.
Side effects Irritation in eye, continued eye redness, Pain in eye, Blurred vision, Redness of the eye.
Counselling Advise not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.

HYPERTONIC SODIUM CHLORIDE EYE DROP

Ophthalmic solution, 3% (5 mL) NH/RRH

Therapeutic group Ocular irrigant.
Indications and dose **Corneal oedema following post cataract surgery and glaucoma,** Instil 1- 2 drops every 3 or 4 hours or as directed by the physician.
Side effects Temporary burning and irritation.
Counselling Advise not to drive or operate heavy machinery after using this medicine as it may cause blurring of vision. Do not touch the tip of the container to any surface. Not to be used longer than one month after the bottle is opened. Remove contact lenses prior to the administration. If more than one topical ophthalmic medicine is used, the medicine should be administered at least 5 minutes apart.

21. MEDICINES FOR REPRODUCTIVE HEALTH, PERINATAL CARE AND URINARY-TRACT DISORDERS

21.1 Contraceptives

21.1.1 Oral hormonal contraceptives

ETHINYLOESTRADIOL + LEVONORGESTREL

Tablet, (0.03 mg + 0.15 mg) NRH/RRH/DH/PH

Therapeutic group Hormonal contraceptive.
Indications and dose **Contraceptive, Females; (with 28-day combined preparations),** PO, 1 active tablet once daily for 21 days, followed by 1 inactive tablet daily for 7 days; subsequent courses repeated without interval, withdrawal bleeding occurs during the interval of inactive tablets being taken, if reasonably certain woman is not pregnant, first course can be started on any day of cycle—if starting on day 6 of cycle or later, additional precautions (barrier methods) necessary during first 7 days, tablets should be taken at approximately the same time each day **Primary amenorrhea, dysfunctional uterine bleeding, endometriosis, menorrhagia and chronic pelvic pain.** ADULT, PO, 1 pill once daily
Note *except after delivery, contraceptive pills should be started within 5 days of the start of menstruation; they should not be started less than 4 weeks after delivery; oral contraceptives should be discontinued one month before elective surgery.*
Contraindications History of thromboembolism, active liver disease, undiagnosed vaginal bleeding, breast, and uterine or other hormone-dependent cancers.
Cautions Diabetes, hypertension, cardiac or renal disease, migraine, epilepsy may all be made worse; varicose veins, inflammatory bowel disease including Crohn's disease, cigarette smoking, obesity, and age over 35 years may all predispose to thromboembolic disease.
Side effects Nausea and vomiting are common in the first few weeks; thromboembolism is more common than in the normal population in patients over 35 years old and smokers.
Renal impairment women with renal disease should be encouraged to use non hormonal forms of contraception.
Pregnancy category X
Breast-feeding Avoid.
Counselling Tablets should be taken daily, at the same time of each day. **Missed doses:** if one dose missed, take as soon as remembered or take 2 tablets next day; if two consecutive doses missed in the first 2 weeks, take 2 tablets as soon as remembered or 2 tablets next day with additional method of contraception for 7 days after missed dose. If two consecutive doses missed in week 3 or 3 consecutive doses missed at any time, an additional method of contraception must be used for 7 days after a missed dose.

LEVONORGESTREL

Tablet, 750 mcg NRH/RRH/DH

Therapeutic group Hormonal contraceptive.
Indications and dose **Emergency hormonal contraception,** PO 1.5 mg (two tabs) as a single dose as soon as possible after unprotected sex (preferably within 12 hours but no later than after 72 hours) or 1 tablet each 12 hours apart.
Contraindications Severe liver disease, porphyria, severe arterial disease, undiagnosed vaginal bleeding.
Cautions Past ectopic pregnancy, severe malabsorption syndromes
Side effects Nausea, vomiting, headache, dizziness, breast discomfort, depression, skin disorders, disturbances of appetite, irregular menstrual period.
Hepatic impairment Caution in severe liver disease and recurrent cholestatic jaundice.
Pregnancy category X
Breast-feeding Avoid.
Counselling Avoid repeated use.

21.2.2 Injectable hormonal contraceptives

MEDROXYPROGESTERONE ACETATE DEPOT (DMPA)

Injection, 150 mg/1mL (1 mL) NRH/RRH/DH/PH

Therapeutic group Hormonal contraceptive.
Indications and dose **Contraception** *By deep IM injection,* (gluteal muscle in average and thin patients and deltoid muscle in obese patients) 150 mg within first 5 days of cycle or within first 5 days after delivery (delay until 6 weeks after delivery if breastfeeding); **For long-term contraception**, repeat 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 methods for 14 days after the injection).
Contraindications Undiagnosed vaginal bleeding, history or family history of arterial disease; breast and other hormone-dependent cancers, acute porphyria.
Cautions Diabetes, hypertension, heart disease, ovarian cysts, malabsorption syndromes, migraine, active liver disease, recent cholestatic jaundice or history of jaundice in pregnancy.
Side effects Irregular menstruation or amenorrhea (50%); nausea and vomiting, headache, breast tenderness, depression, skin disorders and weight changes may sometimes occur, delayed return of fertility (max 24 months).
Hepatic impairment Caution in severe liver disease and recurrent cholestatic jaundice.
Renal impairment Use with caution.
Pregnancy category X
Breast-feeding Excreted in breast milk, however compatible.
Counselling It is recommended that before treatment, full counselling should be provided about the likelihood of menstrual irregularities and the potential of delay in the return to full fertility.

21.2 Ovulation inducers

CLOMIPHENE

Tablet, (50 mg) NRH/RRH/DH

Therapeutic group Ovulation inducer.
Indications and dose **Anovulatory infertility,** PO 50 mg daily for 5 days, starting within about 5 days of onset of menstruation (preferably on 2nd day) or at any time if cycles have ceased; second course of 100 mg daily for 5 days may be given in absence of ovulation; most patients who are going to respond will do so to first course; 3 courses should constitute adequate therapeutic trial; long term cyclical therapy not recommended; **Male infertility,** 25 mg/day for 3 months.
Note Patients planning to conceive should be warned that there is risk of multiple pregnancies.
Contraindications Abnormal uterine bleeding, hormone dependent tumours, ovarian cyst.
Cautions Polycystic ovary syndrome, uterine fibroids.
Side effects Visual disturbance - withdraw treatment; hot flushes, abdominal discomfort; occasionally nausea, vomiting depression, insomnia, breast tenderness, weight gain, rashes, dizziness and hair loss, headache, intermenstrual spotting, menorrhagia, endometriosis, convulsions.
Hepatic impairment Avoid in severe impairment.
Pregnancy category X
Breast-feeding May inhibit lactation, avoid.

21.3 Uterotonics

METHYLERGOMETRINE

Injection, 200 mcg/mL (1 mL) NRH/RRH/DH/PHC
Tablet,0.125 mg NRH/RRH/DH/PHC

Therapeutic group Uterotonic.

Indications and dose **Postpartum haemorrhage,** IM/IV injection, 0.2 mg every 2 to 4 hourly as needed but not to exceed 5 doses, then PO, 0.2 - 0.4 mg every 6 to 8 hourly as needed for 2 to 7 days.
Note *Administer IV only in emergency because of potential for hypertension and cerebrovascular accidents. Administer over >1 minute and monitor BP.*
Contraindications Antepartum haemorrhage; severe hypertension, toxaemia, heart disease, mitral valve stenosis
Cautions Sepsis, peripheral vascular disease, prolonged use.
Side effects Headache, nausea, vomiting, transient hypertension, vasoconstriction, myocardial infarction, seizure
Hepatic impairment Use with caution.
Renal impairment Use with caution.
Pregnancy category C
Breast-feeding Excreted in breast milk, avoid.

MISOPROSTOL

Tablet, 100 mcg NRH/RRH/DH

Therapeutic group Uterotonics (prostaglandin analogues).
Indications and dose **Cervical ripening procedure - Induction of labour,** (Insert) 200 mcg vaginally; leave in for 24 hours or until active labour onset, (Tablet) 20 mcg to 25 mcg orally every 2 hours. **NSAID-induced gastric ulcer; Prophylaxis,**200 mcg ORALLY 4 times daily. **Postpartum haemorrhage** 600 to 1000 mcg orally, sublingually, or rectally one time (guideline dosage). **Termination of pregnancy,**(Buccal, Sublingual or Vaginal) Monotherapy, up to 70 days' gestation: 800 mcg buccally, SL or vaginally every 3 hours for up to 3 doses (3 doses typically used in studies; however, a number of maximum doses not specified.**(Vaginal or Sublingual) Monotherapy, second trimester**: 400 mcg vaginally or SL every 3 hours for up to 5 doses. Vaginal administration is preferred over sublingual administration in nulliparous women. If abortion is not complete after 5 doses, the cycle may be started again following a 12-hour rest period (guideline dosage). **(Vaginal/sublingual) Alternative monotherapy regimen, second trimester:** Loading dose of 600 to 800 mcg vaginally followed by 400 mcg SL (or vaginally) every 3 hours may be more effective (guideline dosage). **Incomplete medication abortion, up to 70 days gestation**: May use a repeat dose of misoprostol 1 week after treatment depending on clinical circumstances or patient preferences (guideline dosage). **Ulcer of duodenum,**800 mcg/day in 2 or 4 divided doses for 4 weeks.
Contraindications Pregnancy, breastfeeding, allergy to prostaglandins.
Cautions Conditions where hypotension might precipitate severe complications (e.g. cerebrovascular disease or cardiovascular disease), inflammatory bowel disease.
Side effects Nausea, vomiting, diarrhoea, abdominal cramps, flatulence, dizziness, dyspepsia, menorrhagia.
Renal impairment Use with caution.
Pregnancy Category X
Breast-feeding Excreted in breast milk, avoid.

OXYTOCIN

Injection, 5 IU /mL (1 mL) NRH/RRH/DH/PHC

Therapeutic group Uterotonic.
Indications and dose **Induction of labour**, by IV infusion, 0.001– 0.004 IU/mins initially (not to be started for at least 6 hours after administration of vaginal prostaglandin), dose increased at intervals of at least 30 minutes until a maximum of 3–4 contractions occur every 10 minutes up to max. 0.02 IU/minute; if regular contractions are not established after a total of 5 units, stop induction attempt (may be repeated next day starting again at 0.001–0.004 IU/minute); **Treatment of postpartum haemorrhage,** by slow IV injection, 5 IU, repeated if necessary.
Note *Do not use as IV bolus; to control bleeding in incomplete abortion, methylergometrine should be used; the uterus in early pregnancy responds better to methylergometrine*.
Contraindications Hypertonia of uterus; mechanical obstruction to delivery; failed trial of labour; severe pre-eclampsia; foetal distress; placenta praevia.
Cautions Hypertension; high parity, previous caesarean section, multiple pregnancies, women over 35 years.

Side effects High doses cause violent uterine contractions leading to uterine rupture and/or foetal asphyxiation; arrhythmias, maternal hypertension and subarachnoid haemorrhage may also occur, headache, nausea, vomiting.
Pregnancy Category X
Breast-feeding Excreted in breast milk, commencement of breastfeeding should be delayed for at least 1 day when discontinued, use caution.

21.4 Other medicines administered to the mother

DEXAMETHASONE

Injection, 4 mg/mL (2 mL) NRH/RRH/DH/PHC

Therapeutic group corticosteroid. *For details, refer to page no. 24.*

TRANEXAMIC ACID

Injection, 50 mg/mL (5 mL) NRH/RRH

Therapeutic group Homeostatic agent.
Indications and dosage **Postpartum haemorrhage Vaginal delivery;** 1 g IV soon after diagnosis; a second dose may be given if bleeding continues after 30 minutes. **Postpartum haemorrhage prophylaxis** 1 g IV after vaginal delivery of anterior shoulder or delivery of baby or 10 to 20 minutes before skin incision or spinal anaesthesia for caesarean delivery. *For details, refer to page no. 78.*

21.5 Medicines administered to the neonate

CAFFEINE CITRATE

Injection, 20 mg/mL (1 mL) NRH/RRH

Therapeutic Group Respiratory stimulant.
Indications and dose Neonatal apnea, By IV infusion, initially 10-20 mg/kg, administered over 30 minutes, then after 24 hours of initial dose administer 5 mg/kg/day over 10 minutes; increased if necessary to 10 mg/kg/day.
Caution Cardiovascular diseases, gastro-esophageal reflux disorder, seizure disorders.
Side effects Fluid and electrolyte imbalance, hyperglycemia, hypertension, hypoglycemia, irritability, restlessness, tachycardia.
Hepatic impairment Use with caution in patients with hepatic impairment.
Renal Impairment Use with caution in patients with renal impairment.

21.6 Medicines used in Genito-urinary disorders

21.6.1 Medicines used in benign prostatic hyperplasia

FINASTERIDE

Tablet, 5 mg NRH/RRH/DH

Therapeutic group Medicines used in benign prostatic hyperplasia.
Indications and dose **Benign prostatic hyperplasia,** ADULT 5mg daily.
Note *Review treatment at 3 - 6 months and then every 6 - 12 months. May require several months of treatment before benefit is obtained.*
Cautions Obstructive uropathy.
Side effects Decreased libido, erectile dysfunction, ejaculation disorders, and reduced volume of ejaculate; rarely gynecomastia, pruritus rash.
Hepatic impairment Use with caution.
Renal impairment No dose adjustment necessary.
Pregnancy Category X

Counselling Take in the morning after breakfast. Women of childbearing potential should avoid handling crushed or broken tablets of finasteride.

TAMSULOSIN

Tablet, 0.4 mg NRH/RRH/DH

Therapeutic group Medicine used in benign prostatic hyperplasia.
Indications and dose **Symptomatic relief in benign prostatic hypertrophy,** PO ADULT, 0.4 mg once daily.
Contraindications History of micturition, syncope, history of postural hypotension.
Caution Cataract surgery, concomitant antihypertensives, elderly.
Side effects Postural hypotension, headache, rhinitis, dizziness, back pain, tachycardia, syncope.
Hepatic impairment Avoid in severe impairment.

Renal impairment Use with caution if eGFR less than 10 mL/min.
Pregnancy Category B
Counselling Dizziness on standing may occur especially when starting treatment or dose is increased; stop the treatment if there is no benefit after 4-6 weeks of maximal treatment.

21.6.2 Medicines used in urinary frequency enuresis and incontinence

OXYBUTYNIN

Tablet, 2.5 mg NRH

Therapeutic group Medicine used in urinary frequency enuresis, and incontinence.
Indications and dose **Urinary frequency, urgency and incontinence; neurogenic bladder disorders instability,** ADULT AND CHILD 12 years and above, PO 5 mg 2-3 times daily increased to 5 mg 4 times daily if required; CHILD 5 – 11 years, initially 2.5 – 3 mg twice daily increased to 5 mg 2-3 times daily; ELDERLY, initially 2.5-3 mg 2 times daily, increased to 5 mg 2 times daily if tolerated. **Nocturnal enuresis associated with overactive bladder,** CHILD 5-17 years, 2.5 – 3 mg twice daily increased to 5 mg 2-3 times a day, last dose to be taken before bed.
Contraindications Myasthenia gravis, bladder outflow obstruction or urinary retention, severe ulcerative colitis, toxic mega colon, and in gastro-intestinal obstruction or intestinal atony; glaucoma, paralytic ileus.
Cautions Acute porphyria.
Side effects Dryness of mouth, constipation, flatulence and taste disturbances, dryness of eyes, blurred vision, dizziness, headache, fatigue, palpitation, difficulty in micturition, heat intolerance and dryness of skin.
Hepatic impairment Use with caution.
Renal impairment Use with caution.
Pregnancy category B
Breastfeeding Excreted in breast milk, avoid.
Counselling Do not drive or operate machinery.

22. MEDICINES FOR MENTAL AND BEHAVIOURAL DISORDERS

22.1 Medicines used in psychotic disorders

ARIPIPRAZOLE

Tablet, 10 mg NRH

Therapeutic group Antipsychotic.
Indications and dose **Schizophrenia** ADULT: Initially 10-15 mg PO once daily. Usual maintenance dose 15 mg PO once daily, MAX. Dose 30 mg once daily. CHILD (15-17 years): Initial 2 mg PO once daily for 2 days, then 5 mg PO once daily for 2 days, and then target dose, 10 mg PO once daily. May increase to MAX. 30 mg daily. **Moderate to severe manic episodes in Bipolar I Disorder and recurrence prevention of mania** ADULT: Initially 15 mg PO once daily MAX. dose 30 mg once daily. CHILD (10 years or older): Initial 2 mg PO once daily for 2 days, then 5 mg PO

once daily for 2 days, and then target dose, 10 mg PO once daily. May increase to MAX. 30 mg daily, titrated in 5 mg daily increments. ELDERLY > 65 years consider lower starting dose (5 mg once daily) when clinical factors warrant.
Contraindications CNS depression, comatose state and pheochromocytoma.
Cautions Cerebrovascular disease, elderly (reduce initial dose). The dose may need to be reviewed if concomitant use with strong CYP3A4/CYP2D6 inhibitors or inducers. Compulsive behaviour and impaired impulse control has been reported.
Side effects Anxiety, abnormal appetites, diabetes mellitus, fatigue, gastrointestinal discomfort, headache, hypersalivation, nausea and vision disorders.
Renal impairment No dosage adjustment required in renal impairment.
Hepatic impairment No dosage adjustment required in mild-moderate hepatic impairment. Use with caution in severe hepatic impairment.
Pregnancy category C
Breast-feeding Excreted in milk, use with caution.

CHLORPROMAZINE

Injection, 25 mg/mL (2 mL) NRH/RRH/DH
Tablet, 100 mg NRH/RRH/DH

Therapeutic group Antipsychotic.
Indications and dose **Psychosis, mania, agitation, violent behaviour** ADULT: PO 25 mg 3 times daily (or 75 mg at night); normal maintenance dose 75-300 mg daily, maximum (psychosis) 1 g daily; CHILD: 1-5 years, 0.5 mg/kg 6 hourly, MAX. 40 mg daily; CHILD 6-12 years, 1/3 to 1/2 adult dose, MAX. 75 mg daily; ELDERLY: 1/3 to 1/2 adult dose; by deep IM injection, ADULT: 25-50 mg 3-4 times daily; CHILD: dose same as by oral administration; **Intractable hiccup** ADULT: PO 25-50 mg 3-4 times daily.
Contraindications Bone marrow depression, closed-angle glaucoma, and coma due to CNS depressants, hypothyroidism, pheochromocytoma.
Cautions Cardiovascular and cerebrovascular disorders, respiratory disease; parkinsonism, epilepsy, acute infections, history of jaundice, leukopenia, hypothyroidism, myasthenia gravis, prostatic hypertrophy, angle-closure glaucoma, the elderly (particularly in very hot or very cold weather; reduce dose), avoid abrupt withdrawal, patients should remain supine and blood pressure monitored for 30 minutes after intramuscular injection (risk of hypotension), diabetes.
Side effects Extrapyramidal symptoms and on prolonged administration, occasionally potentially irreversible tardive dyskinesias; hypothermia (occasionally pyrexia), drowsiness, apathy, pallor, nightmares, dizziness, excitement, insomnia, headache, confusion, depression; more rarely, agitation, EEG changes, convulsions, and nasal congestion; anticholinergic symptoms including dry mouth, constipation, blurred vision, and difficulty in micturition; hypotension, tachycardia, and arrhythmias; respiratory depression; menstrual disturbances, galactorrhea, gynecomastia, impotence, weight gain; sensitivity reactions such as agranulocytosis, leukopenia, leukocytosis, hemolytic anaemia, photosensitization, contact sensitization and rash, jaundice, and alterations in liver function; neuroleptic malignant syndrome; lupus erythematosus-like syndrome; corneal and lens opacities, and purplish pigmentation of the skin, cornea, and retina (with prolonged high dosage); intramuscular injection may be painful and cause hypotension and tachycardia (see cautions) and nodule formation.
Hepatic impairment Can precipitate coma, avoid.
Renal impairment Starts with small doses in severe renal impairment because of increased cerebral sensitivity.
Pregnancy category C
Breast-feeding excreted in breast milk, avoid.
Counselling Tablets should not be crushed; Do not drive or operate machinery, avoid alcohol.

FLUPHENAZINE DECANOATE

Injection, 25 mg/mL (1 mL) NRH/RRH

Therapeutic group Antipsychotic.
Indications and dose **Maintenance in schizophrenia and other psychoses:** By deep IM injection, ADULT: Test dose 12.5 mg, dose to be administered into the gluteal muscle, then 12.5-100 mg after 4-7 days, then 12.5-100 mg every

14-35 days, adjusted according to response; ELDERLY, Test dose 6.25 mg, dose to be administered into the gluteal muscle, then 12.5-100 mg after 4-7 days, then 12.5-100 mg every 14-35 days, adjusted according to response.
Contraindications Comatose states, CNS depression, pheochromocytoma, marked cerebral atherosclerosis.
Cautions QT prolongation, cardiovascular disease, Parkinson's disease, epilepsy (and conditions predisposing to epilepsy), depression, myasthenia gravis, prostatic hypertrophy, or a personal or family history of angle-closure glaucoma, severe respiratory disease, elderly.
Side effects Extrapyramidal symptoms and on prolonged administration, occasionally potentially irreversible tardive dyskinesias; hypothermia (occasionally pyrexia), drowsiness, apathy, pallor, nightmares, dizziness, excitement, insomnia, headache, confusion, depression; more rarely, agitation, EEG changes, convulsions, and nasal congestion; anticholinergic symptoms including dry mouth, constipation, blurred vision, and difficulty in micturition; hypotension, tachycardia, and arrhythmias; respiratory depression; menstrual disturbances, galactorrhea, gynecomastia, impotence, weight gain; sensitivity reactions such as agranulocytosis, leukopenia, leukocytosis, hemolytic anaemia, photosensitization, contact sensitization and rash, jaundice, and alterations in liver function; neuroleptic malignant syndrome; lupus erythematosus-like syndrome; corneal and lens opacities, and purplish pigmentation of the skin, cornea, and retina (with prolonged high dosage); intramuscular injection may be painful and cause hypotension and tachycardia (see cautions) and nodule formation.
Hepatic impairment May precipitate coma. Avoid in hepatic failure.
Renal impairment Start with low doses in severe renal impairment because of increased cerebral sensitivity.
Pregnancy Category C
Breast-feeding Enters breast milk, avoid.
Counselling Drowsiness may affect performance of skilled tasks (e.g., driving or operating machinery) especially at the start of treatment; Effects of alcohol are enhanced; Patients should avoid excessive exposure to sunlight.

HALOPERIDOL

Injection, 5 mg/mL (1 mL) NRH/RRH/DH

Therapeutic group Antipsychotic.
Indications and dose **Psychosis, mania, agitation, violent behaviour,** By IM injection, Initially 2–5 mg, repeated if necessary, repeated dose given according to response and tolerability, for debilitated patients, use elderly dose (max.12 mg/day); ELDERLY, Initially 1-2.5 mg, repeated if necessary, repeated dose given according to response and tolerability; (max.12 mg/day).
Contraindications Bone marrow depression, closed-angle glaucoma, coma due to CNS depressants, Parkinsonism, pheochromocytoma, bradycardia, QT interval prolongation, lesions of basal ganglia.
Cautions Cardiovascular and cerebrovascular disease, respiratory disease, parkinsonism, epilepsy, pregnancy and breast-feeding, history of jaundice; caution in elderly patients who are susceptible to postural hypotension and to hyper- and hypothermia in very hot or very cold weather.
Side effects Extrapyramidal effects are common at higher dosage, hypothermia, drowsiness, insomnia, depression, occasional reactions like agranulocytosis, leukopenia and photosensitivity may occur.
Hepatic impairment May precipitate coma. Avoid in severe impairment.
Renal impairment Start with low doses in severe renal impairment because of increased cerebral sensitivity.
Pregnancy category C
Breast-feeding Excreted in breast milk, avoid.
Counselling May cause drowsiness, if affected do not operate machinery and avoid alcohol.

OLANZAPINE

Tablet, 10 mg NRH/RHH/DH

Therapeutic group Antipsychotic.
Indications and dose **Schizophrenia, combination therapy for mania, preventing recurrence in bipolar disorder** ADULT: PO 10 mg daily adjusted to usual range of 5-20 mg daily; Doses greater than 10 mg daily only after reassessment; MAX 20 mg daily.

Cautions Prostatic hypertrophy, paralytic ileus, diabetes mellitus (risk of exacerbation or ketoacidosis), low leucocyte or neutrophil count, bone marrow depression, hyper eosinophilic disorders, myeloproliferative disease, Parkinson's disease, increased appetite, raised triglyceride concentration, oedema.
Side effects Mild, transient antimuscarinic effects, drowsiness, speech difficulty, exacerbation of Parkinson's disease, akathisia, asthenia, increased appetite, raised triglyceride concentration, oedema, hyperprolactinemia, weight gain, orthostatic hypotension.
Hepatic impairment Consider initial dose of 5 mg daily.
Renal impairment Consider initial dose of 5 mg daily.
Pregnancy category C
Breast-feeding Excreted in breast milk, avoid.
Counselling Orodispersible tablets should be placed on the tongue, allowed to dissolve, and swallowed.

QUETIAPINE

Tablet, 50 mg and 300 mg NRH/RRH

Therapeutic group Antipsychotic.
Indications and doses **Bipolar** ADULT: PO 50 mg twice daily on day 1, 100 mg PO twice daily on day 2, PO 150 mg twice daily on day 3, PO 200 mg twice daily on day 4; usual dose range PO 400 - 800 mg daily in 2 divided doses, MAX. Up to 800 mg per day. ELDERLY: Initially 50 mg PO daily, adjust accordingly to the response in steps of 50 mg daily. CHILD (12 - 17 years): 25 mg twice daily on day 1, increase to 50 mg twice daily on day 2, then 100 mg twice daily on day 3, then 150 mg twice daily on day 4, then continue at the target dose of 200 mg twice daily beginning on day 5. May increase based on clinical response and tolerability at increments ≤100 mg/day up to 300 mg twice daily; Max/dose 600 mg per day. **Schizophrenia** ADULT: Initially PO 25 mg twice daily on day 1, 50 mg twice daily on day 2, 100 mg twice daily on day 3, 150 mg twice daily on day 4; usual dose range: 300 - 450 mg daily; MAX. dose: 750 mg daily. ELDERLY: initially 25 mg daily, adjust accordingly to the response in steps of 25 mg - 50 mg daily. CHILD (12 - 17 years): 25 mg twice daily, adjusted according to the response in steps of 25 - 50 mg; MAX. 750 mg/day.
Contraindications Hypersensitivity to quetiapine or any components of the product.
Cautions Cerebrovascular disease. Treatment of depression in patients under 25 years, increase risk of suicidal thoughts. When taken with a strong CYP3A4 inducer (e.g; phenytoin, carbamazepine, rifampin, St John's wort) greater than 7 – 14 days, titrate dose based on clinical response and tolerability as much as 5 folds. When the CYP3A4 inducer is discontinued, reduce quetiapine to the original dose within 7 to 14 days. When used together with a strong CYP3A4 inhibitor (e.g; ketoconazole, itraconazole, ritonavir) reduce quetiapine dose to one-sixth of the original dose. When the CYP3A4 inhibitor is discontinued, increase quetiapine dose by 6-fold.
Side effects Increase diastolic and systolic arterial pressure (paediatric), orthostatic hypotension, tachycardia, hyperglycemia, serum cholesterol and triglyceride raise, weight gain, increase appetite, nausea, vomiting, dry mouth, somnolence, agitation, drowsiness, dizziness, rhinitis, constipation, indigestion and fatigue.
Hepatic impairment 25 mg once daily; increase dose based on response and tolerability by 25 to 50 mg/day to effective dose.
Renal impairment No dose adjustment necessary
Pregnancy category C
Breast-feeding Excreted in breast milk, use with caution.
Counselling Take with/without food. Advise patients to stand from sitting position slowly, as the medicine may cause orthostatic hypotension and avoid abrupt discontinuation of the medicine. Counsel diabetic patients to monitor signs/symptoms of hyperglycemia. Inform patients of weight gain, dry mouth, nausea and vomiting.

RISPERIDONE

Tablet, 2 mg NRH/RRH/DH

Therapeutic group Antipsychotic.
Indications and dose **Acute and chronic psychoses** ADULT: PO 2 mg in 1-2 divided doses on day 1 then 4 mg in 1-2 divided doses on day 2; doses above 10 mg daily only if benefit considered to outweigh risk (max. 16 mg daily);

ELDERLY, initially 0.5 mg twice daily increased in steps of 0.5 mg twice daily to 1-2 mg twice daily; CHILD under 15 years, not recommended; **Mania**: ADULT: initially PO 2 mg once daily, increased if necessary in steps of 1 mg daily; usual dose range 1-6 mg daily; ELDERLY, initially 0.5mg twice daily increased in steps of 0.5mg twice daily to 1-2 mg twice daily.
Cautions Acute porphyrias, cataract surgery, dehydration, dementia, prolactin-dependent tumours.
Side effects Insomnia, agitation, anxiety, headache, drowsiness, impaired concentration, fatigue, blurred vision, constipation, nausea and vomiting, dyspepsia, abdominal pain, hyperprolactinemia (with galactorrhea, menstrual disturbances, amenorrhea, gynecomastia), sexual dysfunction, priapism, urinary incontinence, tachycardia, hypertension, rash, rhinitis; cerebrovascular accidents, neutropenia and thrombocytopenia have been reported, rarely, seizures, hyponatremia, abnormal temperature regulation, oedema.
Hepatic impairment Initial and subsequent oral doses should be halved.
Renal impairment Initial and subsequent oral doses should be halved.
Pregnancy category C
Breast-feeding Excreted in breast milk, avoid.
Counselling Orodispersible tablets should be placed on the tongue, allowed to dissolve, and swallowed.

22.2 Medicines used in mood disorders

22.2.1 Medicines used in depressive disorders

AMITRIPTYLINE

Tablet, 25 mg NRH/RRH/DH

Therapeutic group Antidepressant.
Indications and dose **Depression with agitation or insomnia and anxiety** ADULT, 50-75 mg PO (ELDERLY and ADOLESCENT), start at 25-50 mg daily in divided doses, or as a single dose at bedtime; Increase gradually as necessary; Usual maintenance dose: 50-100 mg daily, MAX. 150-200 mg/day.
Contraindications Acute porphyria, arrhythmia, recent myocardial infarction, heart block, mania.
Cautions Diabetes, heart disease with arrhythmia, epilepsy, pregnancy (use only if potential benefit outweighs risk), breast feeding, elderly, hepatic impairment, thyroid disease, co-existing psychosis, closed-angle glaucoma, urinary retention; upon completion of treatment, the medicine should be slowly withdrawn.
Side effects Drowsiness and dry mouth, blurred vision, constipation and urinary retention; patients should be encouraged to continue with the treatment, as some side effects will decrease after use.
Hepatic impairment Avoid in severe liver disease.
Pregnancy category C
Breast-feeding The amount secreted into breast milk is too small to be harmful.
Counselling Drowsiness may affect performance of skilled tasks (e.g. driving or operating machinery) especially at start of treatment; effects of alcohol are enhanced.

FLUOXETINE

Tablet, 20 mg NRH

Therapeutic group Antidepressant.
Indications and dose **Depressive illness** 20 mg PO once daily increased after 3 weeks if necessary; Usual dose 20-60 mg (ELDERLY 20-40 mg) once daily; MAX. 80 mg (elderly max. 60 mg) once daily; CHILD 8 -18 YEARS, 10-20 mg per day. **Obsessive-compulsive disorder** Initially PO 20 mg once daily increased after two weeks if necessary, usual dose 20-60 mg (ELDERLY 20-40 mg) once daily; MAX. 80 mg (ELDERLY max. 60 mg) once daily; Discontinue if no improvement within 10 weeks; CHILD 7-18 years, initial 10 mg per day gradually increased after 2 weeks to 20 mg.
Cautions Elderly, ventricular arrhythmia, diabetes, seizures.
Side effects Possible changes in blood sugar, fever, neuroleptic malignant syndrome-like event, abnormal bleeding, aplastic anaemia, cerebrovascular accident, ecchymosis, eosinophilic pneumonia, GI haemorrhage, hemolytic anaemia, pancreatitis, pancytopenia, thrombocytopenia, thrombocytopenic purpura, alopecia, headache

Hepatic impairment Reduce dose or increase dose interval.
Renal impairment Use with caution.
Pregnancy category C
Breast-feeding Excreted in breast milk, avoid.
Counselling Dose should be taken preferably in the morning. Patients should be counselled about the effects on driving and skilled tasks.

MIRTAZAPINE

Tablet, 15 mg NRH

Therapeutic group Antidepressant.
Indications and dose **Major depression** ADULT: Initially PO 15–30 mg daily at bedtime for 2-4 weeks. Adjust according to response up to 45 mg once daily or 45 mg daily in 2 divided doses MAX. 45 once daily. Gradually taper the dose over 2-4 weeks.
Contraindications Use in combination with monoamine oxidase inhibitors (MAOI therapy) including linezolid and IV methylene blue. MAOIs should not be introduced within 2 weeks of cessation of therapy with mirtazapine. Avoid use with benzodiazepines and alcohol.
Cautions Cardiovascular disease or family history of QT-prolongation, concomitant use with other QT prolonging medicines, diabetes mellitus, elderly. History of mania, seizures, and urinary retention. Hypotension, psychoses, susceptibility to angle-closure glaucoma.
Side effects Anxiety, somnolence, xerostomia, appetite increased, arthralgia, back pain, confusion, constipation, diarrhoea, dizziness, drowsiness, dry mouth, fatigue. headache (on discontinuation), myalgia, nausea, oedema, postural, hypotension, sleep disorders, tremor, vomiting, increase cholesterol and weight.
Hepatic impairment Use caution in patients with hepatic impairment.
Renal impairment If CrCl < 30 mL/minute/1.73 m^2; adjust initial dose 7.5-15 mg, titrate dose slowly.
Pregnancy category C
Breast-feeding Present in milk, use with caution (only if potential benefit outweighs risk).
Counselling Cause drowsiness should be taken at bedtime. Advised care giver as it may increase risk of suicidal thoughts and behavior in young adult patients (aged <24 years).

VENLAFAXINE

Tablet (extended release), 75 mg NRH/RRH

Therapeutic group Antidepressant.
Indications and dose **Major depression** PO 75 mg once daily initially, may be increased by 75 mg/day at intervals of at least 2 weeks (MAX. 375 mg/day) **Generalised anxiety** PO 75 mg once daily, increased if necessary up to 225 mg once daily, dose to be increased at intervals of at least 2 weeks (MAX. 225 mg/day).
Contraindications Uncontrolled hypertension, high risk of serious ventricular arrhythmia, electrolyte disturbance.
Cautions History of MI, bleeding disorder; epilepsy, angle closure glaucoma, diabetes.
Side effects Constipation, nausea, dizziness, dry mouth, insomnia, suicidal ideation, nervousness, drowsiness; asthenia, headache, sexual dysfunction, sweating, anorexia, weight changes, diarrhea, dyspepsia, vomiting, abdominal pain, hypertension, palpitation, vasodilation, changes in serum cholesterol, chills, pyrexia, dyspnea, abnormal dreams, agitations, confusions, anxiety, hypertonia, paraesthesia, tremor, urinary frequency, menstrual disturbance, mydriasis, tinnitus, hypotension, postural hypotension, alopecia, Steven-Johnson syndrome.
Hepatic impairment Consider reducing dose by 50% in mild or moderate impairment; use with caution and reduce dose by at least 50% in severe impairment.
Renal impairment Use half normal dose if eGFR less than 30 mL/minute. Use with caution.
Pregnancy Category C
Breast-feeding Excreted in breast milk, avoid.
Counselling To be taken after food. Do not chew or crush the tablet, swallow whole. Do not drive or operate machineries.

22.2.2 Medicines used in bipolar disorders

CARBAMAZEPINE

Tablet, 200 mg — NRH/RRH/DH

Therapeutic group Medicines used in bipolar disorder.
Indications and dose **Prophylaxis of bipolar disorder unresponsive to lithium** ADULT: Initially 400mg PO daily in divided doses, increased until symptoms are controlled up to a maximum 1.6 g/day given 3 to 4 divided doses. *For details, refer to page no. 30.*

22.3 Medicines for anxiety disorders

CLOBAZAM

Tablet, 5 mg — NRH/RRH

Therapeutic group Antianxiety.
Indications and doses **Anxiety (short-term use)** ADULT: 20–30 mg PO daily in divided doses, alternatively 20–30 mg once daily at bedtime; Increase if necessary up to 60 mg daily in divided doses, dose only increased in severe anxiety (in hospital patients). For debilitated patients, use elderly dose. Elderly: 10–20 mg daily.
For details, refer to page no. 31.

CLONAZEPAM

Tablet, 0.5 mg — NRH/RRH

Therapeutic group Antianxiety.
Indications and doses **Panic Disorder** ADULT: Initially 0.25 mg PO twice daily, may increase to 1 mg/day after 3 days (up to 4 mg/day in some patients). *For details, refer to page no. 31.*

DIAZEPAM

Injection, 5 mg/mL (2 mL) — NRH/RRH/DH/PHC
Tablet, 5 mg — NRH/RH/DH/PHC

Therapeutic group Antianxiety.
Indications and dose **Short-term use in anxiety and insomnia** ADULT: PO 2.5-5 mg 3 times daily or PO 5-15 mg at bedtime. **Acute Alcohol withdrawal,** by IM or slow IV injection, ADULT: 10 mg, then 10 mg after at least four if required, IV injection to be administered into a large vein at a rate not exceeding 5 mg/min.
Contraindications Respiratory depression, severe hepatic impairment, chronic psychosis.
Cautions Muscle weakness; reduce dose in elderly; avoid prolonged use and abrupt withdrawal.
Side effects Drowsiness and light-headedness, persisting until the next day, confusion and ataxia in the elderly, tolerance, amnesia, muscle weakness, hypotension, apnoea.
Hepatic impairment Avoid in severe impairment.
Renal impairment Start with small doses in severe impairment.
Pregnancy category D
Breast-feeding Excreted in breast milk, avoid.
Counselling Drowsiness may affect performance of skilled tasks (e.g. driving or operating machinery); effects of alcohol are enhanced.

LORAZEPAM

Tablet, 1 mg — NRH

Therapeutic group Antianxiety.

Indications and dose **Short-term use in anxiety or insomnia** ADULT: PO 1–4 mg daily in divided doses; ELDERLY (or debilitated), half the adult dose. **Insomnia associated with anxiety** ADULT PO 1-2 mg at bedtime.
Contraindications Chronic psychosis, CNS depression, compromised airway, hyperkinesia, obsessional states, phobic states, respiratory depression.
Cautions Muscle weakness, organic brain changes, personality disorder.
Side effects Amnesia, ataxia (especially in elderly), confusion (especially in the elderly), dependence, drowsiness the next day, light-headedness the next day, muscle weakness, paradoxical increase in aggression.
Hepatic impairment May precipitate coma. Avoid in severe impairment.
Renal impairment Start with small doses in severe impairment.
Pregnancy category D
Breast-feeding Excreted in breast milk, avoid.
Counselling Drowsiness may affect performance of skilled tasks (e.g. driving or operating machinery); effects of alcohol are enhanced.

MIDAZOLAM

Injection, 1 mg/mL (10 mL) NRH/RRH/DH

Therapeutic group Antianxiety.
Indications and dose **Anxiety-Induction of amnesia-preoperative sedation** ADULT: IM 70-80 mcg/kg (dose range ~5 mg) 30-60 minutes before surgery (reduce 50% for chronically ill or geriatric patients).IV Initially 0.5-1 mg given over 2 minutes (not to exceed 2.5 mg/dose); wait 2-3 minutes to evaluate sedative effect after each dose adjustment; total dose >5 mg usually not necessary to reach desired sedation; use 30% less midazolam if patient premeditated with narcotics or other CNS depressants. **Debilitated or chronically ill patients** 1.5 mg IV initially; may repeat with 1 mg/dose IV q2-3 min PRN; not to exceed cumulative dose of 3.5 mg; peak effect may be delayed in elderly, so increments should be smaller and rate of injection slower. **Maintenance**: 25% of initial effective dose PRN by slow titration; reduce 30% if premeditated with opiate (50% in elderly/chronically ill). *For details, refer to page no. 15*

22.4 Medicines for disorders due to psychoactive substance use

BUPRENORPHINE

Tablet sublingual, 2 mg NRH

Therapeutic group Medicine for disorders due to psychoactive substances.
Indications and dosage **Little or no opioid withdrawa**l ADULT: sublingual 0.4 mg to 4 mg or delay the initial dose. **Moderate to severe opioid withdrawal** 6 to 8 mg in divided dose. The maximum amount of buprenorphine at the end of the first day of induction ranges from 8 to 16 mg. The maintenance dosage should be individualised for each patient. The maintenance dosage will vary between individuals and should be determined by progressively increasing the dose until the minimal effective dose is identified. The mean maintenance daily dose is 8 mg. The majority of patients will not require doses exceeding 16 mg/day; however, the efficacy and safety of buprenorphine tablets was tested in clinical trials in doses up to 24 mg per day. After a satisfactory period of stabilisation has been achieved, the dosage may be reduced gradually to a lower maintenance dose, when appropriate treatment deemed may be discontinued.
Contraindications hypersensitivity, significant respiratory depression, acute and severe bronchial asthma, children < 16 years of age.
Cautions risk of opioid addiction, abuse and misuse which may lead to overdose.
Side effects Sedation, vomiting, nausea, dizziness, constipation, hypoventilation, headache, hypotension, miosis, dry mouth, euphoria, fatigue, respiratory depression, hepatotoxicity, cyanosis, ECG abnormalities
Hepatic impairment Severe impairment: reduce the starting and titration increment dose by half and monitor for signs and symptoms of hepatotoxicity.
Pregnancy category C
Breast-feeding Enters breast milk, not recommended.

Counselling Do not drink any fluids immediately following administration by sublingual route. May cause dizziness, drowsiness, confusion, or blurred vision (use caution when driving, climbing stairs, rising from sitting or lying position, or engaging in tasks requiring alertness).

DISULFIRAM

Tablet, 250 mg NRH/RRH

Therapeutic group Medicines for disorders due to psychoactive substances.
Indications and dose **Management of chronic alcoholism** ADULT**:** 500mg PO once daily initially for 1-2 weeks, not to exceed 500mg/day. Only administer after the patient has abstained from ethanol for at least 12 hours. **Maintenance**: 250mg once in a day, continue therapy until a basis for self-control is established.
Contraindications Ethanol and any alcohol containing products (e.g, mouth wash, hand rub solution), metronidazole, severe cardiac disease, coronary occlusion, psychosis.
Cautions Never administered to patients in a state of alcohol in-toxification or without patient's full knowledge, diabetes, hypothyroidism, seizures, nephritis and hepatic impairment.
Side effects Fatigue, hepatitis, optic neuritis, psychotic disorder, rash, polyneuritis, acneiform eruption, metallic aftertaste, headache, impotence.
Pregnancy category C
Breast-feeding excretion in breast milk unknown, not recommended.
Counseling Do not drink any alcohol, including products containing alcohol (such as cough and cold syrups or some mouthwashes), or use alcohol-containing skin products while taking this medication and for at least 3 days (preferably 14 days) after stopping this medication. Drowsiness, tiredness, or visual changes may occur.

23. MEDICINES ACTING ON THE RESPIRATORY TRACT

23.1 Anti-asthmatic medicines and medicines for chronic obstructive pulmonary disease

ADRENALINE

Injection, 1 mg/mL (1 mL) NRH/RRH/DH/PHC

Therapeutic group Anti-asthmatic medicine.
Indications and dose **Asthma exacerbation** ADULT and CHILD > 12 years: 0.3 to 0.5 mg (0.3 to 0.5 mL of 1 mg/mL) subcutaneously every 20 minutes for 3 doses. CHILD < 12 years: 0.01 mg/kg/dose up to 0.3 to 0.5 mg (0.01 mL/kg up to 0.3 to 0.5 mL of 1 mg/solution) subcutaneously every 20 minutes for 3 doses. *For details, refer to page no. 23.*

BECLOMETHASONE DIPROPIONATE

Inhalation (MDI), 50 mcg/actuation (200 actuations) NRH/RRH/DH

Therapeutic group Anti-asthmatic medicine.
Indications and dose **Chronic asthma not controlled by short acting β-2 agonists** ADULT: by inhalation, 2 MDIs 2-3 times daily and in severe cases up to 4 times; CHILD: by inhalation,1 MDI 2-3 times daily.
Cautions Systemic therapy may be required during periods of stress or when either airway obstruction or mucus prevents medicine access to smaller airways.
Side effects Inhaled corticosteroids have considerably fewer systemic effects than oral corticosteroids; high doses of inhaled corticosteroids used for prolonged periods have been associated with oropharyngeal candidiasis cough and lower respiratory tract infection including pneumonia; adrenal suppression, growth retardation in children and adolescents, impaired bone metabolism, glaucoma and cataract.
Pregnancy category C
Breast-feeding Excretion in breast milk unknown, Use with caution.
Counselling Advise patient to avoid spraying in or around eyes; advise patient that medicine may cause dizziness and to use caution while driving or performing other tasks requiring mental alertness. Advise patients for MDI inhalation

technique (*refer to salbutamol MDI*). Rinse the mouth with water after inhalation to reduce the risk of oral candidiasis or use a spacer device if available.

FLUTICASONE + SALMETEROL

Inhalation (MDI), (250µg + 50µg)/actuation (200 actuations) NRH/RRH/DH

Therapeutic group Anti-asthmatic medicines and medicines for chronic obstructive pulmonary disease.
Indications and dose **Prophylaxis of asthma and management of chronic obstructive pulmonary disease** ADULT and CHILD over 5 years: by inhalation, initially 1 MDI twice daily, increased up to 2 to 3 MDIs twice daily in severe cases.
Contraindications Hypersensitivity to fluticasone, salmeterol or any ingredients in the formulation.
Cautions Arrhythmia, susceptibility to QT prolongation and diabetes; excessive dose of inhaled corticosteroids should be avoided in children.
Side effects Fine tremor, headache, muscle cramp, palpitation, tachycardia, arrhythmia, myocardial ischemia and disturbances of sleep behaviour; inhaled corticosteroids used in high doses and for prolonged period of time can cause adrenal suppression and reduction in bone mineral density; in older patients with COPD, higher doses of inhaled corticosteroid are associated with increased risk of lower respiratory tract infection including pneumonia; oral candidiasis.
Pregnancy category C
Breast-feeding Excretion in breast milk unknown, use with caution.
Counselling Do not use the preparation for the relief of acute attack; Rinse the mouth with water after inhalation to reduce the risk of oral candidiasis or use a spacer device if available. *For MDI inhalation technique refer to salbutamol MDI.*

IPRATROPIUM

Inhalation solution, 0.25 mg/mL (15 mL) NRH/RRH/DH

Therapeutic group Anti-asthmatic medicines and medicines for chronic obstructive pulmonary disease.
Indications and dose **Chronic obstructive pulmonary disease** ADULT by inhalation of nebulized solution, 250-500 mcg 3-4 times daily. **Adjunct in acute bronchospasm** ADULT 500 mcg repeated as required. CHILD up to 6 years, 125-250 mcg, maximum 1mg daily; CHILD 6-12 years, 250 mcg, MAX. 1mg daily.
Contraindications Hypersensitivity to ipratropium or any ingredients in the formulation.
Cautions Prostatic hypertrophy; pregnancy; glaucoma (in case of nebulized medicine in association with salbutamol); risk of paradoxical bronchospasm.
Side effects Occasionally dry mouth; rarely urinary retention and constipation; tachycardia and atrial fibrillation.
Pregnancy category C
Breast-feeding Excretion in breast milk unknown, use with caution.
Counselling Advise patient to avoid spraying in or around eyes; advise patient that medicine may cause dizziness and to use caution while driving or performing other tasks requiring mental alertness.

SALBUTAMOL

Inhalation (MDI), 100 mcg/actuation (200 actuations) NRH/RRH/DH/PHC
Respiratory solution, 5 mg/mL (15 mL) NRH/RRH/DH/PHC

Therapeutic group Anti-asthmatic medicines and medicines for chronic obstructive pulmonary disease.
Indications and dose Asthma**, Bronchospasm in patients with reversible obstructive airway** ADULT by nebulization (respiratory solution). **For intermittent administration** ADULT, 0.5-1 mL of respiratory solution diluted to a final volume of 2-4 mL with 0.9% sodium chloride to be inhaled from a suitably driven nebulizer until aerosol generation ceases; CHILD under 12 years, 0.03 mL/kg of solution diluted to 2-4 mL with 0.9% sodium chloride and inhaled from a nebulizer. **For continuous administration** 1-2 mL of the respiratory solution diluted to 100 mL with 0.9% sodium chloride to contain 50-100 mcg salbutamol per mL. The diluted solution to be administered as aerosol by a suitably driven nebulizer. The usual rate of administration is 1-2 mg per hour by inhalation. **Management of chronic**

asthma 2 puffs upto 4 times daily; CHILD, 1 puff, increase to 2 puffs, if necessary, up to 4 times daily; **Prophylaxis of allergen or exercise induced bronchospasm** 2 puffs as and when required.
Contraindications Hypersensitivity and thyrotoxicosis.
Cautions Hyperthyroidism, myocardial insufficiency, arrhythmias, hypertension, elderly patients, diabetics.
Pregnancy category C
Breast-feeding Excretion in breast milk unknown, Use with caution.
Side effects Fine tremor, nervous tension, headache, peripheral vasodilatation, tachycardia, sleep and behavioural disturbance in children.
Counselling MDI inhalation technique:

1. **Without spacer**
    0. Put the metal canister into the "boot" making certain it is seated correctly
    1. Shake the inhaler several times. This mixes the propellant and medicine
    2. Remove the cap off from the mouthpiece
    3. Breathe out to the end of a normal breath
    4. Hold the inhaler in its upright position (with the mouthpiece at the bottom)
    5. Put the mouthpiece in your mouth, past your teeth and above your tongue. Close your lips around the mouthpiece so that the medication does not go in your eyes
    6. While breathing in slowly and deeply through your mouth, fully press down once on the top of the metal canister of your inhaler
    7. Hold your breath for 5 to 10 seconds
    8. Breathe out slowly
    9. If you take more than one spray, wait 15 to 30 seconds (or as directed in the package insert) before taking the next puff. Then repeat steps 3-9
    10. Replace the cap on the mouthpiece after you are finished
    11. If you are inhaling a steroid, rinse your mouth out with water, swish, gargle and spit.
2. **With spacer**
    0. Make sure that the metal canister of your MDI is inserted correctly into the plastic "boot" or holder
    1. Remove the cap from the mouthpiece of both the MDI and the spacer
    2. Insert the MDI mouthpiece in the soft opening of the spacer. The MDI canister needs to be in an upright position
    3. Shake the MDI with the attached spacer several times
    4. Breathe out, away from the spacer to the end of your normal breath
    5. Place the mouthpiece of the spacer into your mouth, past your teeth and above your tongue. Close your lips around the mouthpiece. If you are using a spacer with a mask, place the mask over your nose and mouth. Be sure the mask has a good seal against your cheeks and chin. There should be no space between the mask and your skin
    6. Press down on the top of the metal canister once, to release the medicine into the spacer
    7. Breathe in deeply and slowly through your mouth. If the spacer makes a "whistling" sound, you are breathing in too fast. You should NOT hear a whistle
    8. Hold your breath for 5 to 10 seconds
    9. Breathe out slowly
    10. If you are instructed to take more than one puff (spray), wait about 15 to 30 seconds (or as directed by the package insert) before taking the next puff. Then repeat steps 4-10
    11. Replace the cap on the mouthpiece of the MDI inhaler and spacer after you have finished
    12. If you are inhaling a steroid, rinse your mouth out with water, swish, gargle and spit.

THEOPHYLLINE+ETOPHYLLINE

Tablet (retard), (69 mg+231 mg) NRH/RRH/DH

Therapeutic group Anti-asthmatic medicines and medicines for chronic obstructive pulmonary disease.
Indications and dose **Prophylaxis and relief of reversible bronchospasm associated with asthma (Acute and Chronic), bronchitis including chronic bronchitis, emphysema, and other obstructive airway diseases where there is a reversible airway narrowing** ADULT PO 1 tablet 1 to 2 times daily.
Contraindications Hypersensitivity; Neonates and lactation.

Cautions Patients with severe cardiac disease, hypertension, hyperthyroidism, acute myocardial injury, CCF, history of peptic ulcer, children, pulmonary oedema, hepatic dysfunction, pregnancy and smokers.
Side effects Cardiac arrhythmias in pre-existing cardiac disease, tachycardia anorexia, nausea, tremors, CNS excitation, and hyperglycemia.
Pregnancy category C
Breast-feeding Excreted in breast milk, Use with caution.

TIOTROPIUM

Inhalation (MDI), 9 mcg/actuation (200 actuations) NRH/RRH

Therapeutic group Anti-asthmatic and medicines for chronic pulmonary obstructive disease.
Indications and dose **Chronic obstructive pulmonary disease** ADULT by inhalation, 2 puffs once daily.
Contraindications Hypersensitivity to tiotropium or any ingredients in the formulation.
Cautions Immediate hypersensitivity reactions, acute bronchospasm, closed-angle glaucoma, cardiac arrhythmias, anticholinergic medications, bladder obstruction, prostatic hypertrophy, urinary retention, urinary tract obstruction, arthralgia and lymphadenopathy.
Side effects Upper respiratory tract infection, constipation, oral ulcer, dry mouth, sinusitis, atrial fibrillation, urinary retention, angioedema, allergic reaction and abdominal pain.
Pregnancy category C
Breast-feeding Excretion in breast milk unknown, Use with caution.
Renal impairment Moderate to severe renal impairment (creatinine clearance of < 60 mL/min) should be monitored closely for anticholinergic side effects.
Counselling Advise patient to avoid spraying in or around eyes; advise patient that medicine may cause dizziness and to use caution while driving or performing other tasks requiring mental alertness. Advise patients for MDI inhalation technique *(refer under salbutamol MDI)*.

24. SOLUTIONS CORRECTING WATER, ELECTROLYTE AND ACID–BASE DISTURBANCE

24.1 Oral

CALCIUM POLYSTYRENE SULFONATE

Oral powder, 15 g NRH/RRH

Therapeutic group Medicine for correcting water, electrolyte and acid–base disturbance.
Indications and dose **Hyperkalemia** ADULT PO 4 times daily in water (not in fruit squash which has high potassium content); CHILD: PO 0.5 g to 1 g/kg daily in 3-4 divided dose.
Contraindications Obstructive bowel disease; hypokalemia.
Cautions Children (impaction of resin with excessive dosage or inadequate dilution), pregnancy and breastfeeding.
Side effects GI disturbance, constipation; hypokalemia, hypocalcemia, hypomagnesaemia; nausea, vomiting; GI tract ulceration or necrosis which could lead to perforation.
Counselling Reconstitutes powdered resin as suspension in water or syrup; for each 1g of powdered resin add 3-4 mL of water or syrup; do not refrigerate.

ORAL REHYDRATION SALT (ORS)

Powder for reconstitution (1 g) NRH/RRH/DH/PHC

Therapeutic group Medicine correcting water, electrolyte and acid-base disturbance.
Indications and dose **Prevention and treatment of dehydration** by oral administration, usually 200-400 mL solution after every loose motion; **Moderate dehydration** INFANT (up to 4 months) 200-400 mL; INFANT (4 months -12 months) 400-700 mL; CHILD (12 months up to 2 years) 700-900 mL; CHILD (2 years-5 years): 900-1400 mL; **Severe dehydration** By IV injection, 100 mL/kg compound solution of sodium lactate (or sodium chloride 0.9%), divided as follows: INFANT (<12 months) 30 mL/kg in the 1st hour and 70 mL/kg from the 5th hour; CHILD (12 months-5 years): 30 mL/kg in the first ½ hour and 70 mL/kg from 2 ½ hours; repeat once if radial pulse is still very weak or not detectable;

reassess the child every 1-2 hours; if hydration status is not improving, give the IV drip more rapidly; also administer ORS (about 5 mL/kg/hour) as soon as the child can drink; usually after 3-4 hours (infants) and 1-2 hours (children); reassess an infant after 6 hours and a child after 3 hours. *For details, refer to page no. 117.*

POTASSIUM CHLORIDE

Tablet, 600 mg — NRH/RRH/DH/PHC

Therapeutic group Medicine for correcting water, electrolyte and acid–base disturbance.
Indications and dose **Hypokalemia induced by diuretics** ADULT PO 1 tablet 2 to 3 times daily depending on the serum potassium level.
Side effects Hyperkalemia, gastro duodenal ulcerations, diarrhoea, nausea and vomiting.
Contraindications Do not combine with spironolactone and angiotensin-converting-enzyme inhibitors (e.g. enalapril).
Cautions Administer with caution and reduce dosage in elderly patients and in patients with renal impairment due to risk of hyperkalemia.
Pregnancy category B
Counselling Take after meals to reduce the risk of gastrointestinal ulcerations. Hypokalemia is defined as a serum potassium concentration below 3.5 mmol/litre.

SODIUM BICARBONATE

Tablet, 500 mg — NRH/RRH

Therapeutic group Medicine for correcting water, electrolyte and acid–base disturbance.
Indications and dose **Metabolic acidosis** ADULT PO 1 to 2 tablets 2-3 times daily.
Contraindications Alkalosis, hypernatremia, severe pulmonary edema, hypocalcemia.
Cautions Avoid prolonged use in urinary conditions, cardiac disease, elderly, patients on sodium-restricted diet, respiratory acidosis, monitoring of plasma pH is advised.
Side effects Hypokalemia may be exacerbated, increase blood pressure, pulmonary oedema.
Hepatic impairment In patients with fluid retention, avoid large amounts of sodium.
Renal impairment Avoid.
Pregnancy category C
Breastfeeding Excreted in breast milk, however, is safe.
Note *Metabolic acidosis due to early renal failure or diabetic ketoacidosis is usually accompanied by hypernatremia; it is best to correct this by infusion of sodium chloride 0.9% injection, which may restore the kidney's own ability to generate bicarbonate.*

24.2 Parenteral

DEXTROSE

Injection, 5% (500 mL) — NRH/NRH/DH/PH
Injection, 10% (500 mL) — NRH/NRH/DH
Injection, 10% (100 mL) — NRH/RRH
Injection, 25% (100 mL) — NRH/NRH/DH/PHC

Therapeutic group Parenteral
Indications and dose **5% injection** Rehydration in diarrhoea, trauma and post-operatively; **10% injection** Postoperative rehydration when additional energy is required; **25% injection** Correction of hypoglycemia *by IV infusion.*
Note *The dosage, volume, rate and duration of administration depends on the age, weight, clinical conditions of the patients and concomitant therapy and should be determined by a physician.*
Cautions **5% and 10% injection** Monitor for signs of vascular overload and blood glucose; unduly rapid replacement may lead to pulmonary oedema; sodium depletion may occur due to dilution; **10% injection** Thrombophlebitis may occur at the infusion site, use caution in diabetes.
Pregnancy category A

DEXTROSE + SODIUM CHLORIDE

Injection, (5%+0.9%) NRH/RRH/DH
Injection, (5%+0.45%) NRH/RRH/DH

Therapeutic group Parenteral.
Indications and dose **Preoperative and postoperative fluid replacement** By IV infusion, typical rate during surgery, 5 mL/kg/hour.
Cautions Monitor for signs of vascular overload; unduly rapid replacement may lead to pulmonary oedema; restrict intake in impaired renal function, cardiac failure, hypertension, peripheral and pulmonary oedema.
Side effects Administration of large doses may give rise to sodium accumulation and oedema.

POTASSIUM CHLORIDE

Injection, 15% (10 mL) NRH/RRH/DH

Therapeutic group Parenteral electrolyte imbalance and oral electrolyte supplement.
Indications and dose **Hypokalemia,** ADULT **Serum potassium >2.5 mEq/L** IV intermittent infusion. MAX. infusion rate 10 mEq/hr; MAX. concentration 40 mEq/L; MAX. dose 200 mEq/24 hrs; **Serum potassium <2.5 mEq/L Infusion** rate 40 mEq/hr with continuous cardiac monitoring; MAX. dose 400 mEq/24 hrs; CHILD: IV intermittent infusion, 0.5-1 mEq/kg/dose (MAX. 40 mEq), if infusion exceeds 0.5 mEq/kg/hr, monitor ECG continuously.
Note *1 mg KCl is equal to 0.013 mEq KCl. Do not administer IV push.*
Contraindications Plasma-potassium concentration above 5 mmol/litre.
Cautions Acidosis and alkalosis, adrenal insufficiency, burn patients, dehydration, concomitant use of ACEIs and K-sparing diuretics, GI ulcerative, renal failure.
Side effects Diarrhoea, flatulence, hyperkalemia, nausea, vomiting, abdominal pain, cardiac arrest.
Renal impairment Avoid in severe impairment. **Dose adjustments:** Smaller doses must be used in the prevention of hypokalemia, to reduce the risk of hyperkalemia.
Pregnancy category C
Breast-feeding Excreted in milk, however compatible.

SODIUM BICARBONATE

Injection, 7.5% (25 mL) NRH/RRH/DH

Therapeutic group Parenteral electrolyte imbalance and oral electrolyte supplement.
Indications and dose **Metabolic-acidosis** Slow IV injection, 10mL or 2-5 mEq/kg IV infusion over 4-8 hours; subsequent doses should be based on the patient's acid-base status.
Contraindications Alkalosis, hypernatremia, severe pulmonary edema, hypocalcemia.
Cautions Avoid prolonged use in urinary conditions, cardiac disease, elderly, patients on sodium-restricted diet, respiratory acidosis, monitoring of plasma pH is advised.
Side effects Hypokalemia may be exacerbated, increase blood pressure, pulmonary oedema.
Hepatic impairment In patients with fluid retention, avoid large amounts of sodium.
Renal impairment Avoid.
Pregnancy category C
Breast-feeding Excreted in breast milk, safe.
Note *Metabolic acidosis due to early renal failure or diabetic ketoacidosis is usually accompanied by hyponatremia; it is best to correct this by infusion of sodium chloride 0.9% injection, which may restore the kidney's own ability to generate bicarbonate.*

SODIUM CHLORIDE

Injection, 0.9% (500 mL) NRH/RRH/DH/PHC
Injection, 0.9% (100 mL) NRH/RH

Therapeutic group Electrolytes and minerals.

Indications and dose **Hyponatremia**: 4 to 8 mmol/L/day; max. 10 to 12 mmol/L/day. **Intravenous fluid replacement, Additive,** *Maintenance fluids*: 33 to 40 mEq sodium/L based on a patient receiving 2 to 3 L/day. **Management of diabetic ketoacidosis** by IV infusion ADULT 500 mL Given over 10-15 minutes, repeat if blood pressure remains below 90 mmHg, when blood pressure is over 90 mmHg should be given at a rate that replaces deficit and provides maintenance.
Note *Sodium chloride 0.9% solution contains 154 mEq/L (154 mmol/L) sodium and 154 mEq/L ((154 mmol/L)) chloride. Calculated osmolarity is 308 mOsmol/L. Dose, rate and duration of administration should be guided by laboratory values, clinical condition, age, weight and concomitant therapy. It should be determined by a physician.*
Cautions Monitor for signs of vascular overload, unduly rapid replacement may lead to pulmonary oedema, dilutional hyponatremia, hypertension, peripheral oedema.
Side effects Excessive infusion may result in sodium retention; symptoms of hypernatremia include restlessness, flushing of the skin, pyrexia and tachycardia, hyperchloremic acidosis, oedema.

SODIUM CHLORIDE (HYPERTONIC SOLUTION)

Injection, 3% (500 mL) NRH/RRH

Therapeutic group Electrolytes and minerals.
Indications and dose **Hyponatremic seizures** by IV central venous, ADULT 1 mL/kg to raise the Na to ≥ 125mmol/L; **Cerebral oedema and raised intracranial pressure** by IV central venous, 3-5mL/kg over 10-20 minutes.
Note 3 mL/kg of 3% sodium chloride will increase plasma Na by approximately 2-3 mmol/L. The increase may be greater if a large diuresis occurs; Sodium chloride 3% injection solution contains 30 g/L sodium chloride, 513 mEq/L sodium and chloride (each), and an osmolarity of 1027 mOsmol/L.

COMPOUND SODIUM LACTATE SOLUTION

Injection (500 mL) NRH/RRH/DH/PHC

Therapeutic group Electrolytes and minerals.
Indications and dose **Pre-and post-operative fluid and electrolyte replacement; Hypovolemic shock.**
Note: *The dosage, volume, rate and duration of administration depends on the age, weight, clinical conditions of the patients and concomitant therapy. It should be determined by a physician.*
Contraindications Metabolic or respiratory alkalosis; hypocalcemia or hypochlorhydria.
Cautions Restrict intake in impaired renal function, cardiac failure, hypertension, peripheral and pulmonary oedema, and toxaemia during pregnancy.
Side effects Excessive administration may cause metabolic alkalosis; administration of large doses may give rise to oedema.
Pregnancy category C
Breast-feeding Excretion unknown, use with caution.

24.3 Miscellaneous

WATER FOR INJECTION

Injection (Plastic), 5 mL NRH/RRH/DH/PHC

Therapeutic group Parenteral (diluent).
Indication and dose Vehicle for dilution and reconstitution of suitable medicinal products for parenteral administration.

25. VITAMINS & MINERALS

CALCIUM CARBONATE + VITAMIN D3

Tablet, (1250 mg + 250 IU) NRH/RRH

Therapeutic group Vitamins and minerals.
Indications and dose **Management of combined calcium and vitamin D deficiency including chronic kidney disease and hyperparathyroidism** PO, ADULT, 1 tablet twice or thrice daily preferably with food.
Contraindications Hypercalcemia, hypercalciuria, hypervitaminosis D, hypophosphatemia, renal calculi, suspected digoxin toxicity.
Cautions Achlorhydria, hypo parathyroid, history of nephrolithiasis, sarcoidosis.
Side effects Constipation, flatulence, nausea, abdominal pain and diarrhoea, hypercalcemia.
Renal impairment Use with caution.
Pregnancy category Available data suggests safe use during pregnancy.
Breast-feeding Available data suggests safe use during lactation.
Counselling Take the medicine after meals.

CALCIUM CARBONATE

Tablet, 500 mg (Elemental) NRH/RRH/DH/PHC

Therapeutic group Vitamins and minerals.
Indications and dose **Calcium deficiency, Prophylaxis** ADULT: (19-70 years): 1000 mg elemental calcium per day in divided doses; *Age >70 years and Women (51-70 years)*: 1200 mg elemental calcium per day in divided doses. CHILD (*0-6 months*): 200 mg elemental calcium/day; *7-12 months:* 260 mg elemental calcium/day; 1-3 years 700 mg elemental calcium/day; *4-8 years:* 1000 mg elemental calcium/day; *9-18 years:* 1300 mg elemental calcium/day. **Postmenopausal osteoporosis and prophylaxis for bone fracture**: 1200 mg elemental calcium per day in divided doses. **Renal failure-associated hyperphosphatemia** *Stage 3-5 CKD* Not to exceed 2000 mg/day; *Stage 5 CKD* not to exceed 1500 mg/day. **Antenatal care** WHO guideline suggests in populations where calcium intake is low, elemental calcium of 1.5-2 g/day is recommended to prevent preeclampsia in pregnant women.
Contraindications Hypercalcemia, hypercalciuria, renal calculi, hypophosphatemia, suspected digoxin toxicity.
Cautions Achlorhydria, inflammatory bowel disease, mineral stores deficiencies, vitamin D deficiency. Take in doses of less than 500 mg (elemental calcium) at a time for greatest absorption.
Side effects Constipation, flatulence, swollen abdomen, myocardial infarction, urolithiasis, prostate cancer, milk alkali syndrome.
Pregnancy category C
Breast-feeding Excreted in breast milk.
Counselling Take with meals. Advise patients to limit intake of oxalate-rich foods (soy; green, leafy vegetables; animal protein) to avoid reduced absorption through Ca-oxalate formation.

CALCIUM GLUCONATE

Injection, 10% (10 mL) NRH/RRH/DH

Therapeutic group Vitamins and minerals.
Indications and dose **Hypocalcaemia** ADULT by IV infusion, 2-15 g/24 hours as a continuous or in divided doses. NEONATE 200-800 mg/kg/day as a continuous or in 4 divided doses (MAX. 1 g/dose); INFANT and CHILD 200-500 mg/kg/day as a continuous or in 4 divided doses (MAX. 2-3 g/dose). **Hypocalcemia secondary to citrated blood infusion** ADULT by IV 500 mg to 1 g per 500 mL of citrated blood (infused into another vein). NEONATE, INFANt and CHILD by IV infusion 98 mg (0.45 mEq elemental calcium) for each 100 mL citrated blood infused. **Hypocalcemia tetany** ADULT 1-3 g/dose may be administered until therapeutic response occurs; INFANT and CHILD 100-200 mg/kg/dose over 5-10 minutes; may repeat every 6-8 hours or follow with an infusion of 500 mg/kg/day. **Magnesium intoxication or cardiac arrest in the presence of hyperkalaemia or hypocalcaemia** ADULT 500-800 mg/dose (MAX. 3 g/dose); INFANT and CHILD 60-100 mg/kg/dose (maximum: 3 g/dose). **Maintenance electrolyte requirements for TPN** ADULT 1.7-3.4 g/1000 kcal/24 hours.
Not for IM or SC administration; For IV administration only. Administer slowly (1.5 mL calcium gluconate 10% per minute) through a small needle into a large vein in order to avoid too rapid increase in serum calcium and extravasation.
Side effects Arrhythmia, bradycardia, cardiac arrest, hypotension, vasodilation, syncope.

Cautions respiratory acidosis, renal impairment, respiratory failure, severe hyperphosphatemia, kidney stones history.
Contraindications ventricular fibrillation during cardiac resuscitation, digitalis toxicity or suspected digoxin toxicity, hypercalcemia.
Renal impairment CrCl<25 mL/minute: Dosage adjustments may be necessary depending on the serum calcium levels.
Pregnancy category C
Breast-feeding Enters breast milk, use with caution.
IV fluid compatibility Stable in dextrose 5% in compound sodium lactate, dextrose 5% in sodium chloride 0.9%, dextrose 5%, dextrose 10%, dextrose 25%, compound sodium lactate, sodium chloride 0.9%.

CALCITRIOL (1,25-DIHYDROXYCHOLECALCIFEROL)

Tablet/Capsule 0.25 mcg NRH/RRH

Therapeutic group Vitamins and minerals.
Indications and dose **chronic kidney disease on dialysis** and **osteodystrophy** ADULT Initially 0.25 mcg daily, adjusted in steps of 0.25 mcg every 2-4 weeks if required; Usual dose 0.5-1 mcg daily. **Renal osteodystrophy** (**hypocalcaemia**) ADULT Initially 0.25 mcg once daily on alternate days, adjusted in steps of 0.25 mcg every 2-4 weeks if required; Usual dose 0.5-1 mcg daily. **Established postmenopausal osteoporosis** ADULT 0.25 mcg twice daily, plasma-calcium concentration and creatinine to be monitored. **Hypocalcemia in hypoparathyroidism, postsurgical or idiopathic** CHILD (1 to 5 years) Initial 0.25 mcg/day, dose may be increased at 2 to 4 weeks, Usual dose range 0.25 to 0.75 mcg once daily. CHILD (6 years and older) Initial 0.25 mcg/day; Dose may be increased at 2 - 4-week intervals; Usual dose range, 0.5 to 2 mcg once daily. **Secondary hyperparathyroidism** CHILD (predialysis, 3 years and older) Initial 0.25 mcg daily, may be increased to 0.5 mcg/day. CHILD (predialysis, < 3 years) 0.01 to 0.015 mcg/kg/day.
Contraindications Hypercalcemia, Vitamin D toxicity and Hypersensitivity to calcitriol.
Cautions Monitor plasma calcium, phosphate, and creatinine during dosage titration. Monitor plasma-calcium concentration in patients receiving high doses.
Side effects Urinary tract infection, abdominal pain, apathy, dehydration, drowsiness. Muscle weakness.
Renal impairment No dose adjustment required.
Pregnancy category C
Breast-feeding Enters breast milk, not recommended.

MULTIVITAMIN

Injection, (10 mL) NRH/RRH

Therapeutic group Vitamins and minerals.
Indications and dose **Treatment of Wernicke's encephalopathy and Korsakoff psychosis in alcoholic and malnourished patients** by slow IV injection or infusion 10mL every 4-8 hours for up to 2 days.
Contraindications Known hypersensitivity to parenteral thiamine, vitamin B complex, or multivitamin injection.
Cautions Anaphylaxis may occur; facilities for treatment must be available during and shortly after administration.
Pregnancy category A
Breast-feeding Safe.

PYRIDOXINE (Vitamin B_6)

Tablet, 25 mg NRH/RRH/DH

Therapeutic group Vitamins and minerals.
Indications and dose Deficiency states: By oral administration, 20-50 mg 1-3 times a day; **Isoniazid induced neuropathy (prophylaxis)**: 10-20 mg daily; **Isoniazid induced neuropathy** (**treatment**): 50 mg 3 times daily.
Cautions Long term large doses may induce neuropathy.
Side effects sensory neuropathies, unstable gait, paresthesias, decreased sensation, decreased folic acid.
Pregnancy A

Breastfeeding Safe.

RETINOL (Vitamin A)

Capsule (soft gelatin), 200,000 units NRH/RRH/DH/PHC

Therapeutic group Vitamins and minerals.
Indications and dose **Prophylaxis of Vitamin A deficiency**: By oral administration, CHILD over 1 year, 1 capsule every 6 months; CHILD under 1 year, 3 drops every 6 months; **night blindness**, **established vitamin A deficiency**: CHILD over 1 year and ADULT, 1 capsule on day 1, 2 and 14; CHILD under 1 year, 3 drops day 1,2 and 14; all ages: repeat only after 6 months.
Contraindications Hypervitaminosis A, malabsorption syndrome.
Cautions Toxicity with repeated doses.
Side effects Rough skin, dry hair, enlarged liver and raised ESR, raised serum calcium and serum alkaline phosphatase concentrations. may occur with over dosage.
Renal impairment use with caution.
Pregnancy category Excessive doses may be teratogenic. 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.
Breast-feeding Excreted in breast milk, safe at RDA levels.

SEVELAMER

Tablet, 800 mg NRH/RRH/DH

Therapeutic group Vitamins and minerals.
Indications and dose **Hyperphosphatemia, CKD not on dialysis and on dialysis** (based on serum phosphorus level) ADULT, 5.5 mg/dL - < 7.5 mg/dL: 800 mg 3 times daily; 7.5 mg/dL - < 9 mg/dL: 1,200 to 1,600 mg 3 times daily; ≥ 9 mg/dL: 1,600 mg 3 times daily. ***Maintenance dose*** is based on serum phosphorus level (3.5 to 5.5 mg/dL): >5.5 mg/dL: Increase by 400 to 800 mg at 2-week intervals; 3.5 to 5.5 mg/dL: Maintain current dose; < 3.5 mg/dL: Decrease by 400 to 800 mg. **Hyperphosphatemia, CKD not on dialysis** CHILD ≥ 6 year: BSA ≥ 0.75 - < 1.2 m^2: 800 mg 3 times daily with meals (titrate as needed by 400 mg per dose at 2 weeks intervals); BSA ≥ 1.2 m^2: 1,600 mg 3 times daily with meals (titrate as needed by 800 mg per dose at 2 weeks intervals). **CKD on dialysis** CHILD > 6 to 17 years: 800 - 1600 mg 3 times after meals and adjust dose according to serum phosphate level.
Conversion dose

- Calcium acetate 667 mg: initiate 800 mg.
- Calcium acetate 1,334 mg: initiate 1200 mg - 1,600 mg
- Calcium acetate 2,001 mg: initiate 2000 mg - 2,400 mg

Contraindications Hypophosphatemia and bowel obstruction.
Cautions Gastro-intestinal disease and may occur in reduction in folic acid and vitamins (D, E, K), monitor recommended, GI surgery.
Side effects Vomiting, nausea, diarrhoea, constipation, dyspepsia, skin rash, metabolic acidosis, peritonitis.
Hepatic impairment No dose adjustment, use with caution.
Renal impairment No dose adjustment necessary.
Pregnancy category C
Breast-feeding Use only if potential benefits outweigh the potential risk.
Counselling Take with food. Advice pregnant women to take folic acid and vitamins (D, E, K), since reduction of this supplement may occur. Tablets should not be crushed, broken or chewed.

THIAMINE (VITAMIN B1)

Injection, 100 mg/mL (1 mL) NRH/RRH/DH
Tablet, 75 mg NRH/RRH/DH/PHC

Therapeutic group Vitamins and minerals.

Indications and dose **Beriberi** by IM injection or slow IV infusion, 10-20 mg 3 times daily for up to 2 weeks, then PO maintenance 10-25 mg 3 times daily for 1 month. **Prophylactic in alcoholic patients**: *by oral administration,*10-25 mg daily; Wernicke Encephalopathy: by IV injection, 100 mg IV followed by 50-100 mg IM/IV until consuming a regular balanced diet.
Cautions Anaphylactic shock may occur following repeated parenteral doses.
Side effects Injection site reaction, hypersensitivity reaction.
Renal impairment Use with caution (parenteral formulation).
Pregnancy category A, C (exceeding RDA).
Breast-feeding Safe.

VITAMIN B COMPLEX

Injection, 25 mg/mL (10 mL) NRH/RRH/DH
Tablet, 32.5 mg NRH/RRH/DH/PHC

Therapeutic group Vitamins and minerals.
Indications and dose **Treatment of deficiency** PO, ADULT and CHILD (5-14 years) 1 tablet 3 times daily; CHILD (2-4 years) 1 tablet once daily; **Prophylaxis of deficiency** ADULT 1–2 tablets once daily; *By IM injection,* ADULT 2 mL daily.
Contraindications Known hypersensitivity to parenteral thiamine, vitamin B complex or multivitamin injection.
Cautions Injection may occasionally cause anaphylaxis; thiamine deficiency should be treated with thiamine; vitamin B complex does not include pyridoxine, which should be prescribed specifically if indicated.
Side effects Occasional rashes and allergic reactions.
Pregnancy category A (not exceeding RDA).
Breast-feeding Safe.
Counselling Take with or after food.

VITAMIN B_{12} (Mecobalamin)

Injection, 1 mg/mL (1 mL) NRH/RRH/DH

Therapeutic group Vitamins and minerals.
Indications and dose **Pernicious anaemia** by IM or SC injection, ADULT 1mg Q24H x 7 days, then weekly for 1 month, then monthly; CHILD 0.03-0.05 mg/day x 2 or more weeks (to a total dose of 1-5mg), then with 0.1 mcg/month; **B_{12} deficiency** ADULT by IM injection, initially 0.30mcg, Q24H x 5-10 days; **Maintenance** 0.1-0.2 mg monthly; CHILD by IM injection, 0.2 mcg/kg/day x 2 days, followed by 1 mg/day x 2-7 days; then 0.1 mcg/week for 1 month; **Maintenance** 100 mcg.
Cautions Leber optic nerve atrophy, nasal disease.
Side effects Arthralgia, dizziness, headache, nasopharyngitis, hypokalemia.
Pregnancy category A
Breastfeeding Excreted in milk, however safe.
Note Avoid IV route; Anaphylactic shock has occurred.

VITAMIN-C

Tablet, 250 mg NRH/RRH/DH/PHC

Therapeutic group Vitamins and multivitamins.
Indications and dose **Prevention of scurvy** PO 25-75mg daily; **Treatment of scurvy** at least 250mg daily in divided doses.
Cautions G6PD deficiency, may cause iron overload.
Side effects Flushing, flank pain, faintness, headache, diarrhoea, dyspepsia, nausea, vomiting, hyperoxaluria (large doses).
Renal impairment Patients prone to recurrent calculi should not take excessive doses for extended periods of time.
Pregnancy A (not exceeding RDA).
Breast-feeding Safe.

Counselling To be taken after the meals and drink plenty of fluids.

VITAMIN D3 (CHOLECALCIFEROL)

Powder (mega-dose), 60000 IU NRH/RRH

Therapeutic group Vitamins and minerals.
Indications and dose **Hypoparathyroidism** 50,000-200,000 IU PO once daily with calcium supplements; **Prophylaxis and treatment of osteoporosis** (>50 years) PO 800-1000 IU once daily with calcium supplements; **Vitamin D resistant rickets** PO 12,000-500,000 IU once daily; **Familial hypophosphatemia** PO 10,000-60,000 IU once daily with phosphate supplements.
Contraindications Hypercalcemia, Hypervitaminosis D, hypercalciuria, severe renal impairment, nephrolithiasis.
Cautions Concurrent use of cardiac glycosides.
Side effect Constipation, loss of appetite, nausea.
Breast-feeding Distributed into breast milk, Use with caution.
Counselling Instruct patients to maintain adequate intake of calcium and avoid additional vitamin D supplements.
Note *Obtain serum calcium twice weekly during titration, discontinue if the patient becomes hypercalcemic.*

ZINC SULPHATE

Tablet, 20 mg NRH/RRH/DH/PHC

Therapeutic group Vitamins and minerals.
Indications and dose **Zinc deficiency or supplementation in zinc losing conditions** ADULT and CHILD (over 30 kg) 45 mg 1-3 times daily after food; CHILD (10-30 kg) 20 mg 1-3 times daily after food; CHILD (upto 10 kg) 20 mg once daily after food.
Contraindications Hypersensitivity.
Side effects Abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation, gastritis; irritability, headache, lethargy.
Renal impairment Accumulation may occur in acute renal failure.
Pregnancy category C
Breast-feeding Excreted in breast milk, Use with caution.

26. PARENTERAL NUTRITION

AMINO ACID SOLUTION

Injection, 10% (200 mL) NRH/RRH

Therapeutic group Intravenous nutritional supplement.
Indications and dose **Parenteral nutrition when GI absorption is impaired, Amino acid supplement for hypercatabolic or hypermetabolic states** by IV infusion, ADULT 200-800 mL/day at 40-50 drops/minute; CHILD 20-40 mL/Kg/day.**Solid organ transplant**: Perioperative 1.5-2 g/kg/day; **Renal failure** Acute (severely malnourished or hypercatabolic) 1.5-1.8 g/kg/day; Chronic on dialysis 1.2-1.3 g/kg/day; Chronic not on dialysis 0.6-0.8 g/kg/day; **Hepatic failure** With encephalopathy 0.6-1 g/kg/day; Without encephalopathy: 1-1.5 g/kg/day.
Contraindications Inborn errors of amino acid metabolism, pulmonary edema or acidosis.
Cautions Hyperglycemia, hepatobiliary disorder, renal impairment, fluid overload may occur, as bacterial overgrowth may readily occur in amino acid solutions; adequate simultaneous dextrose infusion must be given to allow maximal utilisation of amino acids by the body.
Side effects Electrolyte imbalance, hyperammonemia, refeeding syndrome, thrombosis, infusion reaction, pulmonary embolism.
Pregnancy category C
Breast-feeding Excretion in milk unknown, use with caution.

LIPID EMULSION

Injection, 20% (250 mL) NRH/RRH

Therapeutic group Parenteral nutrition.
Indications and dose **Supplemental parenteral nutrition** by IV, ADULT Initially 1 g/kg/day, increase by 0.5-1 g/kg/day to a maximum of 2.5-3 g/kg/day. PREMATURE INFANT Initially 0.25-0.5 g/kg/day, increase by 0.25-0.5 g/kg/day to a maximum of 3 g/kg/day, Limit to 1 g/kg/day if on phototherapy; should be administered over 24 hours; INFANT and CHILD Initially 0.5-1 g/kg/day, increase by 0.5 g/kg/day to a maximum of 3 g/kg/day.
Note *Strict adherence to proper infusion rates, dosing and monitoring are necessary in premature infants. Infusion rate should not exceed 1 g fat/kg in four hours. Monitor serum triglyceride levels.*
Contraindications Severe allergies to eggs and legumes, hyperlipidemia, lipoid nephrosis, acute pancreatitis associated with hyperlipidemia, severe hemorrhagic disorders.
Cautions Anaemia, bleeding disorders, patients susceptible to fat embolism, pancreatitis and respiratory disease, premature infants.
Side effects Bradycardia, haemorrhage, hyperglycemia, apnea, agitation, vomiting, hypertriglyceridemia.
Hepatic impairment Use with caution in patients with severe hepatic impairment.
Pregnancy category C

27. EAR, NOSE AND THROAT MEDICINES

27.1 Decongestants

BUDESONIDE

Spray, 50 mcg/puff (200 sprays) NRH/RRH

Therapeutic group Decongestant (corticosteroid).
Indications and dose **Prophylaxis and treatment of rhinitis and management of nasal polyps** by nasal administration, ADULT and CHILD (over 12 years) spray into each nostril one to two times daily; Treatment can be continued for up to 3 months.
Contraindications Status asthmaticus, acute bronchospasm, active pulmonary TB and untreated upper respiratory infections.
Side effects Systemic absorption following nasal use may lead to adrenal suppression.

COMPOUND BENZOIN

Tincture for inhalation, (450 mL) NRH/RRH/DH/PHC

Therapeutic group Antitussive and decongestant.
Indications and dose **Nasal obstruction; viral respiratory conditions; adjunct in bacterial respiratory conditions** 5 mL in 500 mL hot water for inhalation.
Cautions The inhalation should not be made with boiling water, to avoid the risk of scalding; children and elderly should be supervised.
Counselling This inhalation will help clear your breathing; in children, care must be taken to prevent burning.

OXYMETAZOLINE

Nasal drops, 0.05% (10 mL) NRH/RRH/DH

Therapeutic group Antitussive and decongestant.
Indications and dose **Relief of nasal congestion** ADULT and CHILD (above 6 years) 1-2 drops in each nostril twice daily for up to 3 days. CHILD (< 6 years) Not recommended.
Caution Hypertension, heart failure, coronary artery disease, diabetes, hyperthyroidism, prostatic hyperplasia, prolonged use may cause rebound congestion, close angle glaucoma.
Side effects local irritation, dryness of mouth and throat, rebound congestion, insomnia.
Pregnancy category C

27.2 Medicines for Meniere's disease

BETAHISTINE DIHYDROCHLORIDE

Tablet,16 mg NRH/RRH/DH

Therapeutic group Medicines for Meniere's disease.
Indications and dose **Vertigo, tinnitus and hearing loss associated with Meniere's disease** PO, initially 16mg 3 times daily, preferably with food; **Maintenance** 32-48mg daily. CHILD Not recommended.
Contraindications Pheochromocytoma.
Cautions Asthma, history of peptic ulcer, pregnancy and breastfeeding.
Side effects GI disturbances, headache, rashes, pruritus.
Counselling Take with or after food.

CINNARIZINE

Tablet, 15 mg NRH/RRH

Therapeutic group Medicines for Meniere's disease.
Indications and dose **Relief of symptoms of vestibular disorders, such as vertigo, tinnitus, nausea, and vomiting in Ménière's disease** ADULT: 30 mg PO 3 times a day; CHILD 12–17 years: 30 mg PO 3 times a day CHILD: 5–11 years: 15 mg PO 3 times a day. **Motion sickness** ADULT: Initially 30 mg, dose to be taken 2 hours before travel, then 15 mg every 8 hours if required, dose to be taken during journey; CHILD 12–17 years: Initially 30 mg, dose to be taken
2 hours before travel, then 15 mg every 8 hours if required, dose to be taken during journey; CHILD 5–11 years: Initially 15 mg, dose to be taken 2 hours before travel, then 7.5 mg every 8 hours if required, dose to be taken during journey.
Contraindications Acute porphyria.
Cautions Epilepsy, glaucoma (in children), Parkinson's disease (in adults), prostatic hypertrophy (in adults), pyloroduodenal obstruction, susceptibility to angle closure glaucoma (in adults), urinary retention.
Side effects Drowsiness, gastrointestinal discomfort, nausea, weight increased, hyperhidrosis, vomiting.
Pregnancy category Advise pregnant patients to avoid using cinnarizine.
Breast-feeding Avoid.
Counselling Advised patients that drowsiness may affect performance of skilled tasks, sedating effects enhanced by alcohol.

27.3 Medicines acting on the oropharynx and oral cavity

27.3.1 Medicines used in treatment of oral ulcer

TRIAMCINOLONE ACETONIDE

Paste, 0.1% (5 g) NRH/RRH/DH

Therapeutic group Medicine used in treatment of oral ulcer.
Indications and dose **Stomatitis** ADULT Apply 0.1% paste to oral mucous membranes at bedtime. If severe symptoms, apply 2-3 times a day. Apply enough to form a thin film over the lesion, do not rub.
Note *Safety and effectiveness of the oral dental paste has not been established in children.*
Contraindications Hypersensitivity to triamcinolone, fungal, viral, or bacterial infections of the mouth or throat.
Cautions If concomitant mucosal infections are present an appropriate antifungal or antibacterial agent should be used, if a favourable response does not occur promptly, 0.1% paste should be discontinued until the infection has been adequately controlled. If not improved in seven days, further investigation of the oral lesion is advised.
Side effects Burning, itching, irritation, dryness, or redness of the treated area. Blistering or peeling not present prior to therapy, perioral dermatitis, allergic contact dermatitis, maceration of the oral mucosa, secondary infection, and atrophy of the oral mucosa.

Pregnancy category C
Breast-feeding Excretion in breast milk unknown, use with caution.
Counselling Do not rub in, attempting to spread this preparation may result in granular, gritty sensation and cause it to crumble. It is for oral use only.

27.3.2 Oropharyngeal antifungal medicines

NYSTATIN

Tablet, 500,000 Units NRH/RRH/DH
Nystatin oral paste (Extemporaneous) NRH/RRH/DH

Therapeutic group Antifungal.
Indications and dose **Intestinal and oral candidiasis** PO, ADULT 500,000 units tablet 4 times daily, double dose in severe infections; CHILD 100,000 units 4 times daily; **Oral thrush** Extemporaneously prepared, 4 times daily after food.
Side effects Nausea, vomiting and diarrhoea may occur at high doses.

28. MEDICINES FOR DISEASES OF JOINTS

28.1 Medicines for gout

ALLOPURINOL

Tablet, 100 mg NRH/RRH/DH

Therapeutic group Medicine used to treat gout (xanthine oxidase inhibitor).
Indications and dose **Prophylaxis of gout** PO, ADULT initially 100 mg daily preferably after food, then adjusted according to plasma uric acid concentration; **Usual maintenance dose in mild conditions** 100-200 mg daily; **Usual maintenance dose in moderately severe conditions** 300-600 mg in divided doses daily (MAX. per dose 300 mg); **Usual maintenance dose in severe conditions** 700-900mg daily in divided doses (MAX. per dose 300 mg); **Prophylaxis of hyperuricemia associated with cancer chemotherapy and hyperuricemia nephropathy, enzyme disorders causing increased serum urate e.g. Lesch-Nyhan syndrome (children)** PO 600-800 mg in divided doses, start 1-2 days before chemotherapy; CHILD (1 month-14 years) 10-20 mg/kg daily (MAX. 400mg per day); CHILD (15-17 years): Initially 100 mg daily; dose to be increased according to response, up to 900 mg daily in divided doses (MAX. per dose 300 mg).
Contraindications Not a treatment for acute gout but continue if attack develops when already receiving allopurinol and treat attack separately.
Cautions Prophylactic administration of NSAIMs (not aspirin) is recommended until a month after the uric acid level becomes normal; adequate fluid intake must be ensured (2-3 litres/day).
Side effects GI disorders, rashes, sometimes with fever may be seen. (If mild, withdraw therapy and then re-introduce cautiously at a very low dose & increase gradually; discontinue immediately if recurrence occurs).
Pregnancy category C
Breast-feeding Excreted in milk, however not known to be harmful.
Hepatic impairment Reduce dose.
Renal impairment Max. 100 mg daily, increased only if response inadequate; in severe impairment, reduce daily dose below 100 mg, or increase dose interval.
Counselling Take after food with plenty of fluids.

28.2 Disease Modifying Anti-Rheumatic Medicines (DMARMs)

CHLOROQUINE

Tablet, 150 mg NRH/RRH/DH/PHC

Therapeutic group Disease modifying anti-rheumatoid medicines (DMARMs).

Indications and dose **Active rheumatoid arthritis and systemic and discoid lupus erythematosus** PO, ADULT 150 mg daily; MAX. 2.5 mg/kg per day; **Dose equivalence and conversion** Chloroquine base 150 mg = chloroquine sulphate 200mg = chloroquine phosphate 250mg (approx.).
Contraindications Psoriasis, porphyria, retinal or visual field changes.
Cautions History of auditory damage, epilepsy, heart failure, cardiac diseases, ventricular arrhythmias, uncorrected hypokalemia and hypomagnesemia, bradycardia.
Side effects GI disturbances, headache, pruritus, rashes, skin reactions; convulsions, discoloration of mucous membranes, discoloration of nails, discoloration of skin, hair depigmentation, hair loss, keratopathy, ototoxicity, retinal damage, visual changes.
Hepatic impairment Use with caution in moderate to severe impairment.
Renal impairment In severe impairment, reduce dose.
Pregnancy category C
Breast-feeding Excreted in breast milk, avoid.
Note *In active rheumatoid arthritis and systemic and discoid lupus erythematosus, to avoid excessive dosage in obese patients, the daily maximum dose should be calculated based on ideal body weight.*
A baseline ophthalmological examination should be performed within the first year of initiating therapy; discontinue if ocular toxicity is suspected.

HYDROXYCHLOROQUINE

Tablet, 200 mg NRH/RRH/DH

Therapeutic group Disease modifying anti-rheumatoid medicines (DMARMs).
Indications and dose **Active rheumatoid arthritis, systemic and discoid lupus erythematosus and dermatological conditions caused or aggravated by sunlight** PO, ADULT 200-400 mg daily, daily maximum dose to be based on ideal body-weight; MAX. 6.5 mg/kg per day; CHILD 5-6.5 mg/kg once daily (MAX. per dose 400 mg), dose given based on ideal body-weight.
Note *To avoid excessive dosage in obese patients, the dose of hydroxychloroquine should be calculated based on ideal body weight.*
Contraindications Long-term therapy in children.
Cautions Acute porphyrias, elderly, G6PD deficiency, alcoholics, concurrent use of hepatotoxic medicines should be avoided; myasthenia gravis; heart failure, psoriasis, neurological disorders (especially in those with a history of epilepsy), Severe GI disorders.
Side effects GI disturbances, headache, pruritus, rashes, skin reactions, corneal changes or deposits, aplastic anaemia, retinal damage with long-term use.
Pregnancy category C
Breast-feeding Excreted in milk, avoid.
Hepatic impairment Caution in moderate to severe impairment.
Renal impairment Use with caution.
Counselling Report if there are any visual disturbances and get the vision checked; Take with food or milk; Do not take antacids for at least 4 hours before or after hydroxychloroquine to reduce possible interference with hydroxychloroquine absorption.

LEFLUNOMIDE

Tablet, 10 mg NRH

Therapeutic group Disease-modifying agents used in rheumatoid disorders (DMARDs).
Indications and dose **Rheumatoid arthritis** PO, ADULT 100 mg daily for 3 days, then 10-20 mg daily, or 10-20 mg daily without loading dose (MAX. 20mg per day). **Psoriatic arthritis** PO, ADULT 100 mg daily for 3 days, then 20 mg daily. **Juvenile idiopathic arthritis**, body weight (< 20 kg) 10 mg alternative days; (20 - 40 kg) 10 mg once daily; (> 40 kg) 20 mg once daily.
Contraindications Hypersensitivity to leflunomide, pregnancy, hepatic impairment.

Cautions Pre-existing intestinal lung disease, severe or uncontrolled infections, severe immunodeficiency, bone marrow dysplasia, concomitant use with live vaccines, malignancy, and lymphoproliferative disorders.
Side effects Nausea and vomiting, diarrhoea and ulcer of mouth, alopecia, rash, Stevens-Johnson syndrome, jaundice, dizziness, hypertension, headache, joint pain, peripheral neuropathy, myelosuppression, hepatotoxicity, and upper respiratory tract infection.
Pregnancy category X
Breast-feeding Excretion in breast milk unknown/Not recommended.
Renal impairment Use with caution.
Hepatic impairment Baseline ALT 2-3 times ULN may reduce dose 10 mg once daily, then monitor ALT weekly. If persistent ALT 2-3 times ULN, stop leflunomide and initiate wash out* procedure.
Note *The active metabolite persists for a long period; to aid medicine elimination in case of serious adverse effect, or before starting another disease-modifying antirheumatic, or before conception, stop treatment and give either cholestyramine or charcoal, activated. Procedure may be repeated as necessary*.
Counselling Advice female patients to avoid pregnancy during therapy and before completion of the medicine elimination process and male patients who wish to father a child should also undergo the drug elimination procedure. Advise patients to avoid live vaccines during therapy. Observe yellow eyes, skin colour changes and tingling sensation. Do not donate blood while on therapy.

METHOTREXATE

Tablet, 2.5 mg NRH/RRH/DH

Therapeutic group Antineoplastic medicine.
Indications and dose **Moderate to severe active rheumatoid arthritis** PO, ADULT 7.5 mg once weekly, adjusted according to response (MAX. 20 mg per week). **Severe psoriasis unresponsive to conventional therapy** PO, ADULT Initially 2.5-10 mg once weekly, then increased in steps of 2.5-5 mg, adjust according to response at intervals of at least 1 week; usual dose 7.5-15 mg once weekly, stop treatment if inadequate response after 3 months at the optimum dose (MAX. 30 mg per week). CHILD (2-17 years) Initially 200 mcg/kg once weekly (MAX. per dose 10 mg), then increase if necessary to 400 mcg/kg once weekly (MAX. per dose 25 mg), adjust according to response, stop treatment if inadequate response after 3 months at the optimum dose.
Contraindications Active infection, ascites, immunodeficiency syndromes (in non-malignant conditions), significant pleural effusion.
Cautions Acute porphyrias, diarrhoea, extreme caution in blood disorders (avoid if severe), peptic ulceration, photosensitivity, ulcerative colitis, ulcerative stomatitis.
Side effects Pneumonitis, ulcerative stomatitis, hyperuricemia, gingivitis, leukopenia, nausea and vomiting, diarrhoea, anorexia, thrombocytopenia, renal failure, headache, blurred vision; uncommon with low dose maintenance therapy.
Pregnancy category X
Breast-feeding Excreted in milk, avoid.
Renal impairment CrCl 10-50 mL/min: 50% of dose at normal dosing interval; CrCl <10 mL/min: avoid; Intermittent hemodialysis: 50% of dose a normal dosing interval.
Hepatic impairment Bilirubin 3.1-5.0mg/dL or AST>3 times ULN: give 75% of dose; bilirubin>5.0 mg/dL: avoid.
Note *The patient should be warned to report immediately the onset of any feature of blood disorders (e.g. sore throat, bruising, and mouth ulcers), liver toxicity (e.g. nausea, vomiting, abdominal discomfort, and dark urine), and respiratory effects (e.g. shortness of breath).*

SULFAZALAZINE

Tablets, 500 mg NRH/RRH

Therapeutic group Disease-modifying agents used in rheumatoid disorders (DMARDs).
Indications and dose **Rheumatoid arthritis** PO, ADULT (*delayed release tablet*) 0.5-1 g/day 2 times per day; Increase weekly to maintenance dose of 2 g/day; if inadequate response, increase to 3 g/day after administering for 12 weeks. **Juvenile idiopathic arthritis** CHILD (6 years or older) gradually titrates at weekly intervals up to 30-50 mg/kg/day 2

times per day after meals; not to exceed 2 g/day. **Ulcerative colitis** ADULT 3-4 g/day PO 3 times per day after meals. *Maintenance*: 0.5 g QID when endoscopic exam confirms improvement. If GI intolerance, reduce dose by 50% and gradually increase to desired dose over several days. If GI intolerance persists, stop therapy for 5-7 days and reintroduce at lower daily dose. CHILD (6 years or older) Initially 40-60 mg/kg/day Q4-8 hour after meals; **Maintenance** 30 mg/kg/day Q8H after meals. **Crohn's Disease** ADULT 3-6 g/day in divided doses for up to 16 weeks.
Contraindications Hypersensitivity to sulfonamides, or to salicylates, intestinal or urinary tract obstruction and porphyria.
Cautions Administer tablets with caution to patients with severe allergy or bronchial asthma. Patients with glucose-6 phosphate dehydrogenase deficiency should be observed closely for signs of hemolytic anaemia. More than 4 g/day can increase risk of haematological and hepatic toxicity.
Side effects Anorexia, alter taste, insomnia, nausea, vomiting, gastric distress, apparently reversible oligospermia.
Hepatic impairment Use not recommended, weigh risk vs benefit.
Renal impairment Use not recommended, weigh risk vs benefit.
Pregnancy category B
Breast-feeding Excreted in milk, use with caution.
Counselling Adequate fluid intake must be maintained to prevent crystalluria and stone formation. Take after meals. Do not crush, chew or break the tablet.

29. MEDICINES FOR OSTEOPOROSIS

ALENDRONATE

Tablet, 70 mg NRH/RRH

Therapeutic group Medicines affecting bone metabolism.
Indications and dose **Postmenopausal osteoporosis** ADULT (Female) 10 mg daily or 70mg once weekly. **Prophylaxis** 35 mg orally once weekly or 5 mg orally once daily. **Osteoporosis in men** 10 mg daily or 70mg once weekly. **Osteoporosis due to corticosteroid** 5 mg orally once daily or 70 mg weekly; **Postmenopausal women not receiving oestrogen replacement therapy** 10 mg orally once daily or 70 mg weekly. **Osteoporosis due to corticosteroid (Prophylaxis**): 5 mg or 10 mg orally once daily or 35 mg orally once weekly.
For details, refer to page no. 123

CALCIUM CARBONATE + VITAMIN D3

Tablet, (1250 mg + 250 IU) NRH/RRH

Therapeutic group Vitamins and minerals.
Indications and dose **Management of combined calcium and vitamin D deficiency including chronic kidney disease and hyperparathyroidism** PO, ADULT, 1 tablet twice or thrice daily preferably with food.
For details, refer to page no. 155

CALCIUM CARBONATE

Tablet, 500 mg (Elemental) NRH/RRH/DH/PHC

Therapeutic group Vitamins and minerals.
Indications and dose **Calcium deficiency, Prophylaxis** ADULT (19-70 years) 1000 mg elemental calcium per day in divided doses. **Age >70 years and Women** (51-70 years) 1200 mg elemental calcium per day in divided doses. CHILD (0-6 months) 200 mg elemental calcium/day; CHILD (7-12 months) 260 mg elemental calcium/day; CHILD (1-3 years) 700 mg elemental calcium/day; CHILD (4-8 years) 1000 mg elemental calcium/day; CHILD (9-18 years) 1300 mg elemental calcium/day. **Postmenopausal osteoporosis and bone fracture for prophylaxis** *women 51 years or older:* 1200 mg elemental calcium per day total intake. **Renal failure-associated hyperphosphatemia** *Stage 3-5 CKD* Not to exceed 2000mg/day; *Stage 5 CKD* Not to exceed 1500 mg/day. **Antenatal care** WHO guideline suggests in populations where calcium intake is low, elemental calcium of 1.5-2g/day is recommended to prevent preeclampsia in pregnant women. *For details, refer to page no. 156*

CALCITRIOL (1,25-DIHYDROXYCHOLECALCIFEROL)

Tablet/Capsule 0.25 mcg NRH/RRH

Therapeutic group Vitamins and minerals.
Indications and dose **Chronic kidney disease on dialysis and osteodystrophy** ADULT Initially 0.25 mcg daily, adjusted in steps of 0.25 mcg every 2-4 weeks; usual dose 0.5–1 mcg daily. **Renal osteodystrophy** (**hypocalcaemia**) ADULT Initially 0.25 mcg once daily on alternate days, adjust in the steps of 0.25 mcg every 2-4 weeks; usual dose 0.5-1 mcg daily. **Established postmenopausal osteoporosis** ADULT: 0.25 mcg twice daily, plasma-calcium concentration and creatinine to be monitored. **Hypocalcemia in hypoparathyroidism, postsurgical or idiopathic** CHILD (1-5 years) Initially 0.25 mcg/day, dose may be increased at 2 to 4 weeks, usual dose range 0.25-0.75 mcg once daily. CHILD (6 years and older) Initially 0.25 mcg/day; Dose may be increased at 2-4 week intervals; usual dose range 0.5 to 2 mcg once daily. **Secondary hyperparathyroidism** CHILD (Predialysis, 3 years and older) Initially 0.25 mcg daily, may be increased to 0.5 mcg/day. CHILD (predialysis, < 3 years) 0.01 to 0.015 mcg/kg/day.
For details, refer to page no. 157.

VITAMIN D3 (CHOLECALCIFEROL)

Powder (mega-dose), 60000 IU NRH/RRH

Therapeutic group Vitamins and minerals.
Indications and dose **Hypoparathyroidism** PO, 50,000 - 200,000 IU once daily with calcium supplements; **Prophylaxis and treatment of osteoporosis** (>50 years) 800-1000 IU once daily with calcium supplements; Vitamin D resistant rickets: 12,000-500,000 IU once daily; Familial Hypophosphatemia: 10,000-60,000 IU once daily with phosphate supplements. *For details, refer to page no. 160.*

30. MEDICINES FOR SOFT TISSUE INFLAMMATION

HYALURONIDASE

Injection, 1500 IU /mL (1 mL) NRH/RRH

Therapeutic group Dispersion agent.
Indications and dose **Enhanced permeation of local anaesthetic in surgical aid in cataract extraction, intraocular implantation, corneal transplant, glaucoma filtration, retinal detachment surgery; osteoarthritis** *by SC or IM injection,* 1500 units dissolved in solution to be injected (ensure compatibility); *by local anaesthesia* 1500 units mixed with local anaesthetic solution (ophthalmology, 15 units/mL); **Hypodermoclysis** 1500 units dissolved in 1 mL water for injection or 0.9% sodium chloride injection, administer before start of 500-1000 mL infusion fluid; **Extravasation or hematoma** 1500 units dissolved in 1 mL water for injections or 0.9% sodium chloride injection, infiltrate into affected area (as soon as possible after extravasation).
Contraindications Do not apply directly to cornea; avoid infection or malignancy sites; not for anaesthesia in unexplained premature labour; not to be used to reduce swelling of bites or stings; not for IV administration.
Cautions Infants or elderly (control speed and total volume and avoid overhydration especially in renal impairment).
Side effects Angioedema, urticarial, local injection site reactions.
Pregnancy category There are no adequate and well-controlled studies in pregnant women.
Breast-feeding Excretion in milk unknown, use caution.

31. MEDICINES FOR USE IN HAEMODIALYSIS

DEXTROSE

Injection 50% (100 mL) NRH/NRH

Therapeutic group Medicines for use in haemodialysis.
Indications and dose **Treatment of haemodialysis-associated hypotension, hypoglycaemia and muscle cramps** 1 mL/kg IV infusion.

SODIUM CHLORIDE

Injection, 0.9% (1000 mL) NRH/RH

Therapeutic group Medicines for use in haemodialysis.

Indications and dose **Priming and rinsing of the extracorporeal circuit** 1000 mL sodium chloride 0.9% for rinsing the blood compartment dialyzer. This is done to eliminate all the air and residual sterilant from the dialyzer, blood lines, and for priming of the circuit.

Appendix 1: Medicine Interactions

Two or more medicines given at the same time may exert their effects independently or may interact. The interaction may be potentiation or antagonism of one medicine by another, or occasionally some other effect. Medicine interactions may be Pharmacodynamic or pharmacokinetic.

Pharmacodynamic interactions

These are interactions between medicines which have similar or antagonistic pharmacological effects or side-effects. They may be due to competition at receptor sites or occur between medicines acting on the same physiological system. They are usually predictable from a knowledge of the pharmacology of the interacting medicines; in general, those demonstrated with one medicine are likely to occur with related medicines. They occur to a greater or lesser extent in most patients who receive the interacting medicines.

Pharmacokinetic interactions

These occur when one medicine alters the absorption, distribution, metabolism, or excretion of another, thus increasing or reducing the amount of medicine available to produce its pharmacological effects. They are not easily predicted and many of them affect only a small proportion of patients taking the combination of medicines. Pharmacokinetic interactions occurring with one medicine cannot be assumed to occur with related drugs unless their pharmacokinetic properties are known to be similar.

Pharmacokinetic interactions are of several types:

Affecting absorption: The rate of absorption or the total amount absorbed can both be altered by medicine interactions. Delayed absorption is rarely of clinical importance unless high peak plasma concentrations are required (e.g. when giving an analgesic). Reduction in the total amount absorbed, however, may result in ineffective therapy.

Due to changes in protein binding: To a variable extent most medicines are loosely bound to plasma proteins. Protein-binding sites are non-specific and one medicine can displace another thereby increasing its proportion free to diffuse from plasma to its site of action. This only produces a detectable increase in effect if it is an extensively bound medicine (more than 90%) that is not widely distributed throughout the body. Even so displacement rarely produces more than transient potentiation because this increased concentration of free medicine results in an increased rate of elimination.

Displacement from protein binding plays a part in the potentiation of warfarin by sulphonamides but the importance of these interactions is due mainly to the fact that warfarin metabolism is also inhibited.

Affecting metabolism: Many medicines are metabolized in the liver. Induction of the hepatic microsomal enzyme system by one medicine can gradually increase the rate of metabolism of another, resulting in lower plasma concentrations and a reduced effect. On withdrawal of the inducer plasma concentrations increase and toxicity may occur. Barbiturates, griseofulvin, many antiepileptics, and rifampicin are the most important enzyme inducers. Medicines affected include warfarin and the oral contraceptives.

Conversely when one medicine inhibits the metabolism of another higher plasma concentration are produced, rapidly resulting in an increased effect with risk of toxicity. Some medicines which potentiate warfarin and phenytoin do so by this mechanism.

Isoenzymes of the hepatic cytochrome P450 system interact with a wide range of drugs. Medicines may be substrates, inducers or inhibitors of the different isoenzymes. A great deal of in-vitro information is available on the effect of medicines on the isoenzymes; however, since medicines are eliminated by a number of different metabolic routes as well as renal excretion, the clinical effects of interactions cannot be predicted accurately from laboratory data on the cytochrome P450 isoenzymes.

In all cases the possibility of an interaction must be considered if toxic effects occur or if the activity of a medicines diminishes.

Affecting renal excretion Medicines are eliminated through the kidney both by glomerular filtration and by active tubular secretion. Competition occurs between those which share active transport mechanisms in the proximal tubule. For example, salicylates and some other NSAIMs delay the excretion of methotrexate; serious methotrexate toxicity is possible.

Relative importance of interactions

Many medicine interactions are harmless and many of those which are potentially harmful only occur in a small proportion of patients; moreover, the severity of an interaction varies from one patient to another. Medicines with a small therapeutic ratio (e.g. phenytoin) and those which require careful control of dosage (e.g. anticoagulants, antihypertensives, and antidiabetics) are most often involved.

Patients at increased risk from medicine interactions include the elderly and those with impaired renal or liver function.

Table 1.1

Important Medicine Interactions				
Medicine	**Interacting Medicine**	**Severity**	**Clinical Effect**	**Clinical Management**
ACEIs, ARBs	Diuretics	Moderate	Additive hypotensive action	Monitor BP closely, do not use together in volume depleted patients
	Potassium sparing diuretics	Severe	Hyperkalemia when used together	Monitor blood potassium levels, avoid use together in renal function derangement
	ACEIs, ARBs	Severe	Hyperkalemia when used together	Monitor blood potassium levels, avoid use together in renal function derangement
	NSAIMs	Moderate	Reduced antihypertensive action due to sodium and fluid retention	Avoid use together
	Severe-dose aspirin	Moderate	Reduced antihypertensive action due to sodium and fluid retention	Avoid use together
Amiodarone	Digoxin	Severe	Increased digoxin concentration, Digoxin toxicity	Avoid use together, decrease digoxin dose by up to 50%, monitor blood digoxin levels and for clinical digoxin toxicity
Atorvastatin	Verapamil, clarithromycin itraconazole, fluconazole, cyclosporine	Severe	Rhabdomyolysis	Avoid use of macrolides and azoles, use rosuvastatin
Beta-blockers	Verapamil, Diltiazem	Severe	Additive bradycardia, AV block	Avoid using together, monitor heart rate, BP, and ECG
	Antidiabetic Medicines, including insulin and GLP-1 analogues	Severe	Suppression of neuroglycopenic symptoms - tremor, sweating, palpitations (hypoglycemia unawareness)	Monitor blood sugars
	Bronchodilators	Moderate	Decreased bronchodilator activity, bronchial spasm	Avoid use in asthma, COPD. Use selective beta-blockers
Carbamazepine	Warfarin	Moderate	Loss of warfarin efficacy, lower INR	Avoid use, monitor INR, increase dose of warfarin, use levetiracetam, oxcarbazepine
	Rifampicin	Moderate	Lower serum carbamazepine levels	Avoid use together, monitor serum carbamazepine levels
	Dextropropoxyphene	Severe	Carbamazepine toxicity	Avoid use together
	Haloperidol, Risperidone, fluoxetine	Moderate	Carbamazepine toxicity	Avoid use together
	Clarithromycin (NOT Azithromycin), fluconazole, isoniazid, metronidazole	Severe	Carbamazepine toxicity	Avoid use together
Carbamazepine, Phenytoin	Oral Contraceptives (OCP) (estrogen containing)	Severe	Loss of contraceptive efficacy	Avoid use together, use OCP with Severe dose estrogen, use alternative method of contraception, use AEDs which do not interact with OCPs*

	Cortisol, dexamethasone, hydrocortisone, methylprednisolone, prednisolone	Moderate	Reduced serum concentrations of steroids	Monitor clinically for loss of efficacy
	Amiodarone, atorvastatin, digoxin, metoprolol, nifedipine, nimodipine, verapamil	Moderate	Reduced serum concentrations of interacting Medicines	Monitor clinically for loss of efficacy
	Doxycycline, itraconazole, metronidazole, albendazole	Moderate	Reduced serum concentrations of interacting Medicines	Monitor clinically for loss of efficacy
	Benzodiazepines, lamotrigine, pregabalin, topiramate, valproic acid	Severe	Reduced serum concentration of interacting AEDs, Loss of efficacy of AED, breakthrough seizures	Monitor serum levels of affected AEDs
Carbamazepine, lamotrigine, phenytoin, valproic acid	Sertraline	Moderate	AED toxicity	Avoid use together
Clarithromycin, Azithromycin	Atorvastatin	Severe	Risk of rhabdomyolysis	Avoid use together, use rosuvastatin
	Warfarin	Severe	Increased INR, bleeding tendency	Monitor clinically and by INR
	NOACs - Dabigatran, Rivaroxaban, Apixaban	Severe	Increased risk of bleeding	Monitor clinically
	Phenytoin, carbamazepine	Severe	Increased blood levels of AED with clarithromycin and erythromycin, AED toxicity	Avoid use together, monitor clinically and blood AED levels, use Azithromycin
	Medicines that prolong QT interval	Severe	Further QT prolongation, risk of TDP	Avoid use together, monitor by ECG
Clonidine	Centrally acting depressant agents (hypnotics, tranquillizers, neuroleptics, anti- epileptics, some anti-depressants, H1-anti-histaminic agents, alcohol)	Severe	Additive sedative effects	Avoid use together, instruct patient to avoid driving, use machinery, prevent falls
Clopidogrel	Proton Pump inhibitors	Moderate	Decreased efficacy of clopidogrel	Avoid use of PPIs with clopidogrel, add aspirin or use prasugrel
Digoxin	Clarithromycin, cyclosporine, itraconazole	Severe	Increased digoxin concentration, Digoxin toxicity	Avoid use together, decrease digoxin dose by up to 50%, monitor blood digoxin levels and for clinical digoxin toxicity
Diuretics	Digoxin	Severe	Increased digoxin toxicity due to hypokalemia	Monitor blood potassium levels
	Aspirin (with thiazide diuretics)	Moderate	Increased blood uric acid levels	Monitor blood uric acid levels
	NSAIMs	Moderate	Lowering of anti- hypertensive effect of loop diuretics	Monitor BP, avoid use of NSAIMs, use acetaminophen
	Steroids	Moderate	Hypokalemia, lowering of anti-hypertensive effect due to sodium retention	Avoid use together, monitor serum potassium levels and BP, supplement potassium
	Aminoglycoside antibiotics	Moderate	Ototoxicity (when used with loop diuretics)	Avoid use together, monitor for ototoxicity
DPP-4 inhibitors (sitagliptin, Vildagliptin etc.)	Diltiazem, Atazanavir, ritonavir, ciprofloxacin, norfloxacin, clarithromycin, chloroquine, hydroxychloroquine,	Moderate	Increased efficacy of DPP-4 inhibitors, hypoglycemia	Dose reduction of DPP-4 inhibitor, blood glucose monitoring
	Rifampicin	Moderate	Decreased efficacy of DPP-4 inhibitors, hyperglycemia	Increase dose of DPP-4 inhibitor, blood glucose monitoring
	GLP-1 analogues	Moderate	Increased risk of pancreatitis	Avoid use together

Isoniazid	Phenytoin, Carbamazepine	Severe	Marked rise in blood levels of phenytoin and carbamazepine, AED toxicity	Monitor clinically and blood AED levels, reduce dose
Itraconazole, Fluconazole	Atorvastatin	Severe	Risk of myopathy	Avoid use together
	Warfarin	Severe	Increased INR, bleeding tendency	Monitor clinically and by INR
	NOACs - Dabigatran, Rivaroxaban, Apixaban	Major	Increased risk of bleeding	Not recommended, Monitor clinically
	Medicines that prolong QT interval	Severe	Further QT prolongation, risk of TDP	Avoid use together, monitor by ECG
Lamotrigine	OCP	Severe	Loss of efficacy of lamotrigine, seizures May lead to loss of OCP efficacy at doses > 300mg/day	Avoid use together, increase dose of lamotrigine Use other AEDs which do not interact with OCPs
	Rifampicin	Moderate	Lamotrigine toxicity	Dose reduction of lamotrigine by 50%, slow up-titration of lamotrigine
Linezolid	Rifampicin	Moderate	Low blood levels of linezolid, therapeutic failure	Increase dose of linezolid, use alternative antibiotic
Meropenem	Valproic acid	Severe	Reduced blood levels of valproic acid, loss of seizure control	Contraindicated
Metformin	Iodinated contrast media	Severe	Severe risk of contrast induced nephropathy	Contraindicated 48 hours prior and 48 hours after use of contrast media
Methotrexate	Leflunomide	Severe	Increase Methotrexate toxicity, bone marrow and hepatic toxicity	Monitor Liver function tests, signs of Methotrexate toxicity
	Trimethoprim and Co- trimoxazole	Severe	Increase risk of myelotoxicity, pancytopenia, megaloblastic anemia	Monitor signs of methotrexate toxicity
	Live vaccines and chemotherapeutic agents	Severe	Increase risk of infection	Monitor signs of infection
	Phenytoin	Severe	Decrease Phenytoin effectiveness and increase risk of methotrexate toxicity	Monitor signs of methotrexate toxicity
	Tamoxifen	Severe	Increased risk of thromboembolism	Monitor signs of thromboembolism
Phenytoin	Warfarin	Moderate	Unpredictable effect, INR may increase or decrease	Avoid use, monitor INR, use levetiracetam, oxcarbazepine
	Rifampicin	Moderate	Lower serum phenytoin levels	Avoid use together, monitor serum phenytoin levels
	Clarithromycin, fluconazole, fluoxetine, isoniazid	Severe	Phenytoin toxicity	Avoid use together, monitor serum phenytoin levels
	Allopurinol, amiodarone, diltiazem, omeprazole	Moderate	Phenytoin toxicity	Avoid use together, monitor serum phenytoin levels
Pyrazinamide	Zidovudine	Severe	Decreased levels and efficacy of pyrazinamide, loss of efficacy in HIV-TB co-infected patients	Increase dose of pyrazinamide, avoid use of zidovudine (use Tenofovir)
	Cyclosporine	Severe	Reduced levels of cyclosporine	Increase dose of cyclosporine
Quinolones	Calcium, Iron containing oral preparations, antacids	Moderate	Reduced absorption of Quinolones	Space out the Medicines by 2-4 hours
	Medicines that prolong QT interval	Severe	Further QT prolongation, risk of TDP	Avoid use together, monitor by ECG, Moxifloxacin is contraindicated
	Amiodarone	Severe	Increased risk of arrhythmia	Avoid use together
Rifampicin	Verapamil, Amlodipine, Nifedipine, diltiazem	Moderate	Reduced levels of calcium channel blockers	Monitor BP, increase dose of calcium channel blockers, use alternative anti-hypertensive

	Beta- blockers (NOT Atenolol)	Severe	Reduced levels of beta-blockers	Monitor BP, increase dose of beta-blockers, use atenolol
	Sulfonylureas	Moderate	Decreased efficacy of sulfonylureas, hyperglycemia	Monitor blood sugar, add other Medicines
	Phenytoin, carbamazepine, valproic acid, benzodiazepines	Severe	Lower serum levels of AEDs, breakthrough seizures	Monitor serum levels of AEDs
	Digoxin	Severe	Reduced serum digoxin levels	Monitor clinically and serum digoxin levels
	OCPs	Moderate	Reduced efficacy of estrogen and progesterone containing OCPs	Avoid use together, use additional method (barrier), injectable progesterone may be used
	Corticosteroids	Severe	Reduced efficacy of steroids	Increase dose of steroids
	Cyclosporine	Severe	Reduced efficacy of cyclosporine	Increase dose of cyclosporine
	Itraconazole, fluconazole, macrolides	Severe	Marked reduction in blood levels of anti-fungal	Use Severer doses of anti- fungal
Sildenafil	Nitrates	Severe	Severe hypotension	Contraindicated for use together
	Amiodarone, itraconazole	Moderate	Increased plasma sildenafil level	Avoid use together
Sulfonylureas	Fluconazole, H2-antagonists, sulfonamides, clarithromycin, verapamil	Moderate	Increased efficacy of sulfonylureas, hypoglycemia	Dose reduction of sulfonylurea, blood glucose monitoring
	Rifampicin, phenytoin, carbamazepine	Moderate	Decreased efficacy of sulfonylureas, hyperglycemia	Increase dose of sulfonylurea, blood glucose monitoring
	Non-selective beta- blockers	Moderate	Decreased efficacy of sulfonylureas, hyperglycemia	Blood glucose monitoring
Thiazolidinediones	Calcium channel blockers, NSAIMs	Severe	Fluid retention, heart failure	Avoid combination, close monitoring
Trimethoprim and Co- trimoxazole	Warfarin*	Severe	Increased INR, bleeding tendency	Monitor clinically and by INR
	Methotrexate	Severe	Methotrexate toxicity	Monitor clinically for signs of liver and hematological toxicity
	Amiodarone	Severe	Increased risk of arrhythmia	Avoid use together
Valproic acid	Amitriptyline, meropenem, imipenem	Moderate	Increased serum concentration of interacting Medicines	Avoid use together
	OCP, Meropenem	Moderate	Loss of efficacy of Valproic acid, seizures No effect on OCP efficacy	Avoid use together, increase dose of valproic acid
	Lamotrigine	Moderate	Lamotrigine toxicity	Dose reduction of lamotrigine by 50%, slow up-titration of lamotrigine
	Carbamazepine	Moderate	Carbamazepine toxicity	Monitor serum levels of affected AEDs
Verapamil, Diltiazem	Digoxin	Severe	Increased digoxin levels, digoxin toxicity (mainly with verapamil)	Avoid use together, decrease digoxin dose by up to 50%, monitor digoxin levels
	Carvedilol, Metoprolol	Moderate	Hepatic interaction leading to Severe blood levels of Verapamil	Use atenolol, bisoprolol or nebivolol (also when using potent hepatic enzyme inducers or inhibitors)
warfarin	Metronidazole	Severe	increased INR and/or bleeding tendency	Monitor INR when starting or stopping, decrease dose of warfarin by 30% when adding metronidazole
	Amiodarone	Severe	increased INR and/or bleeding tendency	Monitor INR when starting or stopping, decrease dose of warfarin by 25% when adding amiodarone

	Aspirin (> 6 g/day), NSAIMs	Severe	increased INR and/or bleeding tendency	Use lower doses of aspirin, monitor for bleeding, use COX-2 inhibitors
	Clopidogrel	Severe	increased INR and/or bleeding tendency	Monitor for bleeding
	Ciprofloxacin, levofloxacin	Severe	increased INR and/or bleeding tendency	Monitor INR when starting or stopping, decrease dose of warfarin by 15% when adding ciprofloxacin
	Phenytoin	Severe	increased INR and/or bleeding tendency	Initially INR is increased, later on with long term use it is decreased - monitor INR, use alternative anti-epileptic Medicine
	Clarithromycin	Severe	increased INR and/or bleeding tendency	Monitor INR when starting or stopping, decrease dose of warfarin by 15% when adding clarithromycin
	Lansoprazole	Moderate	increased INR and/or bleeding tendency	Monitor INR when starting or stopping
	Leflunomide	Severe	increased INR and/or bleeding tendency	Monitor INR when starting or stopping
	Levothyroxine	Severe	increased INR and/or bleeding tendency	Monitor INR when starting or stopping
	Methyl salicylate (topical)	Severe	increased INR and/or bleeding tendency	Monitor INR when starting or stopping, avoid use together
	Ranitidine	Moderate	increased INR and/or bleeding tendency	Monitor INR when starting or stopping, use alternative (famotidine)
	Rosuvastatin	Major	increased INR and/or bleeding tendency	Monitor INR when starting or stopping, decrease dose of warfarin by 20% when adding rosuvastatin, use atorvastatin
	Sulfamethoxazole (with or without trimethoprim)	Major	increased INR and/or bleeding tendency	Severe interaction, Monitor INR, decrease dose of warfarin by 25% when adding sulfamethoxazole
	Tramadol	Moderate	increased INR and/or bleeding tendency	Monitor INR when starting or stopping, decrease dose of warfarin by 20% when adding tramadol
	Lactulose	Moderate	increased INR and/or bleeding tendency	Monitor INR when starting or stopping
	Fenofibrate	Severe	increased INR and/or bleeding tendency	Monitor INR when starting or stopping, decrease dose of warfarin by 15% when adding fenofibrate
	Fluconazole	Severe	increased INR and/or bleeding tendency	Monitor INR when starting or stopping, decrease dose of warfarin by 20% when adding fluconazole
	Isoniazid	Moderate	increased INR and/or bleeding tendency	Monitor INR when starting or stopping, decrease dose of warfarin by 15% when adding isoniazid
	Itraconazole	Severe	increased INR and/or bleeding tendency	Monitor INR when starting or stopping, decrease dose of warfarin by 25% when adding itraconazole
	Methotrexate	Severe	increased INR and/or bleeding tendency	Monitor INR when starting or stopping.
	Azathioprine	Severe	decreased INR and/or clotting tendency	Monitor INR when starting or stopping; 2-to-3-fold Severe dose of warfarin may be required
	Carbamazepine	Moderate	decreased INR and/or clotting tendency	Monitor INR when starting or stopping, increase dose of warfarin by 50% when adding carbamazepine
	Propylthiouracil	Moderate	decreased INR and/or clotting tendency	Monitor INR when starting or stopping
	Rifampicin	Moderate	decreased INR and/or clotting tendency	Monitor INR when starting or stopping; increase dose of warfarin by 25-50% when adding rifampicin
	Sulfasalazine	Moderate	decreased INR and/or clotting tendency	Monitor INR when starting or stopping; may need to increase dose of warfarin by 50%
	Methimazole	Moderate	decreased INR and/or clotting tendency	Monitor INR when starting or stopping

Methotrexate	Doxycycline, NSAID	Severe	Increased risk of leucopenia, thrombocytopenia, anemia, nephrotoxicity and mucosal ulceration	Monitor signs of methotrexate toxicity
	Thiazide Diuretics, levetiracetam	Severe	Enhance myelosuppression and increase methotrexate toxicity	Monitor signs of myelosuppression and methotrexate toxicity
	Penicillin antibiotics	Severe	Increase methotrexate toxicity	Monitor signs of methotrexate toxicity

Reference: Singla S, 2017. Drug Interactions Every Physician Must Know. [online] researchgate.net. Available at: <https://www.researchgate.net/publication /327069239_Drug_Interactions_Every_Physician_Must_Know> [Accessed 11 May 2022].

Appendix 2: Malaria Treatment Regimen

Table 2.1 Treatment regimen for P. vivax: Protocol A

Age Group	Medicine	Day 0	Day 1	Day 2	Day 3 to 13
Infant	Chloroquine	½ tab (7.5 mL syrup)	½ tab (7.5 mL syrup)	¼ tab (3.75 mL syrup)	-
1- 4 years	Chloroquine Primaquine	1 tab (15 mL syrup) ½ tab	1 tab (15 mL syrup) ½ tab	½ tab (7.5 mL syrup) ½ tab	½ tab each
4 - 8 years	Chloroquine Primaquine	2 tabs 1 tab	2 tabs 1 tab	1 tab 1 tab	1 tab each
8 - 14 years	Chloroquine Primaquine	3 tabs 1 ½ tabs	3 tabs 1 ½ tab	1 ½ tab 1 ½ tab	1 and ½ tab each
14 years & above	Chloroquine Primaquine	4 tabs 2 tabs	4 tabs 2 tabs	2 tabs 2 tabs	2 tabs each

Note:

- *The dose for chloroquine is calculated as base. e.g. if you need to give 300 mg of chloroquine, that will be equivalent to 2 tablets of chloroquine. For children under 5 years Chloroquine 50 mg/5ml syrup may be used.*
- *Dosage should be calculated by per kg body weight in children wherever possible, viz. chloroquine, 10 mg/kg on day 0 and 1 and 5 mg/kg on day 2, and primaquine 0.25 mg/ kg.*
- *Primaquine treatment period is 14 days except for pregnant women and children under 1 year where it is contraindicated.*
- *If the patient vomits within 1 hr of taking the medicine, the dose should be repeated.*

Table 2.2 Treatment regimen for uncomplicated falciparum malaria: Protocol B

Patient category	Medicines	Daily dose	No. of days of treatment
< 5 kg	Quinine	10 mg/kg IM 8 hourly (Max of 600 mg/dose)	3 (may be extended up to 7 days depending on clinical response)
5 -14 kg	Artemether (ART) + lumefanthrine(L)	1 tablet at 0, 8, 24, 36, 48 and 60 hrs	3
15 – 24 kg	Artemether (ART) + lumefanthrine(L)	2 tablets at 0, 8, 24, 36, 48 and 60 hrs	3
25 – 34kg	Artemether (ART) + lumefanthrine(L)	3 tablets at 0, 8, 24, 36, 48 and 60 hrs	3
>35 kg	Artemether (ART) + lumefanthrine(L)	4 tablets at 0, 8, 24, 36, 48 and 60 hrs	3
1st trimester pregnancy	Quinine 300mg tab + proguanil 100 mg + dapsone 100mg	600 mg 8 hourly followed by dapsone (1/2 tab) 12 hourly + proguanil 1 tablet 12 hourly for 4 more days.	Three days quinine followed by 4 days of dapsone & proguanil.
* 2nd and 3rd trimester pregnancy	Quinine 300 mg tab + dapsone 100 mg + proguanil 100 mg	100 mg 12 hourly OR 300 mg 8 hourly followed by dapsone (1/2 tab) 12 hourly + proguanil (1 tab) 12 hourly for 4 more days.	Three days quinine followed by 4 days of dapsone & proguanil.

Note:

- The medicine must be administered under direct supervision; total 6 doses at 0, 8,24,36,48 and 60 hours are administered; the second dose is administrated after 8 hours and then there after the rest of the dose must be continued every 12 hourly till last dose at 60 hours.
- If the patient vomits within 1 hour of taking the medicine, the dose should be repeated.
- Coartem® is not recommended in pregnant women; for pregnant women in 1st ,2nd and 3rd trimester, the old regimen with quinine/artesunate with dapsone and proguanil will be followed. WHO recommends dual therapy in pregnancy with clindamycin (not on the NEML).

- For uncomplicated P. falciparum infection, if the coartem® is out of stock or if it is not suitable for some patients due to hypersensitivity reaction, use artesunate/doxycycline combination for adult and artesunate/dapsone/proguanil combination if doxycycline is contraindicated.
- *A stat dose of primaquine on day 3 should be given to treat gametocytes of falciparum except in pregnant women and children less than 5 years of age.*

Table 2.3 Antimalarial medicines for the treatment of severe malaria: Protocol C

Medicine	Route of administration	Schedule
Artesunate	IV	ADULT and CHILD (20 kg and greater): 2.4 mg/kg IV (slow bolus over 1 to 2 minutes) at 0 hours, at 12 hours, at 24 hours, and then once daily until parasite density is 1% or less; MAX. 7 days. Follow with a full course of oral antimalarial therapy when patient can tolerate oral medications; administer with an antimalarial agent that is active against the hypnozoite liver stage forms of *Plasmodium*, such as primaquine, to patients with severe malaria due to *P. vivax* or *P. ovale*. CHILD (Less than 20 kg): 3 mg/kg IV at 0 hours, at 12 hours, at 24 hours, and then once daily, if necessary, until parasite density is 1% or less; MAX duration, 7 days. Follow with a full course of oral antimalaria therapy when patient can tolerate oral medications.
Quinine	IV	Loading dose of 20 mg/kg body weight of quinine given over a 4 hour period in IV fluid (glucose 5% preferred to prevent hypoglycemia); then give maintenance dose of 10 mg/kg after 8 hours. This should be repeated until the patient is able to take quinine tablet orally. The oral dose of quinine is 10 mg/kg body weight given every 8 hours. The total duration of treatment is 7 days including both IV and oral treatment. Quinine can be given by IM injections in the same dosage if IV infusion is not possible. It should be diluted in 0.9% sodium chloride to a concentration of 60-100 mg/ml salt, the dose divided equally and administered on the two anterior thighs (not on the buttock).

Note: *Primaquine should be given to all cases except pregnant women and children under 1 year; dose of primaquine (each primaquine tablet is 7.5 mg base) is as follows:*

Children 1-4 years:	7.5 mg base (1 tablet)
Children 5-8 years:	15 mg base (2 tablets)
Children 9-14 years:	22.5 mg base (3 tablets)
Above 15 years:	30 mg base (4 tablets)

A loading dose of quinine should not be given:

- If the patient has received quinine within the preceding 12 hrs, or the previous history of medicine intake cannot be ascertained
- The weight of the patient cannot be taken
- Facilities for controlled rate of flow of quinine infusion is not available
- Facilities to treat complications of quinine toxicity do not exist.

If above conditions exist, patient should be treated with maintenance dose of quinine only. If there is no clinical improvement after 48 hours of parenteral quinine therapy, the maintenance dose of parenteral quinine should be reduced by one-third to one half (i.e. 5-7 mg/kg quinine). Total daily dose of quinine in patients requiring parenteral therapy beyond 48 hours is as follows:

Adults:

- Day 0: 30-40 mg/kg of body weight
- Day 1: 30 mg/kg of body weight
- Day 2 and subsequent days: 15-21 mg/kg of body weight.

The maximum dosage should not exceed 2000 mg per day.

Children:

- Day 0: 30-40 mg/kg of body weight
- Day 1: 20 mg/kg of body weight
- Day 2 and subsequent days: 10-14 mg/kg of body weight.

The maximum dosage should not exceed 600mg per dose or 1800 mg per day.

- Loading dose of quinine can be given at recommended doses even in acute renal failure (ARF) or severe jaundice up to 48 hrs. Subsequent doses should be reduced to half. In such cases, the volume of infusion fluid for administration of quinine can be reduced to half (quinine dihydrochloride 10 mg salt/ kg body weight diluted in 5% dextrose, 5 ml/kg body weight, or 1 mg of quinine salt/ 0.5 ml of fluid).
- Quinine is not contraindicated in pregnancy.
- Monitor pulse and blood pressure at least every 2 hrs while the patient is on quinine infusion.
- Avoid standing and sitting postures of the acutely sick patient during quinine therapy to prevent severe postural hypotension.

An uncomplicated P. falciparum malaria patient can progress to severe and complicated state if not treated early and appropriate.

Appendix 3: Routine Immunization Schedule for children and adolescents

Table 3.1

Vaccines	Number of doses	Schedule and age for vaccination	Minimum interval between doses	Dosage	Route/site
BCG (Bacille Calmette Guerin)	1	At birth or at first contact	NA	0.05ML	Intradermal, right upper arm
Hepatitis B (Pediatric)	1	Hep. B At birth (Within 24 hours as "Zero" dose)		0.5 ML	Intramuscular (IM) antero-lateral aspect of left mid-thigh
DTP-Hep,B-Hib	3	DTP-Hep.B-Hib 1 at 6 Weeks DTP-Hep.B-Hib 2 at 10 Weeks DTP-Hep.B- Hib 3 at 14 Weeks	4 Weeks	0.5 ML	Intramuscular (IM) antero-lateral aspect of left mid thigh
Inactivated Polio Vaccine (IPV)	2	At 14 weeks At 8 Months	5 months	0.5 ML	antero-lateral aspect of left mid thigh
Oral Polio Vaccine (bOPV)	4	OPV 0 at birth (Within 0-14 days as "Zero dose) OPV 1 at 6 Weeks OPV 2 at 10 Weeks OPV 3 at 14 Weeks	4 weeks	2 drops	Oral
Pneumococcal conjugate Vaccine (PCV)	3	PCV 1 at 6 Weeks PCV 2 at 10 Weeks PCV 3 at 9 months	4 Weeks	0.5 ML	antero-lateral aspect of left mid-thigh
Measles, Mumps and Rubella (MMR)	2	MMR 1 at 9 Months MMR 2 at 24 Months	15 months	0.5 ML	Subcutaneous-left upper arm
Diphtheria, Tetanus & Pertussis (DTP)	1	DTP booster AT 24 Months	NA	0.5 ML	Intramuscular (IM) antero-lateral aspect of left mid-thigh
Tetanus diphtheria (Td)	2	Td 1 at PP Class student Td 2 at Class seven students Out of school 6 years and 13 years old		0.5 ML	Intramuscular (IM) left upper arm
Human Papilloma Virus (HPV) vaccine	2 doses girls and boys below 15 years of age	• Class six girls and boys • Out of school girls and boys at 12 years of age • For 15 years and above 3 doses	• 6 Months • 0, 2 and 6 months	0.5 ML	Intramuscular (IM) left upper arm

Reference: *EPI services manual for health workers 5th edition, 2020*

Note:

- If BCG is provided after the age of one year, dose is 0.1 ml
- If the child misses the birth dose of OPV, a dose of OPV should be provided with the MMR1 at 9 months and recorded as OPV0.
- HPV vaccine should be administered exactly as per the schedule. However, should there be any defaulters for subsequent doses after having administered first dose, following criterion should be applied for those defaulters:
  a. For less 15 years, if the 2nd dose is not given on time, it can be given within 15 months from the due date.
  b. For 15 years and above, if the 3rd dose is not given on time, it can be given up to 1 year from the due date.
  c. If the client misses the 2nd or 3rd doses as mentioned above, repeat the HPV vaccination from 1st dose.

Table 3.2

For Pregnant women having no record of Tetanus Toxoid Vaccination			
Vaccine	**Frequency/time**	**Dosage**	**Route/site**
Td1	*As soon as possible*	0.5 mL	Intramuscular (IM) left upper arm
Td2	*4 weeks after 1st dose*		
Td3	*6 months after 2nd dose*		
Td4	*1 year after 3rd dose*		
Td5	*1 year after 4th dose*		

Table 3.3

Number of prior Td received	*Td dose*	*Frequency /Time*	*Dose*	*Route/Site*
Pregnant women who have received 1st dose of Td vaccine	*- 2nd dose* *- 3rd dose* *- 4th dose* *- 5th dose* *- 6th dose*	*- As soon as possible* *- 4 weeks after 1st dose* *- 6 months after 3rd dose* *- 1 year after 4th dose* *- 1 year after 5th dose*	*0.5 mL*	Intramuscular (IM) left upper arm
Pregnant women who have received 2nd dose of Td vaccine	*- 3rd dose* *- 4th dose* *- 5th dose* *- 6th dose*	*- As soon as possible* *- 4 weeks after 3rd dose* *- 6 Months after 4th dose* *- 1 year after 5th dose*		
Pregnant women who have received 3rd dose of Td vaccine	*- 4th dose* *- 5th dose* *- 6th dose*	*- As soon as possible* *- 4 weeks after 4th dose* *- 1year after 5th dose*		
Pregnant women who have received 4th dose of Td vaccine	*- 5th dose* *- 6th dose*	*- As soon as possible* *- 1 year after 5th dose*		
Pregnant women who have received 5th dose of Td vaccine	*- 6th dose*	*- As soon as possible*		

Appendix 4: Emergency treatment of poisoning (specific medicines)

These notes are only guidelines and it is strongly recommended that appropriate health professionals be consulted where there is a doubt.

HOSPITAL ADMISSION: All patients who show feature of poisoning should generally be admitted to hospitals. Patients who have taken poisons with delayed action should also be admitted, even if they appear well; delayed-action poisons include aspirin, iron, paracetamol etc.

GENERAL CARE

General care in principle is always ABC.

A. Airway

An obstructed airway requires immediate attention. Lift the chin, remove dentures and oral secretions, hold the jaw forward, and insert an oropharyngeal airway if available, and the turn the patient to semi prone position with the head down.

B. Breathing

Assisted ventilation by mouth-to-mouth may be needed, where available an ambu bag is a better choice. Oxygen is not a substitute for adequate ventilation, but it should always be given in the highest concentration possible in poisoning especially in carbon monoxide poisoning and other irritant gases. Respiratory stimulants do not help and are potentially dangerous.

C. Circulation

Hypotension or shock is common in severe poisoning especially with CNS depressants. The patients should be carried head down on a stretcher and must be in this position in the ambulance also. Oxygen should be given to relieve hypoxia and an IV infusion set up if necessary. Cardiac conduction defects and arrhythmias may occur in any acute poisoning, e.g. tricyclic antidepressants. If serious ventricular arrhythmias are confirmed by ECG, the injection lignocaine 2% IV will be needed (bolus and infusion).

Body temperature

Hypothermia may develop in patients who have been deeply unconscious for several hours. It is best treated by wrapping the patients to conserve body heat. Hyperthermia is initially managed by removing all unnecessary clothing.

Sponging with tepid water will promote evaporation; iced water should not be used. Both hypothermia and hyperthermia require urgent hospitalization for assessment and supportive treatment.

Convulsions

Diazepam 10-20 mg by slow IV injection should be given if convulsions are protracted or reoccurs frequently. The dose may be repeated after 30-60 minutes if necessary. Child: 200-300 mcg/kg-body weight.

Removal and Elimination

Removal from the stomach

The dangers of attempting to empty the stomach have to be balanced against the toxicity of the ingested poison. Gastric emptying is clearly unnecessary if the risk of toxicity is small or if the patients arrive too late. Emesis induced by ipecacuaha has been used in adults (30 mL) and children (5-15 mL), but there is no evidence that it presents clinically significant absorption. It should only be considered if the patient is fully conscious if the poison ingested is neither corrosive nor a petroleum distillation or if it is not adsorbed by activated charcoal.

Prevention of absorption

Given by mouth; activated charcoal can bind many poisons thereby reducing their absorption. The sooner it is given, the more effective it is. The usual dose for activated charcoal is as follows is as follows: ADULT: 50 g every 2-4 hours; CHILD: 10-15 g ever 2-4 hours.

Other Poisons

Snake Bites and Insect Stings

SNAKE BITE

Indications for antivenom

Antivenom treatment is recommended if and when a patient with proven or suspected snake bite develops one or more of the following signs:

Systemic envenoming:

- Hemostatic abnormalities: spontaneous systemic bleeding (clinical), coagulopathy (20WBCT or other laboratory) or thrombocytopenia (<100 x 109/liter) (laboratory)
- Neurotoxic signs: ptosis, external ophthalmoplegia, paralysis etc. (clinical)
- Cardiovascular abnormalities: hypotension, shock, cardiac arrhythmia (clinical), abnormal ECG
- Acute renal failure: oliguria/anuria (clinical), rising blood creatinine/ urea (laboratory)
- (Hemoglobin-/myoglobin-urea:) dark brown urine (clinical), urine dipsticks, other evidence of intravascular hemolysis or generalized rhabdomyolysis (muscle aches and pains, hyperkalemia) (clinical, laboratory)

Local envenoming:

- Local swelling involving more than half of the bitten limb (in the absence of a tourniquet) Swelling after bites on the digits (toes and especially fingers)
- Rapid extension of swelling (for example beyond the wrist or ankle within a few hours of bites on the hands or feet)
- Development of an enlarged tender lymph node draining the bitten limb

How long after the bite can antivenom be expected to be effective?

Antivenom treatment should be given as soon as it is indicated. It may reverse systemic envenoming even when this has persisted for several days or, in the case of hemostatic abnormalities, for two or more weeks. However, when there are signs of local envenoming, without systemic envenoming, antivenom will be effective only if it can be given within the first few hours after the bite.

Administration of antivenom

Dried anti-snake venom serum power is reconstituted usually with 10 mL of sterile water for injection. Following two methods of administration are recommended: **Intravenous "push" injection**: reconstituted antivenom is given by slow intravenous injection (not more than 2 mL/minute). *Note: doctor/nurse giving the antivenom must remain with the patient during the time when some early reactions may develop*. OR **Intravenous infusion**: reconstituted antivenom is diluted in approximately 5-10 mL of isotonic fluid per kg body weight (i.e., 250-500 mL of isotonic saline or 5% dextrose in the case of an adult patient) and is infused at a constant rate over a period of about one hour.

Criteria for giving more antivenom

- ✓ Persistence or recurrence of blood in-coagulability after 6 hr of bleeding after 1-2 hr
- ✓ Deteriorating neurotoxic or cardiovascular signs after 1-2 hr

Note: *Local administration of antivenom at the site of the bite is not recommended. Antivenom must never be given by the intramuscular route if it could be given intravenously. Situations in which intramuscular administration might be considered; at a peripheral first aid station, before a patient with obvious envenoming is put in an ambulance for a journey to hospital that may last several hours; on an expedition exploring a remote area very far from medical care, when intravenous access has proved impossible.*

Antivenom reactions

Note*: All lifesaving medicines like adrenaline, antihistamine, and steroids are to be kept ready before administering anti-snake venom. Test dose is usually not recommended as it may delay treatment and can in themselves be sensitizing.*

- A proportion of patients, usually more than 20%, develop a reaction either early (within a few hours) or late (5 days or more) after being given antivenom.
- Early anaphylactic reactions: usually within 10-180 minutes of starting antivenom.
- Pyrogenic (endotoxin) reactions usually develop 1-2 hours after treatment.
- Late (serum sickness type) reactions develop 1-12 (mean 7) days after treatment.

Observation of the response to antivenom

If an adequate dose of appropriate antivenom has been administered, the following responses may be seen.

- ✓ General: the patient feels better. Nausea, headache and generalized aches and pains may disappear very quickly. This may be partly attributable to a placebo effect.
- ✓ Spontaneous systemic bleeding (e.g. from the gums) usually stops within 15- 30 minutes.
- ✓ Blood coagulability (as measured by 20WBCT) is usually restored in 3-9 hours. Bleeding from new and partly healed wounds usually stops much sooner than this.
- ✓ In shocked patients, blood pressure may increase within the first 30-60 minutes and arrhythmias such as sinus bradycardia may resolve.
- ✓ Neurotoxic envenoming of the post-synaptic type (cobra bites) may begin to improve as early as 30 minutes after antivenom, but usually take several hours. Envenoming with presynaptic toxins (kraits and sea snakes) is unlikely to respond in this way.
- ✓ Active hemolysis and rhabdomyolysis may cease within a few hours and the urine returns to its normal colour.

Recurrence of systemic envenoming

In patients envenomed by vipers, after an initial response to antivenom (cessation of bleeding, restoration of blood coagulability), signs of systemic envenoming may recur within 24-48 hours. This is attributable to:

1. Continuing absorption of venom from the "depot" at the site of the bite, perhaps assisted by improved blood supply following correction of shock, hypovolemia etc.,
2. A redistribution of venom from the tissues into the vascular space, as the result of antivenom treatment. Recurrent neurotoxic envenoming after treatment of cobra bite has also been described.

Criteria for repeating the initial dose of antivenom

If the blood remains incoagulable (as measured by 20WBCT) six hours after the initial dose of antivenom, the same dose should be repeated. This is based on the observation that, if a large dose of antivenom (more than enough to neutralize the venom procoagulant enzymes) is given initially, the time taken for the liver to restore coagulable levels of fibrinogen and other clotting factors is 3-9 hours.

In patients who continue to bleed briskly, the dose of antivenom should be repeated within 1-2 hours. In case of deteriorating neurotoxicity or cardiovascular signs, the initial dose of antivenom should be repeated after 1-2 hours, and full supportive treatment must be considered.

Reference: *World Health Organization. Regional Office for South-East Asia. Guidelines for the clinical management of snake bites in the South-East Asia Region. 2005 [cited 2022 May 25]; Available from: https://apps.who.int/iris/handle/10665/205171.*

INSECT STINGS from ants, bees, and wasps cause local pain and swelling. If the sting is in the mouth or on the tongue, marked swelling may cause airway obstruction. The stings from these insects are usually treated by cleaning the area, applying ice and if necessary local application of steroids. Anaphylactic reactions require treatment with IM adrenaline.

Specific Medicines

General care should be given as above, the first and foremost being active elimination by vomiting. Other signs and symptoms may be treated specifically as outlined. The "remarks" column indicates specific actions that need to be taken

Table 4.1

Medicines	Signs and Symptoms	Remarks
Salicylates e.g. aspirin, methyl salicylate, salicylic acid	Fast breathing, fever and sweating, dry tongue, drowsiness, nausea and vomiting	Other ways to remove salicylates from the body is by making the urine alkaline by giving sodium bicarbonate or by haemodialysis
Atropine, antihistamines, ephedrine and related substances	**Antihistamines** - drowsiness, dry mouth, headache, nausea, fast pulse, shallow breathing (Child-wide pupils, shaking, high temp, fits) **Atropine** - red, dry skin, wide pupils, blurred vision, dry mouth, confusion, fast pulse, fever, fits **Ephedrine** - nausea, vomiting, headache, irritability, hallucinations, fever, fast pulse, high BP, wide pupils	Do not use chlorpromazine to treat agitated patients who are poisoned by atropine
Aminophylline and theophylline	Nausea and vomiting, fast pulse, restlessness, headache, sleeplessness, hallucinations, fast breathing, unconsciousness in some cases, vomiting blood, fits which may occur suddenly, low BP, irregular pulse	Haemodialysis may be indicated in severe poisoning
Amitriptyline, chloroquine and quinine	**Amitriptyline** - dry mouth, blurred vision, fast-irregular pulse, shallow breathing, fits, low BP, hallucinations & confusion **Chloroquine** (within 3 hrs) - vomiting, diarrhoea, headache, dizziness, fits, low BP, irregular pulse. (*NOTE* the patient may be very ill within 1 hr and may die within 2-3 hrs of taking the medicine*) **Quinine** - nausea and vomiting, large pupils, blurred vision, dizziness, headache, fever, excitement, fast pulse, fits, low BP, blindness (partial or complete), unconsciousness	
Phenobarbital, chlorpromazine, haloperidol and benzodiazepines (diazepam, lorazepam, etc.)	**Phenobarbital** - drowsiness, unconsciousness (may last for many days), low temperature, low BP, shallow breathing, skin blisters between the fingers or on body/knees/ankles, no bowel sounds (means that the gut has stopped working and poisoning is serious) **Chlorpromazine and Haloperidol** - drowsiness, unconsciousness, low BP, low temperature, fast/irregular pulse, rigid/stiff limbs, abnormal eye movements **Benzodiazepines** - staggering walk, slurred speech, drowsiness, shallow breathing and unconsciousness	If the patient is an epileptic taking phenobarbital, wait 48 hrs after the patient has woken up before you start giving doses of phenobarbital again
Carbamazepine, phenytoin & valporic acid	**Carbamazepine** - dry mouth, aggressive behaviour, drowsiness, wide pupils, blurred vision, shallow breathing, irregular pulse, jerking movements, nausea, vomiting and diarrhoea **Phenytoin** - nausea, vomiting, drowsiness, slurred speech, blurred vision, the patient cannot walk properly **Valporic acid** - confusion, restlessness, shallow breathing, low BP and drowsiness	Neither haemodialysis nor forced diuresis is useful for treating poisoning with any of these medicines
Dapsone	Signs may be delayed up to 24 hrs after a single dose: blue colour to skin and lips, restlessness, drowsiness, nausea, vomiting and severe belly pain, low BP, fast breathing, hallucinations, fits	Oxygen is not useful for treating cyanosis due to dapsone; dapsone poisoning is worse in patients who are deficient in G6PD

Medicines	Signs and Symptoms	Remarks
Digoxin	Nausea, vomiting, drowsiness, low BP, irregular pulse, weakness, confusion and hallucinations	
Insulin	Anxiety, confusion, shaking, sweating without fever, fast pulse, blurred vision, drowsiness, fits	
Glyceryl trinitrate, hydralazine and beta-blockers	**GTN**- throbbing headache, warm face, dizziness, palpitations, low BP **Hydralazine** - warm skin, nausea and vomiting, headache, fast irregular pulse and low BP **Beta-blockers** - slow pulse, hallucinations, drowsiness, low BP, fits, unconsciousness, the heart and breathing may stop completely	For bronchospasm, give IV salbutamol or aminophylline
Ibuprofen	Nausea, vomiting, headache, abdominal pain, shaking, drowsiness	Very rarely kidney failure may occur after acute overdose
Iron containing medicines	**Within 6 hrs**: vomiting, belly pain, diarrhoea, stools may be coloured black by the iron or may be dark because they contain blood. **Within 12-48 hrs**: low BP, yellow skin caused by liver damage, lung oedema, low output of urine and signs of kidney damage; patients may die from liver failure	
Isoniazid	Nausea, vomiting, stomach pain, large pupils, fever, fits, fat pulse, low BP, shallow breathing	
Magnesium hydroxide, magnesium sulphate and senna	Diarrhoea, vomiting, stomach pain, blood in stools, low BP, fast pulse, unconsciousness	It is not necessary to make the patient vomit
Opiates	Very small pupils, drowsiness then unconsciousness, slow breathing, twitching, fits, low body temp, low BP, lung oedema; the patient may suddenly stop breathing and die	
Oral contraceptives	Nausea and vomiting; girls over 4 years of age may have bleeding like a monthly period	There is no need to do anything
Paracetamol	**Within 24 hrs**: nausea, vomiting and belly pain **After 24-48 hrs**: pain on the right side of the belly **After 2-6 days**: yellow colour to skin and whites of eye showing that liver is damaged, vomiting, fast pulse, confusion, unconsciousness	
Penicillin and tetracyclines	**If the patient is not allergic**: nausea, vomiting, and diarrhoea. **If the patient is allergic**: itching, rash, difficulty in swallowing, swelling around the eyes, weakness, dizziness, chest pain, weak pulse, low BP, unconsciousness. In severe cases, encephalopathy may occur	
Proguanil	Nausea, vomiting, diarrhoea, blood in the urine	
Rifampicin	Orange-red colour in the skin, urine, faeces, sweat, tears, itching and swelling of the face, nausea, vomiting, belly pain, lethargy, fits, signs of liver and kidney damage	
Salbutamol	Excitement, agitation, hallucinations, fast pulse, shaking, fits, lung oedema	Severe arrhythmias can be treated with slow IV injection of propranolol

Appendix 5: Equivalent analgesic dose

When changing medicines, equi-analgesic doses must be considered. It is wise to start at a lower dose than that indicated in the table because there may be incomplete cross-tolerance between opioids. Titrate the dose upwards depending on assessment of pain control. Use breakthrough doses of opioid as well, if required, to establish adequate analgesia.

Table 5.1

Medicine (action at opioid receptors)	Dose equivalent to 10mg IM/SC morphine	Approx. duration of action	Active metabolite	Dose adjustment in renal Impairment	Clinical use
Codeine(agonist)	130mg IM; 200mg oral	3 - 4 hours	Morphine	Yes	Mild to moderate pain; do not exceed 60mg single dose
Morphine(agonist)	30mg oral	2 - 3 hours; controlled release 12 - 24 hours	Morphine 6 glucuronide (M6G), morphine 3 glucuronide (M3G)	Yes	M6G produces analgesia and some adverse effects; M3G is neuroexcitatory and can cause delirium
Pethidine (agonist)	75- 100 mg IM/SC	2 - 3 hours	Norpethidine (CNS excitation)	Yes, contraindicated in renal failure	Use not recommended
Tramadol(agonist)	40 - 50mg IM;100mg oral	3 - 6 hours	Desmethyl tramadol	Yes	Moderate to severe pain

Appendix 6: Compounding formulae

Labelling instructions

Following details should be included in the label to be pasted on the container for extemporaneous liquid dosage forms:

1. Name and strength of the medicine
2. Dose, Interval and Duration
3. Expiry
4. "Shake well before use"
5. Prepared by.

PART A: EXTERNAL PREPARATIONS

1. Magnesium sulphate paste

Magnesium sulphate	**75 g**
White soft paraffin	**25 g**

Expiry: 6 months

Directions:

- Weigh magnesium sulphate and grind to a fine powder
- Weigh the white soft paraffin and gradually mix with the powder

Use: to draw pus from boils and infected wounds

2. Methyl salicylate (M/S) ointment

Methyl salicylate	**6 mL**
White soft paraffin	**100 mg**

Expiry: 1 year

Directions:

- Weigh the white soft paraffin
- Measure methyl salicylate and add gradually to the paraffin

Use: to be applied by rubbing on the site of muscular pain

3. Potassium permanganate 1:1000 Solution

Potassium permanganate	**1 g**
Water	**to 1000 mL**

Expiry: 10 days

Directions:

- Wash the bottle and mark for 1000 mL
- Weigh the potassium permanganate and add 250 mL of water to it; stir well
- Add to the bottle and use more water to dissolve the remaining crystals
- Add water to make up to 1000 mL

Use: cleaning of ulcers and abscesses, wet dressing; for gargle or mouthwash, it should be diluted 1 in 4

4. Salicylic acid 40% ointment

Salicylic Acid	**40 g**
White Soft Paraffin	**60 g**

Expiry: 6 months

Directions:

- Weigh the salicylic acid and grind to a fine powder
- Weigh white soft paraffin and gradually mix with the powder using a spatula

Use: warts (apply to the warts only, 3 times a day; protect the skin around it with Vaseline.

5. Sulphur 10% ointment

Sulphur	**10 g**
White soft paraffin	**90 g**

Expiry: 6 months

Directions:

- Weigh the sulphur powder and white soft paraffin
- Gradually mix together using a spatula

Use: antiseptic; treatment of scabies

6. Tincture iodine

Iodine	**20 g**
Potassium iodide	**24 g**
Spirit	**500 mL**
Water	**to 1000 mL**

Expiry: 6 months

Directions:

- Wash the bottle and mark 1000 mL on it
- Measure the spirit
- Weigh iodine and potassium iodide and mix with a little spirit
- Add to the bottle and add the rest of the spirit
- Add water up to 1000 mL

Use: antiseptic

7. Gentamycin 0.3% ointment

Gentamycin	**300 mg (7. 5 mL)**
White soft paraffin	**100 g**

Expiry: 14 days

Directions:

- Measure gentamycin
- Weigh the white soft paraffin and mix well with the gentamycin

Use: bed sores and other infected wounds which are resistant to other antibiotics

8. Whitfield's ointment

Benzoic acid	**12 g**
Salicylic acid	**6 g**
White soft paraffin	**182 g**

Expiry: 6 months

Directions:

- Weigh the benzoic acid and salicylic acid, grind together
- Weigh the white soft paraffin and gradually mix with the powders

Use: fungal infections (ringworms); apply 2-3 times daily for at least 2 weeks

9. Zinc oxide 15% ointment

Zinc oxide	**15 g**
White soft paraffin	**85 g**

Expiry: 6 months

Directions:

- Weigh the zinc oxide
- Weight the white soft paraffin and gradually mix with the powder

Use: to protect the skin and relieve skin irritation

10. Calamine lotion

Calamine	**80 g**
Zinc oxide	**80 g**
Water	**to 1000 mL**

Expiry: 14 days

Directions:

- Wash the bottle and mark 1000 mL on it
- Weigh the calamine and zinc oxide powder; mix well with a little water
- Rinse the container several times with water and add the mixture to it
- Add water to make up to 1000 mL

Use: antipruritic (to relieve itching)

11. Calamine ointment

Calamine	**4 g**
Zinc oxide	**3 g**
White soft paraffin	**93 g**

Expiry: 6 months

Directions:

- Weigh calamine and zinc oxide
- Weigh the white soft paraffin and gradually mix with the powders

Use: antipruritic (to relieve itching)

12. Coal tar and salicylic acid ointment

Coal tar solution	**6ml (7g)**
Salicylic acid	**2 g**
White soft paraffin	**91 g**

Expiry: 6 months

Directions:

- Weigh the salicylic acid and grind
- Weigh the white soft paraffin and gradually mix with the powder
- Measure coal tar solution and mix into the ointment

Use: psoriasis and other scaly skin conditions

13. Salicylic acid 2% ointment

Salicylic acid	**2 g**
White soft paraffin	**98 g**

Expiry: 6 months

Directions:

- Weigh the salicylic acid and grind
- Weigh the white soft paraffin and gradually mix with the powder

Use: to breakdown hard scaly skin

14. Boric acid 1% and zinc oxide ointment

Boric acid	**2.4 g**
Zinc oxide	**34 g**
White soft paraffin	**206 g**

Expiry: 6 months

Directions:

- Weigh boric acid and zinc oxide and mix well
- Weigh white soft paraffin and gradually mix with the powder

Use: mild antiseptic and soothing ointment

15. Boroglycerine 10% paint

Boric acid	**10 g**
Glycerine	**100 mL**

Expiry: 6 months

Directions:

- Clean and measure the bottle
- Weigh boric acid and grind to a fine powder. Gradually add glycerine, mix well
- Add to the bottle and rinse the mortar until all the glycerine is added

Use: mild antiseptic for mouth lesions

16. Sodium bicarbonate 5% ear drops

Sodium bicarbonate	**5g**
Glycerine	**30ml**
Water	**to 100ml**

Expiry: 1 month

Directions:

- Wash the bottle and mark 100 mL on it

- Weigh sodium bicarbonate and dissolve in a little hot water; add to the bottle
- Add glycerine
- Add water up to 100 mL

Use: to soften wax; put into ear at night for 3 nights

17. Compound podophylline paint 15%

Podophylline resin	**15 g**
Compound benzoin tincture	**to 100 mL**

Expiry: 6 months

Directions:

- Wash the bottle and mark 100 mL on it
- Weigh the podophylline resin and mix well with a little compound benzoin tincture
- Add to the bottle and rinse the mortar several times with benzoin tincture
- Add benzoin tincture up to 100 mL

Use: genital warts

Cautions: *podophylline is irritant to the skin and eyes; use with care. Apply only to the wart and protect the surrounding skin with vaseline*

18. Salicylic acid 2% ear drops

Salicylic acid	**0.2 g**
Spirit	**5 mL**
Water	**to 10 mL**

Expiry: 10 days

Directions:

- Weigh the salicylic acid and grind in a mortar
- Add spirit and then dissolve

Use: *Dermatitis* of the ear

19. Chlorine 0.1% solution

If using bleaching powder calculate the ratio of bleach to water by using the following formula:

$$\frac{\text{\% chlorine desired}}{\text{No of gm of powder in 1 litre of water}} \times 1000 = \text{\% chlorine in bleaching powder}$$

Example: To make 0.1% Chlorine solution from calcium hypochlorite powder containing 30% active Chlorine

0.1% / 30% x 1000 = 3.3

Therefore, we must dissolve 3.3gms of chlorine hypochlorite (30%) in each litre of water used to make 0.1% chlorine solution.

PART B: INTERNAL PREPARATIONS

Note: For internal medicines boiled and filtered water should be used

1. Methyl hydroxybenzoate 0.2% solution as preservative and medicine vehicle (sugar as sweeting agent)

Methyl hydroxybenzoate	**2 g**
Sugar	**200 g**
Water	**to 1000 mL**

Expiry: 14 days

Directions:

- Boil sugar in water until it dissolves
- Add water to make up to 1000 mL
- Add 2 g Methyl hydroxybenzoate as a preservative in above Luke-warm 1000 ml and stir until dissolve.

Use: Preservative, vehicle for medicines, sweeting agent.

2. Potassium chloride 8 mEq/5 mL

Potassium chloride 600 mg tab (8 mEq)	**20 tablets**
Methyl hydroxybenzoate 0.2% solutions	**to 100 mL**

Expiry: 14 days

Directions:

- Wash the bottle and mark 100 mL on it
- Grind 20 tablets potassium chloride and dissolve in methyl hydroxybenzoate solutions
- Add methyl hydroxybenzoate to make up to 100 mL

Use: potassium supplement

3. Nystatin paste

Nystatin	**4 tablets**
Glycerine	**10 mL**

Expiry: 6 months

Directions:

1. Crush the nystatin tablets and mix with 10 mL hot glycerine
2. Add to the bottle; rinse the mortar with 10 mL glycerine and add

Use: fungal infection of the mouth (1 mL applied in the mouth 4 times a day, after meals)

4. Digoxin syrup

Digoxin (0.25 mg tab)	**5 tablets**
Methyl hydroxybenzoate 0.2% solutions	**to 25 mL**

Each mL contains 0.05 mg digoxin

Expiry: 14 days

5. Furosemide syrup

Furosemide (40 mg tab)	**20 tablets**
Methyl hydroxybenzoate 0.2% solutions	**to 80 mL**

Each mL contains 10 mg furosemide

Expiry: 14 days

6. Metoclopramide syrup

Metoclopramide (10 mg tab)	**10 tablets**
Methyl hydroxybenzoate 0.2% solutions	**to 100 mL**

Each mL contains 1 mg metoclopramide

Expiry: 14 days

7. Isoniazid syrup

Isoniazid (300 mg tab)	**4 tablets**
Methyl hydroxybenzoate 0.2% solutions	**to 40 mL**

Each mL contains 30 mg isoniazid

8. Erythromycin syrup

Erythromycin (250 mg)	**18 tablets**
Methyl hydroxybenzoate 0.2% solutions	**to 90 mL**

Each 2.5 mL contains 125 mg erythromycin

Expiry: 14 days

9. Pyridoxine syrup

Pyridoxine (25 mg)	**1 tablet**
Methyl hydroxybenzoate 0.2% solutions	**to 100 mL**

Each mL contains 0.25 mg pyridoxine

Expiry: 14 days

10. Phenobarbitone syrup

Phenobarbitone (30 mg)	**5 tablets**
Methyl hydroxybenzoate 0.2% solutions	**to 30 mL**

Each 3 mL contains 15 mg phenobarbitone

Expiry: 14 days

Appendix 7: Definition of Pregnancy Categories of Medicines

(As per United States FDA categorization)

Category A: adequate and well controlled studies have failed to demonstrate a risk to foetus in the first trimester of pregnancy (and there is no evidence of risk in later trimesters).

Category B: animal reproduction studies have failed to demonstrate a risk to the foetus and there are no adequate and well controlled studies in pregnant women or animal studies have shown and adverse effect, but adequate and well controlled studies in pregnant women have failed to demonstrate a risk to foetus in any trimester.

Category C: animal reproduction studies have shown an adverse effect on the foetus and there are no adequate and well controlled studies in human, but potential benefits may warrant use of the medicine in pregnant women despite potential risks.

Category D: there is positive evidence of human foetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the medicine in pregnant women despite potential risks.

Category X: studies in animals or humans have demonstrated foetal abnormalities and/or there is positive evidence of human foetal risk based on adverse reaction data from investigational or marketing experience, and the risk involved in the use of medicine in pregnant women clearly out weight potential benefits.

Table 7.1 Pregnancy Categories of Medicines

MEDICINE	PREGNANCY CATEGORY	LACTATION
Acetazolamide	C	Excreted in milk; not recommended
Acetylcysteine	B	Excretion unknown; use with caution
Acyclovir (topical)	B	Excretion unknown; systemic exposure minimal after tropical application
Acyclovir (oral)	B	Excreted in milk; use with caution
Adenosine	C	Potential for serious adverse reaction in nursing infants; decision to interrupt nursing after administration of adenosine or not should take into account the importance of medicine to mother
Adrenaline	C	Excretion unknown; use with caution
Albendazole	C	Excretion unknown; use with caution
Allopurinol	C	Excreted in milk; use with caution
Aluminium hydroxide + Magnesium hydroxide	C	Excreted in milk; use with caution
Amikacin	D	Excretion unknown; not recommended
Amino acid solution	C	Excretion unknown
Amiodarone	D	Excreted in milk; not recommended
Amitriptylline	C	Excreted in milk; do not feed
Amlodipine	C	Excretion unknown; not recommended
Amoxicillin	B	Excreted in milk; use with caution
Amphotericin	B	Excretion in milk unknown, use with caution
Ampicillin	B	Excreted in milk; use with caution
Anti-haemorrhoidal ointment	C	Insufficient systemic absorption to produce detectable quantities in human milk; use with caution
Antisnake venom serum	NA	
Coartem®	C	Excretion unknown; use with caution
Aspirin	C; D in 3rd trimester	Excreted in milk; decision should be made whether to discontinue feeding or medicine taking into account the importance of medicine to mother
Atenolol	D	Excreted in milk; neonates born to mothers who are receiving atenolol at parturition or Breast-feeding may be at risk for hypoglycaemia and bradycardia; use with caution
Atorvastatin	X	Excreted in milk; do not feed
Atracurium besylate	C	Excretion in milk unknown; use with caution
Atropine sulphate	C	Excreted in breast; use with caution
Baclofen	C	Excreted in milk: not recommended
BCG vaccine	C	Excretion unknown recommended
Beclomethasone dipropionate	C	Excreted in milk; use only if benefits greatly out weight the risk
Benzathine benzylpenicillin	B	Excreted in milk; use with caution

MEDICINE	PREGNANCY CATEGORY	LACTATION
Benzoic acid powder	C	Excreted in milk; use with caution
Benzylpenicillin	B	Excreted in milk
Betamethasone valerate (topical)	C	Excreted in milk; use with caution
Brimonidine eye drop	C	Excretion unknown; use only if the benefits out weight risk
Budesonide nasal spray	B	Excreted in milk; use only if the benefits out weight risk
Bupivacaine	C	Excretion unknown; not recommended
Caffeine Citrate	C; crosses placenta, can remain in foetus or neonates 64 to 300hrs	Excreted in milk; use with caution
Calcium carbonate with Vit D3	C	Excreted in milk; safe
Calcium gluconate	C	Excreted in milk; use with caution
Calcium lactate	C	Excreted in milk; safe
Carbamazepine	D	Excreted in milk; not recommended
Carbimazole	C	NA
Carvedilol	C; D in 2nd and 3rd trimester	Excretion unknown; not recommended
Cefixime	B	Excretion unknown
Cefotaxime	B	Excreted in milk; use with caution
Ceftriaxone	B	Excreted in milk; use with caution
Cephalexin	B	Excreted in milk; use with caution
Cephazolin	B	Excreted in milk; use with caution
Cetirizine	B	Excreted in milk; not recommended
Chloramphenicol (ophthalmic)	C	Excreted in milk; do not feed
Chloramphenicol	C	Excreted in milk; do not feed
Chloroquine	Uncategorized	Excreted in milk; not recommended
Chlorpromazine	C; exposure during 3rd trimester of pregnancy are at risk for EPS or withdrawal symptoms after delivery	Excreted in milk; not recommended
Ciprofloxacin (ophthalmic)	C	Excreted in milk; not recommended
Ciprofloxacin	C	Excreted in milk; not recommended
Clarithromycin	C	Excreted in milk; use with caution
Clobazam	C	Excreted in milk; effect on infant unknown
Clobetasol propionate (topical)	C	Excretion unknown; use with caution
Clofazimine	C	Excreted in milk; do not administer to Breast-feeding women unless clearly indicated
Clomiphene	X	Excretion unknown; use with caution
Clonazepam	D	Excreted in milk; not recommended
Clopidogrel	B	Excretion unknown; not recommended

MEDICINE	PREGNANCY CATEGORY	LACTATION
Clotrimazole (topical)	B (during 2nd and 3rd trimester; safety in 1st trimester is not established)	Excretion unknown; use with caution
Clotrimazole (as pessary)	B (during 2nd and 3rd trimester; safety in 1st trimester is not established)	Excretion unknown; use with caution
Cloxacillin	B	
Codeine phosphate	C; D if used for prolong periods or near term	Excreted in milk; use with caution
Compound benzoin inhalation	B	
Compound solution of sodium lactate	C	Excretion unknown; use with caution
Conjugated oestrogen	X	
Cotrimoxazole	D	Avoid; near term kernicterus in the newborn.
Cyclopentolate (ophthalmic)	C	Excretion in milk unknown; use with caution
Cyclophosphamide	D	Drug excreted in milk; do not feed
Cycloserine	C	Safe
Cyclosporin	C	Excreted in breast milk; do not feed
Dapsone	C	Excreted in breast milk; not safe
Deflazacort	C	
Dexamethasone 4mg tab	C	Excreted in breast milk; not recommended
Dextrose	A; maternal or foetal hyperglycaemia may occur during labour and delivery; monitor	Excretion in milk unknown; use with caution
Diazepam	D	Excreted in breast milk; not recommended
Diclofenac Sodium	C; D if >30 weeks after gestation	Excreted in breast milk; not recommended
Dicyclomine	B	Excreted in breast milk; not recommended
Digoxin	C	Excreted in breast milk; use with caution
Diltazem	C	Not safe; decision should be made either to discontinue medicine or feeding taking into account importance of medicine to mother
Dopamine	C	Excretion unknown; use with caution
Doxorubicin	D	Excreted in breast milk; not recommended
Doxycycline	D	Excreted in breast milk; not recommended
Efavirenz	D	Excretion unknown; do not feed
Enalapril	C: 1st trimester; D; 2nd and 3rd trimester	Excreted in breast milk; not recommended
Ephedrine	C	Excreted in breast milk; not recommended
Ergotamine tartrate + Caffeine	X	Excreted in breast milk; do not feed
Erythromycin	B	Excreted in breast milk; use with caution
Ethambutol	B	Excreted in breast milk; use with caution

MEDICINE	PREGNANCY CATEGORY	LACTATION
Ethinyloestradiol	X	
Ethionamide	C	Excretion unknown; use with caution
Etofylline +Theophylline	C	Excreted in breast milk; serious adverse effects in infants are unlikely unless mother has a toxic serum theophylline concentration
Fenofibrate 200mg tab	C	Excretion unknown; not recommended
Fentanyl citrate	C	Excreted in breast milk; not recommended
Ferrous sulphate + Folic acid	A	Excreted in breast milk; safe
Finasteride 5mg tab	X	NA
Fluconazole	D	Excreted in breast milk; use with caution
Fluconazole (topical)	D	
Fluorouracil	D	Excretion unknown; do not feed
Fluoxetine	C	Excreted in breast milk; not recommended
Fluphenazine	C	Excreted in breast milk; not recommended
Folic acid	A	Excreted in breast milk; safe
Furosemide	C: close monitoring of foetal growth required because of risk for higher foetal birth weights	Excreted in breast milk; use with caution, may inhibit lactation
Gabapentin	C	Excreted in breast milk; use with caution
Gentamicin	D	Excreted in breast milk; use with caution
Glipizide	C	Excretion unknown; not recommended
Glycerine suppository	C	Excretion unknown; probably compatible with feeding
Griseofulvin	X	Excretion unknown; do not feed
Haloperidol	C: neonates exposed to antipsychotic drugs during 3rd trimester of pregnancy are at risk of extrapyramidal or withdrawal symptoms after delivery	Excreted in breast milk; not recommended
Halothane inhalation		
Hepatitis B vaccine	C	Excretion unknown
Homatropine (ophthalmic)	C	Excretion unknown; not recommended
Human Insulin (soluble)	B	Safe
Human Insulin (Isophane)	B	Safe
Human papiloma vaccine	B; not recommended for use in pregnant women	Excretion unknown; not recommended.
Human rabies immunoglobulin (HRIG	C	No adverse events reported; may be excreted in breast milk
Hyaluronidase	C	Excretion unknown; use with caution
Hydralazine	C	Excreted in breast milk; use with caution
Hydrochlorothiazide	B	Excreted in breast milk; use with caution
Hydrocortisone (topical)	C	Excreted in breast milk; use with caution

MEDICINE	PREGNANCY CATEGORY	LACTATION
Hydrocortisone sodium succinate	C	Excreted in breast milk; use with caution
Hydroxychloroquine	C	Excreted in breast milk; safe to feed
Ibandronate	C	Excretion unknown; use with caution
Ibuprofen	C; D at ≥ 30 weeks gestation; may cause premature closure of ductus arteriosus	Excreted in breast milk; not recommended
Indomethacin	C; D at ≥ 30 weeks gestation; may cause premature closure of ductus arteriosus.	Excreted in breast milk; not recommended
Iodine	Not studied	Excreted in breast milk; use with caution
Iohexol	B	Excretion unknown; not recommended
Enoxaparin	B	Excretion unknown; not recommended
Ipratropium respiratory	B	Excretion unknown; not recommended
Isoflurane inhalation	C	Use with caution
Isoniazid	C	Excreted in milk; safe
Isoprenaline		
Isosorbide dinitrate	C	Excretion unknown; not recommended
Kanamycin	D	Usually compatible
Ketamine	C	Excretion unknown; not recommended
Ketorolac (ophthalmic)	C; D in 3rd trimester (may cause premature closure of ductus arteriosus)	Excreted in milk; contraindicated
Lactulose	B	Excretion unknown; use with caution
Lamivudine	C	HIV+ women are advised not to breast feed
Lamotrigine	C	Excreted in milk; use with caution
Levetiracetam	C	Excretion unknown; not recommended
Levodopa + Carbidopa	C	Inhibits lactation; use with caution
Levofloxacin	C	Excretion unknown; not recommended
Levonorgestrel + Ethinyloestradiol	X	Excreted in milk; lactation inhibited; use with caution
Levonorgestrel	X	Not recommended
Lignocaine	B	Excreted in milk; use with caution
Lignocaine + Adrenaline	C	Excretion unknown; use with caution
Lopinavir with ritonavir	C; increased risk for congenital adrenal hyperplasia	Excretion unknown; HIV+ women should not breast feed anyway
Lorazepam	D	Excreted in milk; not recommended.
Losartan	D; use during 2nd and 3rd trimester reduces renal function and increases fetal morbidity and death	Excretion unknown; not recommended

MEDICINE	PREGNANCY CATEGORY	LACTATION
Magnesium sulphate	D; foetal skeletal demineralization, hypocalcaemia and hypermagnesia	Safe
Measles Rubella vaccine	C	Excretion unknown
Medroxyprogesterone acetate	X	Safe
Mefenamic acid	C; D if used for prolong periods, or near term (premature closure of ductus arteriosus)	Excreted in milk; contraindicated
Metformin	B	Excretion unknown; not recommended
Methotrexate	X	Excreted in milk; do not feed
Methylprednisolone	C	Excreted in milk; use with caution
Methyl salicylate (topical)	C	Excretion unknown
Methyldopa	B	Excreted in milk at low concentration; compatible with feeding
Methylergometrine	C	Excreted in milk; adverse effect on nursing infants; may inhibit lactation; not recommended or wait at least 12hrs after last dose to breastfeed
Metoclopramide	B	Excreted in milk; use with caution
Metoprolol	C	Excreted in milk; use with caution
Metronidazole	B	Excreted in milk; not recommended
Midazolam	D; should be avoided in 1st trimester due increased risk of congenital malformation	Excreted in milk; use with caution
Misoprostol	X	Excreted in breast milk; use with caution
Morphine	C; D if used near term	Excreted in milk; not recommended
Moxifloxacin (ophthalmic)	C	Excretion unknown; do not feed
Multivitamin	A	Safe
Mycophenolate mofetil	D	Excretion unknown; not recommended
Naloxone	C	Excretion unknown; use with caution
Neomycin + Polymixin + Bacitracin (topical)	C	Excretion unknown; use with caution
Neostigmine	Unknown; use with caution	Excretion unknown; use with caution
Niclosamide		
Nifedipine	C	Excreted in milk; safe
Nitrofurantoin	B; but contraindicated in 3rd trimester	Excretion milk; do not feed
Nitrofurazone		
Nitroglycerin	C	Excretion unknown; use with caution
Norfloxacin	C; crosses placenta	Excreted in milk; do not feed
Nystatin	C	Excretion unknown; use with caution
Olanzapine	C; exposure during 3rd trimester increases the risk for EPS or	Excretion unknown; not recommended

MEDICINE	PREGNANCY CATEGORY	LACTATION
	withdrawal symptoms after delivery	
Omeprazole	C	Excreted in milk; use with caution
Ondansetron	B	Excretion unknown; use with caution
Oral polio vaccine	B	Excretion unknown
Oxybutynin	B	Excretion unknown; use with caution
Oxygen	NA	
Oxymetazoline (ophthalmic)	C	Excretion unknown
Oxytocin	X	May be excreted in milk, commencement of feeding should be delayed for at least one day when discontinued, use with caution
Paracetamol	B; crosses placenta, safe to use in all stage of pregnancy for a short term	Excreted in milk; use with caution
Penicillin V	B	Excreted in milk; safe
Pentoxifylline	C	Excreted in milk; do not feed
Pethidine	B; use for prolonged periods or near term not established	Excreted in milk; not recommend
Phenobarbitone	D	Do not feed
Phenylephrine	C	Safe
Phenytoin	D; prenatal exposure may increase the risk for congenital malformation and other adverse development outcomes; risk of foetal hydantoin syndrome	Excreted in milk; not recommended
Phytomenadione	C	Excreted in milk; use with caution
Pioglitazone	C	Excretion unknown; do not feed
Podophyllum	X	Excretion unknown; do not feed
Potassium chloride	C	NA
Povidone Iodine Solution (topical)	B	
Pralidoxime	C	NA
Prednisolone	C	Excreted in milk; use with caution
Procaine Benzylpenicillin	B	Excreted in milk; use with caution
Promethazine	C	Excretion unknown; do not feed
Propofol	B	Excreted in milk; effect on nursing infant unknown
Propranolol	C; intrauterine growth retardation, small placentas and congenital abnormalities reported but no adequate and well controlled studies conducted	Use is controversial; amount excreted in milk insignificant
Protamine sulphate	C	Excretion unknown
Pyrazinamide	C	Excreted in milk

MEDICINE	PREGNANCY CATEGORY	LACTATION
Pyridoxine	A; C when exceeded RDA recommendation.	Safe
Quetiapine	C; exposure during 3rd trimester are at risk for EPS or withdrawal symptom after delivery	Excreted in milk; not recommended
Quinine	X; 1st trimester	Excreted in milk
Ranitidine	B	Excreted in milk; use with caution
Retinol	A(oral); C (doses exceeding RDA); X (above 6000 units/day administered parenterally)	Excreted in milk; safe at RDA levels
Rifampicin	C; reported to cross placental barrier; congenintal malformation	Excreted in milk
Risperidone	C; exposure during third trimester are at risk for EPS or withdrawal symptoms after delivery.	Excreted in milk; do not feed
Salbutamol	C	NA
Salmeterol + Fluticasone MDI	C	Excretion unknown; use with caution (salmeterol plasma levels very low following inhalation
Salicylic acid powder	C	NA
Senna	C	Not excreted in milk; compatible
Silver sulphadiazine (topical)	C; X (near term)	Excretion unknown; use with caution
Sodium bicarbonate	C	Excretion unknown
Sodium chloride	A	Not excreted in milk; safe
Sodium citrate	C	NA
Sodium cromoglycate (ophthalmic)	B	Excretion unknown; use with caution
Sodium valproate	D; known to cause neural tube defects	Excreted in milk; use with caution
Spironolactone	C	Excretion unknown; do not feed
Streptomycin	D	Excreted in milk; compatible to feed
Sulphur sublime (topical)	C	Insufficient data: medicine absorbed through intact and broken skin
Suxamethonium	C	Excretion unknown; effect on nursing infant unknown
Tacrolimus	C	Excreted in milk; not recommended
Tamsulosin	B	NA
Tenofovir	B	HIV+ women are advised not to feed
Tetanus immunoglobulin	C	Excretion unknown; no adverse effect reported
Tetatus Diptheria (Td)	C	Excretion unknown; use with caution.
Thiamine	A; C (if > RDA)	Safe
Thiopental sodium	C	NA
Thyroxine	A	Excreted in milk; use with caution
Timolol maleate (ophthalmic)	C	Excreted in milk; do not feed

MEDICINE	PREGNANCY CATEGORY	LACTATION
Tobramycin (ophthalmic)	B	Excretion unknown; do not feed
Tramadol	C	Excreted in milk; not recommended
Tranexamic acid	Not indicated in pregnant women	
Triamcinolone acetonide	C	Excretion unknown; use with caution
Trihexyphenidyl 2 mg tab.	C	No data, may inhibit lactation
Tropicamide	C	Excretion unknown
Vancomycin	C (injection); B (oral)	Excretion unknown; not recommended
Vecuronium	C	Excretion unknown; use with caution
Venlafaxine	C	Excreted in milk; not recommended
Verapamil	C	Excreted in milk; not recommended
Vitamin B complex	A (not exceeding RDA)	Safe
Vitamin B12	A; C (for doses exceeding RDA and for intranasal products)	Excreted in milk; safe
Vitamin C	A; C (dose exceeding RDA)	Excreted in milk; safe
Warfarin	D (for women with mechanical heart valves who are at risk for thromboembolism); X for other pregnant population	Because of potential serious adverse reactions, including bleeding in breast fed infant, consider developmental and health benefits Breast-feeding along with mother's clinical need for therapy; monitor breast fed infant for bruising or bleeding
Zidovudine 300 mg tab	C	HIV + women are advised not to feed
Zinc oxide powder 450 g	C	Excretion unknown
Zinc sulphate 20 mg tab	A	Excreted in milk; use with caution

Appendix 8: Renal Impairment

Table 8.1 Medicines to be avoided or used with caution in renal impairment

Medicine	Degree of impairment	Comment
Acetazolamide	Mild	Avoid; metabolic acidosis
Acetylsalicylic Acid	Severe	Avoid; sodium and water retention; deterioration in renal function; increased risk of GI bleeding
Acyclovir	Mild	Reduce intravenous dose
	Moderate to severe	Reduce dose
Allopurinol	Moderate to severe	100-200mg daily; increased toxicity; rashes 100mg on alternate days (max 100 mg daily)
Aluminium Hydroxide	Severe	Aluminium is absorbed & may accumulate
Amikacin	Mild	Reduce dose (individualized dosing)
Amoxicillin	Severe	Reduce dose; rashes more common
Ampicillin	Severe	Reduce dose; rashes more common
Artemether + Lumefantrine	Severe	Caution; monitor ECG & plasma potassium
Atenolol	Moderate	Reduce dose (excreted unchanged); start with small dose; higher plasma conc. after oral administration
	Severe	may reduce renal blood flow and adversely affect renal function
Baclofen	Severe	Avoid
	Mild to moderate	Reduce dose

Medicine	Degree of impairment	Comment
Benzathine Benzylpenicillin	Severe	Neurotoxicity-high doses may cause convulsions
Benzyl Penicillin	Severe	Max 6g daily; Neurotoxicity-high dose may cause convulsions
Carbamazepine		Manufacturer advises caution
Chloramphenicol	Severe	Avoid unless no alternative; dose-related depression of haematopoiesis
Chloroquine	Mild to moderate	Reduce dose in rheumatic disease; Reduce dose for malaria prophylaxis
Chlorpromazine	Severe	Start with small doses; Increased cerebral sensitivity; Monitor kidney function-dose dependent; increase in serum creatinine and urea during first few weeks may necessitate dose reduction
Ciprofloxacin	Moderate	Use half normal dose
Cloxacillin	Severe	Reduce dose
Codeine	Moderate to severe	Reduce dose or avoid; increased and prolonged effect; increased cerebral sensitivity
Colchicine	Moderate	Reduce dose
	Severe	Avoid or reduce dose if no alternative
Diazepam	Severe	Start with small doses; increased cerebral sensitivity
Digoxin	Mild	Reduce dose; toxicity increased by electrolyte disturbances
Doxycycline	Mild	Use with caution; avoid excessive doses
Efavirenz	Severe	No information available; caution advised
Enalapril	Mild to moderate	Use with caution and monitor response; initial dose 2.5mg once daily
Ephedrine	Severe	Avoid; increased CNS toxicity
Ergotamine	Moderate	Avoid; nausea and vomiting; risk of renal vasoconstriction
Ethambutol	Mild	Reduce dose; if cc less than 30 ml/min monitor plasma ethambutol concentration; optic nerve damage
Fluphenazine	Severe	Start with small dose; increase cerebral sensitivity
Furosemide	Moderate	May need high dose; deafness may follow rapid IV injection
Gentamicin	Mild	Reduce dose; monitor plasma concentration
Glipizide	Mild to moderate	Increased risk of hypoglycaemia
Haloperidol	Severe	Start with small doses; increased cerebral sensitivity
Heparin	Severe	Risk of bleeding increased
Hydralazine	Mild	Reduce dose if cc less than 30 ml/minute
Hydrochlorothiazide	Moderate	Avoid; ineffective
Ibuprofen	Mild	Use lowest effective dose and monitor renal function; sodium and water retention; deterioration in renal function possibly leading to renal failure
Iohexol	Moderate to Severe	Increased risk of nephrotoxicity; avoid dehydration
Isoniazid	Severe	Maximum 200 mg daily for peripheral neuropathy
Lamivudine	Mild	Reduce dose; consult manufacturer's literature
Levetiracetam	Severe	Max. 1g daily if cc less than 30ml/min
	Moderate	Max. 1.5g daily if cc 30-50ml/min
	Mild	Max. 2g daily if cc 50-80ml/min
Lopinavir + Ritonavir		Avoid oral solution due to propylene glycol content in severe impairment
Magnesium sulfate	Moderate	Avoid or reduce dose; increased risk of toxicity
Mannitol		Avoid unless test dose produces diuretic response
Metformin	Mild	Avoid; increased risk of lactic acidosis
Methotrexate	Mild	Reduce dose; accumulates; nephrotoxic
	Moderate	Avoid

Medicine	Degree of impairment	Comment
Methyldopa	Moderate	Start with small dose; increased sensitivity to hypotensive and sedative effect
Metoclopramide	Severe	Avoid or use small dose; increased risk of extrapyramidal reactions
Morphine	Moderate to severe	Reduce dose or avoid; increased and prolonged effect; increased cerebral sensitivity
Neostigmine	Moderate	May need dose reduction
Nitrofurantoin	Mild	Avoid; peripheral neuropathy; ineffective because of inadequate urine concentrations
Phenobarbital	Severe	Avoid large doses
Polyvidone-Iodine	Severe	Avoid regular application to inflamed or broken mucosa
Potassium Chloride	Moderate	Avoid routine use; high risk of hyperkalaemia
Procainamide	Mild	Avoid or reduce dose
Procaine Benzylpencillin	Severe	Neurotoxicity high doses may cause convulsions
Proguanil	Mild	100 mg once daily
	Moderate	50 mg on alternate days
	Severe	50 mg once weekly; increased risk of haematological toxicity
Propranolol	Severe	start with small dose; higher plasma concentrations after oral administration; may reduce renal blood flow and adversely affect renal function
Quinine		Reduce parenteral maintenance dose for malaria treatment
Ranitidine	Severe	Use half normal dose; occasional risk of confusion
Sodium Chloride	Severe	Avoid
Sodium Valproate	Mild to Moderate	Reduce dose
Spironolactone	Mild	Monitor plasma K+; high risk of hyperkalaemia in renal impairment
Stavudine	Mild	20 mg twice daily (15 mg if body weight less than 60 kg)
	Moderate to severe	20 mg once daily (15 mg if body weight less than 60 kg)
Streptomycin	Mild	Reduce dose; monitor plasma concentration
Sulfamethoxazole + Trimethoprim	Mild	Use half normal dose if cc 15-30 ml/minute; avoid if cc less than 15 ml/minute and if plasma sulfamethoxazole concentration cannot be monitored
Tranexamic acid	Mild	Dose reduction required
Vencomycin	Mild	Reduce dose - monitor plasma vancomycin concentration and renal function regularly
Vecuronium	Severe	Reduce dose; duration of block possibly prolonged
Warfarin	Severe	Avoid
Zidovudine	Severe	Reduce dose; manufacturer advises oral dose of 300-400 mg daily in divided doses or intravenous dose of 1 mg/kg 3-4 times daily

Appendix 9: Hepatic Impairment

Table 9.1 Medicine to be avoided or used with caution in Hepatic impairment

Medicine	Comment
Acetylsalicylic acid	Avoid - increased risk of gastrointestinal bleeding
Allopurinol	Reduce dose
Aluminium hydroxide	In patient with fluid retention, avoid antacids containing large amounts of sodium; also avoid those causing constipation (can precipitate coma)
Amitriptyline	Sedative effects increased (avoid in severe liver disease)
Artemether + Lumefantrine	Caution in severe impairment; monitor ECG and plasma potassium

Medicine	Comment
Bupivacaine	Avoid (or reduce dose) in severe liver disease
Carbamazepine	Metabolism impaired in advanced liver disease
Ceftriaxone	Reduce dose and monitor plasma concentration if both hepatic and severe renal impairment
Chloramphenicol	Avoid if possible- increased risk of bone marrow depression; reduce dose and monitor plasma-chloramphenicol concentration
Chlorphenamine	Sedation inappropriate in severe liver disease – avoid
Chlorpromazine	Can precipitate coma; hepatotoxic
Cyclosporin	May need dose adjustment
Ciprofloxacin	Hepatic dysfunction reported
Cloxacillin	Cholestatic jaundice may occur up to several weeks after treatment has been stopped; administration for more than 2 weeks and increasing age are risk factor
Codeine	Avoid or reduce dose – may precipitate coma
Contraceptives, Oral	Avoid in active liver disease and if history of pruritus or cholestasis during pregnancy
Diazepam	Can precipitate coma
Doxycycline	Avoid (or use with caution)
Efavirenz	In milk to moderate liver disease, monitor liver function; avoid in severe hepatic impairment
Enalapril	Closely monitor patients with impaired liver function
Ergotamine	Avoid in severe liver disease – risk of toxicity increased
Erythromycin	May cause idiosyncratic hepatotoxicity
Ethinylestradiol	Avoid, see also contraceptives, oral
Fluorouracil	Caution advised
Fluphenazine	Can precipitate coma; hepatotoxic
Furosemide	Hypokalaemia may precipitate coma (use potassium-sparing diuretic to prevent this); increased risk of hypomagnesaemia in alcoholic cirrhosis
Glipizide	Avoid
Griseofulvin	Avoid in severe liver disease
Haloperidol	Can precipitate coma
Halothane	Avoid if history of unexplained pyrexia or jaundice following previous exposure to halothane
Heparin	Reduce dose in severe liver disease
Hydralazine	Reduce dose
Hydrochlorothiazide	Avoid in severe liver disease; hypokalaemia may precipitate coma (potassium-sparing diuretic can prevent this); increased risk of hypomagnesaemia in alcoholic cirrhosis
Ibuprofen	Increased risk of gastrointestinal bleeding and can cause fluid retention; avoid in severe liver disease
Isoniazid	Use with caution; monitor liver function regularly and particularly frequently in the first 2 months
Levonorgestrel	Avoid in active liver disease and if history of pruritus or cholestatis during pregnancy
Lidocaine	Avoid (or reduce dose) in severe liver disease

Medicine	Comment
Lopinavir + Ritonavir	Avoid oral solution because of propyleneglycol content; use capsules with caution in mild to moderate hepatic impairment and avoid in severe impairment
Magnesium sulphate	Avoid in hepatic coma if risk of renal failure
Medroxyprogesterone	Avoid in active liver disease and if history of pruritus or cholestasis during pregnancy
Metformin	Withdraw if tissue hypoxia is likely
Methotrexate	Dose-related toxicity-avoid in non-malignant conditions (for example, rheumatic disorders)
Methyldopa	Manufacturer advises caution in history of liver disease; avoid in active liver disease
Metoclopramide	Reduce dose
Metronidazole	In severe liver disease, reduce total daily dose to one-third and give once daily
Morphine	Avoid or reduce dose-may precipitate coma
Nifedipine	Reduce dose
Nitrofurantoin	Cholestatic jaundice and chronic active hepatitis reported
Paracetamol	Dose-related toxicity- avoid large doses
Phenobarbital	May precipitate coma
Phenytoin	Reduce dose to avoid toxicity
Prednisolone	Adverse effects more common
Promethazine	Avoid – may precipitate coma in severe liver disease; hepatotoxic
Propranolol	Reduce oral dose
Pyrazinamide	Avoid-idiosyncratic hepatotoxicity more common
Ranitidine	Increased risk of confusion; reduce dose
Rifampicin	Impaired elimination; may be increased risk of hepatotoxicity; avoid or do not exceed 8 mg/kg daily

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