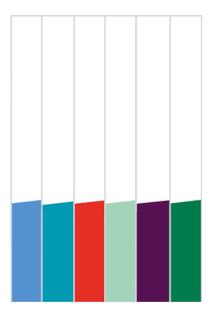
## **Essential drugs**

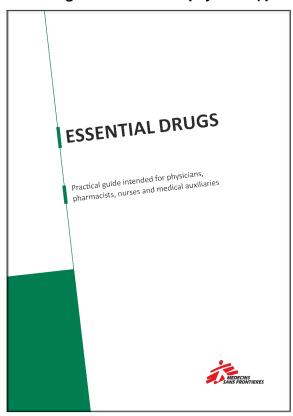


MEDICALGUIDELINES.MSF.ORG



## **Essential drugs**

### Practical guide intended for physicians, pharmacists, nurses and medical auxiliaries



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## **Contributors**

This guide has been developed by Médecins Sans Frontières with valuable contributions from:

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And Jacques Pinel who initiated the collection of MSF guides.

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## **Preface**

The 1978 Alma Ata Conference on primary health care recognized that essential drugs are vital for preventing and treating illnesses which affect millions of people throughout the world. Essential drugs save lives and improve health.

In 1981, the World Health Organization established the Action Programme on Essential Drugs to support countries to implementing national drug policies and to work towards rational use of drugs. This work was broadened in 1998 when WHO created the department of Essential Drugs and Other Medicines (EDM), combining the responsibilities of the former DAP with WHO's global efforts to promote quality, safety, efficacy, and accurate information for all medicines.

EDM works with countries, international agencies, NGOs like Médecins Sans Frontières, and other organizations to ensure that people everywhere have access to the essential drugs they need at a price which is affordable; that the drugs are safe, effective, and of good quality; and that they are prescribed and used rationally.

Appropriate tools are critical to the effective implementation of essential drugs policies. This practical handbook, based on Médecins Sans Frontières' field experience, is one of the tools which we strongly recommend.

Designed to give practical, concise information to physicians, pharmacists and nurses, this "Essential drugs - practical guidelines" is an important contribution from Médecins Sans Frontières to improve the rational use of drugs, which will be a continuing challenge in the coming years.

Dr Jonathan D. Quick Director, Essential Drugs and Other medicines World Health Organization

## **Foreword**

This guide is not a dictionary of pharmacological agents. It is a practical manual intended for health professionals, physicians, pharmacists, nurses and health auxiliaries involved in curative care and drug management.

We have tried to provide simple, practical solutions to the questions and problems faced by medical staff, using the accumulated field experience of Médecins Sans Frontières, the recommendations of reference organizations such as the World Health Organization (WHO) and specialized documentation in each field.

This manual is not only used by Médecins Sans Frontières, but also in a wide range of other programmes and contexts.

The list of drugs in this edition has been revised: in accordance to the most recent WHO list of essential medicines (https://apps.who.int/iris/handle/10665/325771), certain drugs have been added, others have been removed.

Among the entries in this guide, some are not listed in the WHO list of essential medicines. However these drugs are in the same pharmaceutical class for which the WHO has named only one "example of a therapeutic group" preceded by a square symbol to indicate that various drugs can be used as alternatives.

Certain medicines, which are not on the WHO list, are still frequently administered although their use is not recommended. These medicines have been included in this guide by entries marked by a grey diagonal line.

The entries are classified according to the route of administration and in alphabetical order. This classification reflects the drug management system proposed in this manual (see Organization and management of a pharmacy(see page 331)).

Only the main contra-indications, adverse effects, precautions and drug interactions of each drug have been indicated in this manual. For further detailed information refer to specialised literature. Concerning antiretrovirals, the interactions are too many to be listed: it is therefore essential to refer to specialised literature.

This manual is a collective effort by medical professionals from many disciplines, all with field experience.

Despite all efforts, it is possible that certain errors may have been overlooked in this manual. Please inform the authors of any errors detected. It is important to remember, that if in doubt, it is the responsibility of the prescribing medical professional to ensure that the doses indicated in this manual conform to the manufacturer's specifications.

To ensure that this guide continues to evolve while remaining adapted to field realities, please send any comments or suggestions.

As treatment protocols are regularly revised, please check the monthly updates.

## Use of the guide

- Nomenclature of drugs(see page 7)
- Dosage(see page 7)
- Symbols(see page 7)
- Abbreviations(see page 7)

## Nomenclature of drugs

The International Non-proprietary Names (INN) of drugs is used in this guide.

## **Dosage**

Prescription tables showing average dosage in drug units (tablets, ampoules etc.) according to weight or age of patients are included for the most commonly used drugs.

For children, oral drug dosages are expressed in milligrams per kilogram per dose, followed by the number of doses per day (e.g. 10 mg/kg 3 times daily). For certain antiretrovirals, dosage is expressed in milligrams per square meter (mg/m<sup>2</sup>). Injectable drug dosages are also expressed in milligrams per kilogram per injection, followed by the interval between injections (e.g. 10 mg/kg every 8 hours).

For adults, oral drug dosages are expressed in milligrams or grams per dose, followed by the number of doses per day (e.g. 500 mg 3 times daily). Injectable drug dosages are in general expressed in milligrams or grams per injection, followed by the interval between injections (e.g. 500 mg every 8 hours).

## **Symbols**

Prescription under medical supervision

This box indicates potentially toxic drugs, administered under medical prescription only in many European countries (e.g. Belgium, France, Spain, United Kingdom).



This symbol is used to draw attention to drugs whose toxic potential is greater, or for which experience has shown they are frequently misused.

Practical recommendations for drug storage:

drug very sensitive to light

f drug very sensitive to humidity

If no temperature for storage is recommended, this indicates that no information was found in medical literature.

## **Abbreviations**

#### Units

kg = kilogram g = gram mg = milligram m² = square meter IU = international unit M = million mEq = milliequivalent mmol = millimole ml = millilitre (1 cc = 1 ml) tsp = teaspoon (= 5 ml) ssp = soupspoon (= 15 ml)

#### **Route of administration**

IM = intramuscular IV = intravenous SC = subcutaneous

#### **Dosage forms**

tab = tablet cap = capsule amp = ampoule susp = suspension

#### Others

v/v = volume in volume D = day (e.g. D1 = first day)

## **Oral drugs**

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## ABACAVIR = ABC oral

Prescription under medical supervision

## Therapeutic action

- Antiretroviral, HIV-1 and HIV-2 nucleoside reverse transcriptase inhibitor

### **Indications**

- HIV-1 or HIV-2 infection, in combination with other antiretroviral drugs

## Forms and strengths

- 60 mg dispersible tablet
- 300 mg tablet

## **Dosage**

- Child less than 25 kg: 8 mg/kg 2 times daily (max. 600 mg daily)
- Child 25 kg and over and adult: 300 mg 2 times daily

### **Duration**

- Depending on the efficacy and tolerance of abacavir.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with severe hepatic impairment or history of severe intolerance to abacavir that led to discontinuation of treatment.
- May cause:
- hypersensitivity reactions: skin rash, gastrointestinal disturbances (nausea, vomiting, diarrhoea, abdominal pain), cough, dyspnoea, malaise, headache, lethargy, oedema, lymphadenopathy, hypotension, myalgia, arthralgia, renal impairment;
- lactic acidosis and hepatic disorders.

In all these cases, stop taking abacavir immediately and permanently.

- <u>Pregnancy</u>: avoid, except if there is no therapeutic alternative.

### Remarks

- Tablets are not scored. When half a tablet is required, use a cutter or a tablet cutter to cut the tablet into two equal parts.
- Also comes in fixed-dose combination tablets containing abacavir-lamivudine and abacavir-zidovudine-lamivudine.
- Also comes in 20 mg/ml oral solution.
- Storage: below 25 ℃

## ACETAMINOPHEN oral

See PARACETAMOL oral(see page 129)

## ACETYLSALICYLIC acid = ASPIRIN = ASA oral

Prescription under medical supervision

## Therapeutic action

- Analgesic, antipyretic, non steroidal anti-inflammatory (NSAID)
- Platelet antiaggregant (at low dose)

#### **Indications**

- Mild pain, fever
- Secondary prevention of severe pre-eclampsia

## Forms and strengths

- 300 mg and 500 mg tablets
- 75 mg enteric coated tablet

## **Dosage and duration**

- Pain and fever

Adolescent over 16 years and adult: 300 mg to 1 g every 4 to 6 hours (max. 4 g daily), for 1 to 3 days

- Prevention of pre-eclampsia

75 to 150 mg once daily from the 12<sup>th</sup> to the 36<sup>th</sup> week of gestation. Stop treatment 5 to 10 days before the expected date of delivery.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to aspirin and NSAID, peptic ulcer, coagulation disorders, haemorrhage, severe renal, hepatic or cardiac impairment.
- Do not administer to children for pain or fever (use paracetamol).

- Administer with caution to elderly patients or patients with asthma.
- Do not exceed indicated doses, particularly in elderly patients. Intoxications are severe, possibly fatal.
- May cause:
- allergic reactions, epigastric pain, peptic ulcer, haemorrhage;
- dizziness, tinnitus (early signs of overdose);
- Reye's syndrome in children (encephalopathy and severe hepatic disorders).

For all cases above, stop aspirin.

- Do not combine with methotrexate, anticoagulants and NSAID.
- Monitor combination with insulin (increased hypoglycaemia) and corticosteroids.
- Pregnancy:
- pain and fever: avoid. **CONTRA-INDICATED** from the beginning of the 6<sup>th</sup> month. Use paracetamol.
- prevention of pre-eclampsia: do not exceed 150 mg daily.
- Breast-feeding: avoid. Use paracetamol.

### Remarks

- Take during meals, preferably with a lot of water.
- Do not crush enteric coated tablets.
- Aspirin may be administered in secondary prevention of atherothrombosis, at a dose of 75 to 300 mg daily.
- Storage: below 25°C 🌽

Do not use if tablets have a strong smell of vinegar. A slight vinegar smell is always present.

## **ACICLOVIR** oral

Prescription under medical supervision

## Therapeutic action

- Antiviral active against herpes simplex virus and varicella zoster virus

### **Indications**

- Treatment of recurrent or extensive oral and oesophageal herpes in immunocompromised patients
- Treatment of herpetic kerato-uveitis
- Treatment of genital herpes
- Secondary prophylaxis of herpes in patients with frequent and/or severe recurrences
- Treatment of severe forms of zoster: necrotic or extensive forms, facial or ophthalmic zoster

## Forms and strengths

- 200 mg and 800 mg tablets
Also comes in 40 mg/ml oral suspension.

## **Dosage and duration**

- Treatment of recurrent or extensive oral and oesophageal herpes in immunocompromised patients, treatment of herpetic kerato-uveitis

Child under 2 years: 200 mg 5 times daily for 7 days

Child 2 years and over and adult: 400 mg 5 times daily for 7 days

- Treatment of genital herpes

Child 2 years and over and adult: 400 mg 3 times daily for 7 days; in immunocompromised patients, continue treatment until clinical resolution

Secondary prophylaxis of herpes in patients with frequent and/or severe recurrences
 Child under 2 years: 200 mg 2 times daily
 Child 2 years and over and adult: 400 mg 2 times daily

Treatment of severe forms of zoster
 Adult: 800 mg 5 times daily for 7 days

## Contra-indications, adverse effects, precautions

- Do not administer to patients with hypersensitivity to aciclovir.
- May cause: headache, skin rash, allergic reactions, gastrointestinal disturbances, raised transaminases, neurologic disorders in patients with renal impairment and elderly patients; rarely, haematological disorders.
- Reduce dosage in patients with renal impairment.
- Drink a lot of liquid during treatment.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

### Remarks

- For the treatment of herpes simplex, aciclovir should be started as soon as possible (within 96 hours) after the appearance of lesions to reduce severity and duration of infection.
- For the treatment of herpes zoster, aciclovir should be start preferably within 72 hours after the appearance of lesions. Aciclovir administration does not reduce the likelihood of developing zosterassociated pain but reduces the overall duration of this pain.
- Storage: below 25 °C Ţ

## ALBENDAZOLE oral

Prescription under medical supervision

## Therapeutic action

- Anthelminthic

### **Indications**

- Ascariasis (*Ascaris lumbricoides*), enterobiasis (*Enterobius vermicularis*), hookworm infections (*Ancylostoma duodenale*, *Necator americanus*)
- Trichuriasis (Trichuris trichiura), strongyloidiasis (*Strongyloides stercoralis*)
- Trichinellosis (*Trichinella* sp)

## Forms and strengths

- 400 mg tablet

## **Dosage and duration**

Ascariasis, enterobiasis, hookworm infections
 Child over 6 months and adult: 400 mg single dose
 Child over 6 months but under 10 kg: 200 mg single dose
 In the event of enterobiasis, a second dose may be given after 2 to 4 weeks.

Trichuriasis, strongyloidiasis
 Child over 6 months and adult: 400 mg once daily for 3 days
 Child over 6 months but under 10 kg: 200 mg once daily for 3 days

- Trichinellosis

Child over 2 years: 5 mg/kg 2 times daily for 10 to 15 days Adult: 400 mg 2 times daily for 10 to 15 days

## Contra-indications, adverse effects, precautions

- Do not administer to children under 6 months.
- Do not administer to patients with ocular cysticercosis.
- May cause:
- gastrointestinal disturbances, headache, dizziness;
- neurological disorders (headache, seizures) in patients with undiagnosed neuro cysticercosis.
- <u>Pregnancy</u>: avoid during the first trimester
- Breast-feeding: no contra-indication

### Remarks

- Tablets are to be chewed or crushed: follow manufacturer's recommendations.
- In the treatment of strongyloidiasis, ivermectin is more effective than albendazole.
- Albendazole is also used in the treatment of cutaneous larva migrans (*Ancylostoma braziliense* and *caninum*), larval cestode infections (hydatid disease, certain forms of neurocysticercosis) and in mass treatment for lymphatic filariasis (check national recommendations).
- Storage: below 25 °C W 🖣

## **ALBUTEROL** aerosol

See SALBUTAMOL aerosol(see page 152)

## **ALBUTEROL** nebuliser solution

See SALBUTAMOL nebuliser solution(see page 153)

# ALUMINIUM HYDROXIDE/MAGNESIUM HYDROXIDE oral

## Therapeutic action

- Antacid

### **Indications**

- Stomach pain associated with gastritis and peptic ulcer

## Forms and strengths

- 400 mg aluminium hydroxide/400 mg magnesium hydroxide chewable tablet

## **Dosage**

- Child over 5 years: rarely indicated. When necessary: half a tablet 3 times daily
- Adult: 1 to 2 tablets 3 times daily 20 minutes to one hour after meals, or 1 tablet during painful attacks

### **Duration**

- According to clinical response

## Contra-indications, adverse effects, precautions

- Decreases intestinal absorption of many drugs. Do not administer simultaneously with:
- atazanavir, chloroquine, digoxin, doxycycline, iron salts, gabapentin, itraconazole, levothyroxine (take at least 2 hours apart).
- ciprofloxacin (take ciprofloxacin 2 hours before or 4 hours after antacids), dolutegravir (take dolutegravir 2 hours before or 6 hours after antacids), velpatasvir (take 4 hours apart).
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

### **Remarks**

- Chew tablets.
- There are numerous preparations of aluminium and/or magnesium hydroxide and different dosages.
- Antacids are not included in the WHO list of essential medicines.
- Storage: below 25 °C

## **AMITRIPTYLINE** oral

Prescription under medical supervision



## Therapeutic action

- Tricyclic antidepressant

### **Indications**

- Neuropathic pain
- Major depression

## Forms and strengths

- 25 mg tablet

## **Dosage**

- Neuropathic pain

Adult: 25 mg once daily at bedtime (Week 1); 50 mg once daily at bedtime (Week 2); 75 mg once daily at bedtime (as of Week 3)

- Depression

Adult: 25 mg once daily at bedtime. Depending on efficacy and tolerance, increase over 8 to 10 days, up to 75 mg once daily at bedtime.

– Do not exceed 150 mg daily. Reduce the dose by half in elderly patients.

### **Duration**

- Neuropathic pain: 3 to 6 months after pain relief is obtained. If pain reappears, recommence treatment.
- *Depression*: minimum 9 months. Treatment should be discontinued gradually (over 4 weeks). If signs of relapse or withdrawal occur, increase the dose.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with recent myocardial infarction, arrhythmia, closed-angle glaucoma, prostate disorders.
- Administer with caution and carefully monitor use in elderly patients and in patients with epilepsy, chronic constipation, renal or hepatic impairment (reduce the dose by half), history of bipolar disorders and suicidal ideation.
- May cause:
- drowsiness, orthostatic hypotension, sexual dysfunction;
- anticholinergic effects: dry mouth, constipation, blurred vision, tachycardia, disorders of micturition. Treatment should be discontinued in the event of severe reactions (mental confusion, urinary retention, cardiac rhythm disorders);
- Administer with caution and monitor combination with: CNS depressants (opioid analgesics, sedatives, H1 antihistamines, etc.), drugs known to have anticholinergic effects (atropine, chlorpromazine, promethazine, etc.), drugs which lower the seizure threshold (antipsychotics, mefloquine, etc.), serotonergic drugs (SSRI, tricyclic antidepressants, ondansetron, tramadol, etc.), anti-hypertensive drugs.
- Avoid alcohol during treatment.
- <u>Pregnancy</u>: re-evaluate whether the treatment is still necessary; if it is continued, decrease the dose at the end of pregnancy to limit gastrointestinal and neurological adverse effects in the neonate.
- Breast-feeding: monitor the child for excessive somnolence.

### Remarks

– Sedative effect occurs following initial doses, analgesic effect is delayed for 7 to 10 days and the antidepressant effect is delayed for at least 4 weeks. This must be explained to the patient.

- For neuropathic pain, amitriptyline is often administered in combination with carbamazepine.
- Storage: below 25°C 🌽

## **AMLODIPINE** oral

Prescription under medical supervision



## Therapeutic action

- Antihypertensive vasodilator (calcium channel blocker)

### **Indications**

- Hypertension

### **Presentation**

- 5 mg tablet

## **Dosage**

Adult: 5 mg once daily. Increase to 10 mg once daily if necessary (max. 10 mg daily).
 In elderly patients or patients with hepatic impairment, start with 2.5 mg once daily then increase gradually if necessary.

### **Duration**

- According to clinical response.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with severe hypotension, shock, unstable heart failure after acute myocardial infarction.
- May cause:
- headache, dizziness, sensation of flushing or warmth, fatigue, ankle oedema (common at the start of treatment);
- hypotension, palpitations, abdominal pain, nausea, gingival hyperplasia.
- Administer with caution and monitor use with:
- other antihypertensive drugs (risk of hypotension);
- drugs with hypotensive effects (e.g. haloperidol, amitriptyline);
- fluconazole, erythromycin, fluoxetine, ritonavir (effects of amlodipine increased, particularly the antihypertensive effect);
- rifampicin, phenytoin, phenobarbital, carbamazepine (effects of amlodipine decreased).
- <u>Pregnancy</u>: no contra-indication. For the management of hypertension in pregnancy, use labetalol.
- Breast-feeding: avoid

### Remarks

- <u>Storage</u>: below 25 ℃ - 🏏 - Ť

## ! Amodiaquine = AQ oral

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see AMODIAQUINE = AQ oral(see page 318)

## AMOXICILLIN oral

Prescription under medical supervision

## Therapeutic action

- Penicillin antibacterial

### **Indications**

- Acute otitis media, streptococcal tonsillitis, sinusitis, bronchitis, pneumonia
- Infection due to *Helicobacter pylori* (in combination with omeprazole and clarithromycin), leptospirosis, uncomplicated cutaneous anthrax
- Typhoid fever if the strain is susceptible (recent drug susceptibility test)
- Completion treatment following parenteral therapy with penicillins or cephalosporins

## Forms and strengths

- 250 mg and 500 mg tablets or capsules
- 250 mg dispersible scored tablet, for paediatric use
- 125 mg/5 ml powder for oral suspension, to be reconstituted with filtered water

## **Dosage**

- Usual dosage (e.g. leptospirosis, tonsillitis, infection due to H. pylori)

Child: 25 mg/kg 2 times daily Adult: 1 g 2 times daily

Age	Weight	125 mg/5 ml susp.	250 mg tablet	500 mg tablet
< 3 months	< 6 kg	1 tsp x 2	½ tab x 2	-
3 to < 24 months	6 to < 12 kg	2 tsp x 2	1 tab x 2	-
2 to < 8 years	12 to < 25 kg	4 tsp x 2	2 tab x 2	1 tab x 2
≥8 years and adult	≥ 25 kg	-	4 tab x 2	2 tab x 2

- Severe infections (e.g. typhoid fever) or suspicion of resistant pneumococci (e.g. pneumonia, otitis) Child: 30 mg/kg 3 times daily (max. 3 g daily)

Adult: 1 g 3 times daily

Age	Weight	125 mg/5 ml susp.	250 mg tablet	500 mg tablet
< 3 months	< 6 kg	1 tsp x 3	½ tab x 3	-
3 to < 24 months	6 to < 12 kg	2 tsp x 3	1 tab x 3	-
2 to < 8 years	12 to < 25 kg	4 tsp x 3	2 tab x 3	1 tab x 3
≥8 years and adult	≥ 25 kg	-	4 tab x 3	2 tab x 3

### **Duration**

- Otitis media: 5 days; tonsillitis: 6 days; leptospirosis, typhoid fever. 7 days; pneumonia, sinusitis, cutaneous anthrax: 7 to 10 days; H. pylori infection: 7 days

## Contra-indications, adverse effects, precautions

- Do not administer to penicillin-allergic patients or patients with mononucleosis.
- Administer with caution to patients allergic to cephalosporins (cross-sensitivity may occur).
- May cause: gastrointestinal disturbances, allergic reactions, sometimes severe. In the event of allergic reaction, stop treatment immediately.
- Reduce dosage in patients with severe renal impairment.
- Do not combine with methotrexate.
- Pregnancy and breast-feeding: no contra-indication

### Remarks

– <u>Storage</u>: below 25 °C - ₩ - Ť

For the oral suspension (powder or reconstituted suspension): follow manufacturer's instructions.

## AMOXICILLIN/CLAVULANIC acid = CO-AMOXICLAV oral

Prescription under medical supervision

## Therapeutic action

– Combination of two antibacterials. The addition of clavulanic acid to amoxicillin extends its spectrum of activity to cover beta-lactamase producing Gram-positive and Gram-negative organisms, including some Gram-negative anaerobes.

### **Indications**

- Animal bites, if antibiotic therapy or antibiotic prophylaxis is clearly indicated
- Second line treatment of acute otitis media and acute bacterial sinusitis, when amoxicillin alone given

at high dose failed

- Acute uncomplicated cystitis (no systemic signs) in girls over 2 years
- Postpartum upper genital tract infection
- Parenteral to oral switch therapy in severe infections (e.g. severe pneumonia)

## Forms and strengths

- The ratio of amoxicillin and clavulanic acid varies according to the manufacturer:

Ratio 8:1	<ul><li>500 mg amoxicillin/62.5 mg clavulanic acid tablet</li><li>500 mg amoxicillin/62.5 mg clavulanic acid/5 ml powder for oral suspension</li></ul>
Ratio 7:1	<ul> <li>875 mg amoxicillin/125 mg clavulanic acid tablet</li> <li>400 mg amoxicillin/57 mg clavulanic acid/5 ml, powder for oral suspension</li> <li>200 mg amoxicillin/28.5 mg clavulanic acid dispersible tablet</li> </ul>

## **Dosage**

(expressed in amoxicillin)

- Animal bites; second line treatment of acute otitis media and acute sinusitis
- Child < 40 kg: 25 mg/kg 2 times daily
- Child ≥ 40 kg and adult:

Ratio 8:1: 2000 mg daily = 2 tablets of 500/62.5 mg 2 times daily Ratio 7:1: 1750 mg daily = 1 tablet of 875/125 mg 2 times daily

Acute uncomplicated cystitis in girls > 2 years

12.5 mg/kg 2 times daily

- Postpartum upper genital tract infection; parenteral to oral switch therapy in severe infections
- Child < 40 kg: 50 mg/kg 2 times daily
- Child ≥ 40 kg and adult:

Ratio 8:1: 3000 mg daily = 2 tablets of 500/62.5 mg 3 times daily Ratio 7:1: 2625 mg daily = 1 tablet of 875/125 mg 3 times daily

#### Duration

– Animal bites: 5 to 7 days; otitis media: 5 days; sinusitis: 7 to 10 days; cystitis: 3 days; upper genital tract infection: 7 days; parenteral to oral switch therapy in severe pneumonia: to complete a total of 10 to 14 days of treatment.

## Contra-indications, adverse effects, precautions

- Do not administer to penicillin-allergic patients and patients with history of hepatic disorders during a previous treatment with co-amoxiclav.
- Administer with caution to patients allergic to cephalosporins (cross-sensitivity may occur).
- Administer with caution to patients with hepatic impairment; reduce dosage and give every 12 to 24 hours in patients with severe renal impairment.
- May cause: gastrointestinal disturbances (mainly diarrhoea); allergic reactions sometimes severe (stop treatment immediately); jaundice and cholestatic hepatitis in the event of prolonged treatment (> 10 to 15 days).
- The dose of clavulanic acid should not exceed 12.5 mg/kg daily or 375 mg daily.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

### Remarks

- Take with meals.
- Also comes in formulations with a ratio of amoxicillin/clavulanic acid of 4:1: 125 mg amoxicillin/31.25 mg clavulanic acid/5 ml powder for oral suspension and 500 mg amoxicillin/125 mg clavulanic acid tablet. The maximum dose (expressed in amoxicillin) that can be given with these formulations is 50 mg/kg daily, without exceeding 1500 mg daily.
- <u>Storage</u>: below 25 °C **∅** <del>†</del>

## ARTEMETHER/LUMEFANTRINE = AL oral

Prescription under medical supervision

## Therapeutic action

– Antimalarial

### **Indications**

- Treatment of uncomplicated falciparum malaria
- Treatment of uncomplicated malaria due to other Plasmodium species, when chloroquine cannot be used
- Completion treatment following parenteral therapy for severe malaria

## Forms and strengths

- Co-formulated tablets of artemether/lumefantrine, in blister packs, for a complete treatment for one individual
- There are 5 different blister packs corresponding to 4 different categories of weight:
- 20 mg artemether/120 mg lumefantrine dispersible tablet, blister pack of 6 tablets
- 20 mg artemether/120 mg lumefantrine dispersible tablet, blister pack of 12 tablets
- 20 mg artemether/120 mg lumefantrine tablet, blister pack of 18 tablets
- 20 mg artemether/120 mg lumefantrine tablet, blister pack of 24 tablets
- 80 mg artemether/480 mg lumefantrine tablet, blister pack of 6 tablets

## **Dosage and duration**

– The treatment is administered 2 times daily for 3 days. On D1, the first dose is given at 0 hour and the second dose at 8-12 hours. Subsequent doses on D2 and D3 are given 2 times daily (morning and evening).

	20/120 mg tablet			80/480 mg tablet		
Weight	D1	D2	D3	D1	D2	D3
5 to < 15 kg	1 disp tab x 2	1 disp tab x 2	1 disp tab x 2	-	-	_
15 to < 25 kg	2 disp tab x 2	2 disp tab x 2	2 disp tab x 2	-	_	_

25 to < 35 kg	3 tab x 2	3 tab x 2	3 tab x 2	-	_	-
≥ 35 kg	4 tab x 2	4 tab x 2	4 tab x 2	1 tab x 2	1 tab x 2	1 tab x 2

## Contra-indications, adverse effects, precautions

- May cause: headache, dizziness and gastrointestinal disturbances.
- Administer with caution to patients taking drugs that prolong the QT interval: amiodarone, other antimalarials, antipsychotics, fluconazole, fluoroquinolones, hydroxyzine, macrolides, ondansetron, etc.
- If the patient vomits within 30 minutes after administration: re-administer the full dose. If the patient vomits between 30 minutes and 1 hour after administration, re-administer half of the dose.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

### Remarks

- Take with meals or a fat containing drink (e.g. milk).
- Lumefantrine is also called co-artemether.
- <u>Storage</u>: below 30 °C **∅ †**

Leave tablets in blisters until use. Once a tablet is removed from its blister, it must be administered immediately.

## ! Artesunate = AS oral

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see ARTESUNATE = AS oral(see page 320)

## ARTESUNATE/AMODIAQUINE = AS/AQ oral

Prescription under medical supervision

## Therapeutic action

- Antimalarial

### **Indications**

- Treatment of uncomplicated falciparum malaria
- Treatment of uncomplicated malaria due to other Plasmodium species, when chloroquine cannot be used
- Completion treatment following parenteral therapy for severe malaria

## Forms and strengths

- Co-formulated tablets of artesunate (AS)/amodiaquine (AQ), in blister packs, for a complete treatment for one individual
- There are 4 different blister packs corresponding to 4 different categories of weight:
- 25 mg AS/67.5 mg AQ base tablet blister pack of 3 tablets
- 50 mg AS/135 mg AQ base tablet blister pack of 3 tablets
- 100 mg AS/270 mg AQ base tablet blister pack of 3 tablets
- 100 mg AS/270 mg AQ base tablet blister pack of 6 tablets

## **Dosage and duration**

- Tablets are to be taken once daily for 3 days.

Weight	Tablets	D1	D2	D3
4.5 to < 9 kg	25 mg AS/67.5 mg AQ base	1 tab	1 tab	1 tab
9 to < 18 kg	50 mg AS/135 mg AQ base	1 tab	1 tab	1 tab
18 to < 36 kg	100 mg AS/270 mg AQ base blister pack of 3 tab	1 tab	1 tab	1 tab
≥36 kg	100 mg AS/270 mg AQ base blister pack of 6 tab	2 tab	2 tab	2 tab

## Contra-indications, adverse effects, precautions

- Do not administer in the event of previous severe adverse reaction to treatment with amodiaquine (e.g. hypersensitivity reaction, hepatitis, leucopenia, agranulocytosis).
- Do not administer to patients taking efavirenz.
- Avoid combination with drugs that prolong QT interval: amiodarone, other antimalarials, antipsychotics, fluconazole, fluoroquinolones, hydroxyzine, macrolides, ondansetron, etc.
- May cause: gastrointestinal disturbances, pruritus, somnolence or insomnia, cough.
- If the patient vomits within 30 minutes after administration, re-administer the full dose. If the patient vomits between 30 minutes and 1 hour after administration, re-administer half of the dose.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

- For patients unable to swallow the tablets (e.g. young children), the tablets can be dispersed by gentle agitation for approximately one minute in a small amount of water. After administration, give children some sugar or sugared water to cover amodiaquine's bitter taste.
- <u>Storage</u>: below 30 °C  $\sqrt{N}$   $\sqrt{1}$ Leave tablets in blisters until use. Once a tablet is removed from its blister, it must be administered immediately.

# !Artesunate + sulfadoxine/pyrimethamine = AS + SP oral

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see ARTESUNATE + SULFADOXINE/ PYRIMETHAMINE = AS + SP oral(see page 321)

## ASCORBIC acid = VITAMIN C oral

## Therapeutic action

– Vitamin

### **Indications**

- Treatment and prevention of scurvy (vitamin C deficiency)

## Forms and strengths

- 50 mg, 250 mg and 500 mg tablets

## **Dosage and duration**

- Treatment of scurvy

The optimal dose has not been established. For information:

Child 1 month to 11 years: 100 mg 3 times daily

Child 12 years and over and adult: 250 mg 3 times daily

or

Child 1 month to 3 years: 100 mg 2 times daily Child 4 to 11 years: 250 mg 2 times daily

Child 12 years and over and adult: 500 mg 2 times daily

Treatment is administred at least 2 weeks or longer (until symptoms resolve), then preventive treatment is given as long as the situation requires.

- Prevention of scurvy

Child and adult: 50 mg daily, as long as the situation requires

## Contra-indications, adverse effects, precautions

- Ascorbic acid is well tolerated at indicated doses.
- May cause: gastrointestinal disturbances and nephrolithiasis for doses > 1 g daily; may interfere with the measurement of glucose in blood and urine for doses ≥ 2 g daily.
- <u>Pregnancy</u>: no contra-indication, do not exceed 1 g daily.
- Breast-feeding: no contra-indication

### Remarks

- <u>Storage</u>: below 25 °C - **∅** - <del>Ť</del>

## ASPIRIN oral

See ACETYLSALICYLIC ACID = ASA(see page 13)

## ATAZANAVIR = ATV

Prescription under medical supervision

## Therapeutic action

- Antiretroviral, HIV protease inhibitor

### **Indications**

- HIV infection, in combination with ritonavir (booster) and other antiretrovirals

## Forms and strengths

- 200 mg capsule
- 300 mg atazanavir/100 mg ritonavir tablet

## **Dosage**

- Child 20 to < 25 kg: one 200 mg capsule once daily (+ 100 mg ritonavir once daily)
- Child ≥ 25 kg and adult: one 300 mg/100 mg tablet once daily

#### **Duration**

- The duration of treatment depends on the efficacy and tolerance of atazanavir and ritonavir.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with moderate and severe hepatic impairment or in combination with rifampicin.
- Administer with caution and monitor use in patients with haemophilia (increased bleeding) or in patients with mild hepatic impairment.
- May cause:
- jaundice, gastrointestinal disturbances, headache, insomnia, fatigue, peripheral neuropathy, asymptomatic hyperbilirubinaemia, cholelithiasis, urolithiasis, conduction disorders, hyperglycaemia, lipodystrophy;
- skin rash sometimes severe, hepatic disorders; in this event, stop treatment immediately.
- Administer with caution and monitor combination with drugs that prolong the QT interval (amiodarone, co-artemether, mefloquine, quinine, haloperidol, etc.).
- Monitor combination with omeprazole and antacids containing aluminium or magnesium hydroxide

(effects of atazanavir decreased).

- Atazanavir in combination with ritonavir reduces the efficacy of oral contraceptives: use a non-hormonal contraception or injectable medroxyprogesterone or an oral contraceptive containing at least 30 micrograms of ethinylestradiol per tablet.
- <u>Pregnancy</u>: no contra-indication; monitor bilirubin levels and/or signs of jaundice in neonates.

### Remarks

- Take with meals together with ritonavir.
- Do not open the capsules.
- Also comes in 300 mg capsules, not in combination with ritonavir.
- Storage: below 25 °C 🖊

## **AZITHROMYCIN** oral

Last updated: January 2021

Prescription under medical supervision

## Therapeutic action

- Macrolide antibacterial

### **Indications**

- Trachoma, conjunctivitis due to *Chlamydia trachomatis*
- Cervicitis and urethritis due to *Chlamydia trachomatis* (in combination with a treatment for gonorrhoea), donovanosis, chancroid, early syphilis
- Cholera (if the strain is susceptible), typhoid fever, yaws, leptospirosis
- Pertussis, diphtheria, pneumonia due to Mycoplasma pneumoniae and Chlamydophila pneumoniae
- Second-line treatment of shigellosis
- Streptococcal tonsillitis, acute otitis media, in penicillin-allergic patients only

## Forms and strengths

- 250 mg and 500 mg capsules or tablets
- 200 mg/5 ml powder for oral suspension, to be reconstituted with filtered water

## **Dosage and duration**

Trachoma, cholera, cervicitis and urethritis due to C. trachomatis, chancroid, early syphilis
 Child: 20 mg/kg single dose (max. 1 g)

Adult: 1 g single dose (2 g single dose in early syphilis)

- Yaws

Child and adult: 30 mg/kg single dose (max. 2 g)

- Conjunctivitis due to C. trachomatis

Child: 20 mg/kg once daily for 3 days (max. 1 g daily)

Adult: 1 g once daily for 3 days

- Typhoid fever

Child: 10 to 20 mg/kg once daily for 7 days (max. 1 g daily)

Adult: 1 g once daily for 7 days

- Donovanosis (granuloma inguinale)

Adult: 1 g on D1 then 500 mg once daily until healing of lesions

- Pertussis, pneumonia due to M. pneumoniae and C. pneumoniae

Child: 10 mg/kg once daily for 5 days (max. 500 mg daily) Adult: 500 mg on D1 then 250 mg once daily from D2 to D5

- Leptospirosis

Child: 10 mg/kg on D1 (max. 500 mg) then 5 mg/kg once daily on D2 and D3 (max. 250 mg daily)

Adult: 1 g on D1 then 500 mg once daily on D2 and D3

- Shigellosis

Child: 12 mg/kg on D1 then 6 mg/kg once daily from D2 to D5 Adult: 500 mg on D1 then 250 mg once daily from D2 to D5

- Diphtheria

Child: 10 to 12 mg/kg once daily for 14 days (max. 500 mg daily)

Adult: 500 mg once daily for 14 days

Streptococcal tonsillitis, only in penicillin-allergic patients
 Child: 20 mg/kg once daily for 3 days (max. 500 mg daily)

Adult: 500 mg once daily for 3 days

Acute otitis media, only in penicillin-allergic patients
 Child: 10 mg/kg once daily for 3 days (max. 500 mg daily)

## Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to azithromycin or another macrolide, and to patients with severe hepatic impairment.
- May cause: gastrointestinal disturbances, heart rhythm disorders (QT prolongation), allergic reactions sometimes severe. In the event of allergic reaction, stop treatment immediately.
- Do not administer simultaneously with antacids (aluminium or magnesium hydroxide, etc.). Administer 2 hours apart.
- Avoid combination with drugs that prolong the QT interval (amiodarone, chloroquine, co-artemether, fluconazole, haloperidol, mefloquine, moxifloxacin, ondansetron, pentamidine, quinine, etc.).
- Administer with caution and monitor use in patients taking digoxin (increased digoxin plasma levels).
- <u>Pregnancy and breast-feeding</u>: no contra-indication

### Remarks

- Also comes in 250 mg or 500 mg capsules, to be taken one hour before or 2 hours after a meal.
- <u>Storage</u>: below 25 °C 💋 Ť

For the oral suspension (powder or reconstituted suspension): follow manufacturer's instructions.

## **BECLOMETASONE** aerosol

Prescription under medical supervision

## Therapeutic action

- Anti-inflammatory drug (corticosteroid)

### **Indications**

- Long term treatment of persistent asthma

## Forms and strengths

– Pressurized inhalation solution of beclomatesone dipropionate, delivering 50, 100 and 250 micrograms per inhalation

## **Dosage**

The dosage varies from one person to another. The initial dose depends on the severity of symptoms. It may be increased or reduced over time. Always try to administer the lowest effective dose. For information:

Child: 50 to 100 micrograms 2 times daily; increase to 200 micrograms 2 times daily if necessary (max. 800 micrograms daily)

Adult: 100 to 250 micrograms 2 times daily; increase to 500 micrograms 2 times daily if necessary (max. 1500 micrograms daily)

Shake the inhaler. Breathe out as completely as possible. Place the lips tightly around the mouthpiece. Inhale deeply while activating the inhaler. Hold breath 10 seconds before exhaling. Verify that the inhalation technique is correct.

Co-ordination between the hand and inhalation is very difficult in certain patients (children under 6 years, elderly patients, etc.). Use a spacer to facilitate administration and improve the efficacy of treatment.

### **Duration**

- According to clinical response

## Contra-indications, adverse effects, precautions

- Do not administer to patients with untreated active tuberculosis.
- May cause: throat irritation, hoarseness at the beginning of treatment, oro-pharyngeal candidiasis.
- In the event of cough and/or bronchospasm following inhalation of beclometasone: administer salbutamol if necessary, stop inhalation of beclometasone and replace with an oral corticoid.
- In the event of bronchial infection, administer appropriate antibiotic treatment in order to optimise the diffusion of beclometasone in the respiratory tract.
- If the maximum dosage becomes insufficient, re-evaluate the severity of asthma and combine with a short oral anti-inflammatory treatment.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

- Beclometasone is not a bronchodilator. For asthma attack, use inhaled salbutamol.
- Relief of symptoms may require several days or weeks of continuous therapy.
- Clean the mouthpiece before and after each use.

- Do not pierce or incinerate used aerosol containers. Empty all residual gas, then bury.
- <u>Storage</u>: below 25 °C 🌽

## **BIPERIDEN** oral

Prescription under medical supervision

## Therapeutic action

- Anticholinergic antiparkinson drug

### **Indications**

- First-line treatment of extrapyramidal reactions induced by antipsychotics

## Forms and strengths

- 2 mg tablet

## **Dosage**

- Adult: 2 mg once daily, then increase if necessary up to 2 mg 2 to 3 times daily (max. 12 mg daily)
- Administer at the lowest effective dose in elderly patients and do not exceed 10 mg daily.

### **Duration**

- As long as the antipsychotic treatment lasts.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with closed-angle glaucoma, prostate disorders, gastrointestinal obstruction or atony.
- Administer with caution and carefully monitor use in elderly patients (risk of confusion, hallucinations).
- May cause: anticholinergic effects (dry mouth, constipation, blurred vision, tachycardia, disorders of micturition), confusion, hallucinations, memory impairment.
- Avoid or monitor combination with other drugs known to have anticholinergic effects (atropine, amitriptyline, chlorpromazine, promethazine, etc.).
- <u>Pregnancy</u>: re-evaluate whether the antipsychotic treatment is still necessary; if treatment is continued, administer biperiden at the lowest effective dose and observe the child if the mother was under treatment in the 3<sup>rd</sup> trimester (risk of anticholinergic effect, e.g. tremors, abdominal distension).
- <u>Breast-feeding</u>: if treatment is necessary, administer at the lowest effective dose and observe the child (risk of anticholinergic effects, e.g. tachycardia, constipation, thickening of bronchial secretions).

- Also comes in 4 mg extended-release tablet, administered once daily.
- Biperiden is also used in the treatment of Parkinson's disease.
- <u>Storage</u>: below 25 °C **∅** <del>Ť</del>

## **BISACODYL** oral

## Therapeutic action

- Stimulant laxative

### **Indications**

- Prevention of constipation in patients taking opioid analgesics (codeine, morphine, etc.)
- Short-term, symptomatic treatment of constipation

## Forms and strengths

- 5 mg enteric-coated tablet

## **Dosage**

- Child over 3 years: 5 to 10 mg once daily
- Adult: 10 to 15 mg once daily

### **Duration**

- Prevention of constipation in patients taking opioids: start bisacodyl when analgesic treatment continues more than 48 hours. Tablets must be taken daily, at night (onset of effect within 6 to 12 hours after administration), until the end of the opioid treatment. Regular follow up (frequency/consistency of stools) is essential in order to adjust dosage correctly.
- Treatment of constipation: until the patient passes stools, maximum 7 days.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with Crohn's disease, ulcerative colitis, intestinal obstruction, undiagnosed abdominal pain and dehydration.
- May cause: diarrhoea, abdominal cramps, hypokalaemia.
- In the event of diarrhoea: exclude a faecal impaction or intestinal obstruction, stop treatment for 24 hours and then start again with a half dose.
- In the event of abdominal cramps: reduce or divide the daily dose. Stop treatment if pain continues.
- Do not combine with drugs that induce *torsades de pointe* (halofantrine, erythromycin IV, pentamidine, etc.).
- Closely monitor patients taking drugs that induce hypokalaemia (furosemide, amphotericin B, corticosteroids, etc.) or cardiac glycosides.
- <u>Pregnancy and breast-feeding</u>: avoid; for routine prevention of constipation due to opioids, use lactulose.

- To prevent constipation in patients taking opioids, use lactulose if the patient's stools are solid; use bisacodyl if the patient's stools are soft.
- In children from 6 months to 3 years, do not use the oral route. Use only 5 mg paediatric suppositories (one suppository daily).
- Swallow tablets whole; do not crush or chew.
- Bisacodyl is equivalent to senna, the representative example of laxative stimulants in the WHO list of

essential medicines.

- The treatment must be accompanied by dietary measures (plenty of fluids and fibre).
- Storage: below 25 °C

## **BISOPROLOL** oral

Prescription under medical supervision



## Therapeutic action

- Cardioselective beta-blocker

### **Indications**

- Hypertension, treatment of chronic stable angina pectoris
- Chronic stable heart failure in combination with a converting enzyme inhibitor (enalapril)

## Forms and strengths

- 2.5 mg breakable tablet
- 10 mg breakable in ¼ tablet

## **Dosage**

- Hypertension, angina pectoris

Adult: 5 to 10 mg once daily, preferably in the morning (max. 20 mg daily) In patients with renal or hepatic impairment: start with 2.5 mg once daily then increase, if necessary, according to clinical response (max. 10 mg daily)

- Heart failure

Adult: start with 1.25 mg once daily and increase according to the table below, as long as the drug is well tolerated (heart rate, blood pressure, signs of worsening heart failure)

Weeks	Daily dose	Tablet(s)
Week 1	1.25 mg once daily	2.5 mg tab: ½ tab daily
Week 2	2.5 mg once daily	2.5 mg tab: 1 tab daily or 10 mg tab: ¼ tab daily
Week 3	3.75 mg once daily	2.5 mg tab: 1½ tab daily
Week 4 to 8	5 mg once daily	10 mg tab: ½ tab daily
Week 9 to 12	7.5 mg once daily	2.5 mg tab: 1 tab daily + 10 mg tab: ½ tab daily or 10 mg tab: ¾ tab daily

Weeks	Daily dose	Tablet(s)
From week 13	10 mg once daily (max. 10 mg daily)	10 mg tab: 1 tab daily

### **Duration**

- According to clinical response. Do not stop treatment abruptly, decrease doses gradually.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with asthma, chronic obstructive bronchopneumonia, acute heart failure, severe hypotension, bradycardia < 50/minute, atrio-ventricular heart blocks, Raynaud's syndrome.
- May cause:
- bradycardia, hypotension, worsening of heart failure (reduce dose);
- bronchospasm in patients with an obstructive respiratory disease;
- hypoglycaemia, gastrointestinal disturbances, headache, fatigue, muscle weakness, erectile dysfunction.
- Administer with caution to patients with diabetes (risk of hypoglycaemia).
- In the event of anaphylactic shock, risk of resistance to epinephrine.
- Avoid or monitor combination with:
- mefloquine, digoxin, amiodarone, diltiazem, verapamil (risk of bradycardia);
- tricyclic antidepressants, antipsychotics, anti-hypertensive drugs (risk of hypotension).
- <u>Pregnancy and breast-feeding:</u> use labetalol, particularly for the management of hypertension in pregnancy.

### Remarks

- <u>Storage</u>: below 25 °C - ₩ - Ť

## **BUTYLSCOPOLAMINE** oral

See HYOSCINE BUTYLBROMIDE oral(see page 89)

## **CABERGOLINE** oral

Prescription under medical supervision

## Therapeutic action

- Long-lasting lactation inhibitor

### **Indications**

– Inhibition of lactation or suppression of established lactation in case of intrauterine foetal death or neonatal death

## Forms and strengths

- 0.5 mg scored tablet

## **Dosage and duration**

- Lactation inhibition1 mg single dose on the first day post-partum

- Lactation suppression0.25 mg every 12 hours for 2 days

## Contra-indications, adverse effects, precautions

- Do not administer to patients with postpartum hypertension or psychosis, preeclampsia, valvulopathy, and history of pulmonary, retroperitoneal or pericardial fibrosis.
- May cause: hypotension, valvulopathy, dizziness, headache, nausea, drowsiness, hallu cinations.
- Do not combine with chlorpromazine, haloperidol, metoclopramide, promethazine (effect of cabergoline antagonised), methylergometrine (risk of vasoconstriction and hypertensive crisis), and macrolides (effect of cabergoline increased).
- Pregnancy: CONTRA-INDICATED

### Remarks

- The use of cabergoline is not recommended to inhibit lactation in women who chose to not breastfeed: it is not justified to expose women to the adverse effects of cabergoline, lactation will stop spontaneously.
- Cabergoline is not included in the WHO list of essential medicines.
- Cabergoline is a dopamine agonist also used in the treatment of Parkinson's disease.
- Storage: below 25 °C 

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## **CALCIUM FOLINATE = FOLINIC acid oral**

Prescription under medical supervision

## Therapeutic action

- Antidote to folate antagonists

### **Indications**

– Prevention of haemotological toxicity of pyrimethamine when pyrimethamine is used as prophylaxis for, or in the treatment of toxoplasmosis or isosporiasis in immunodeficient patients

## Forms and strengths

– 15 mg tablet

Also comes in 5 mg and 25 mg capsules.

### **Dosage**

When pyrimethamine is used as primary or secondary prophylaxis for toxoplasmosis
 Adult: 25 to 30 mg once weekly

- During treatment of toxoplasmosis

Adult: 10 to 25 mg once daily

- During treatment of isosporiasis

Adult: 5 to 15 mg once daily

### **Duration**

- For the duration of the pyrimethamine treatment

## Contra-indications, adverse effects, precautions

- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

### Remarks

- Folic acid cannot be used as an alternative to folinic acid for the treatment of toxoplasmosis: folic acid reduces the antiprotozoal activity of pyrimethamine.
- Calcium folinate is also called calcium leucovorin.
- Storage: below 25°C 🖊

## CARBAMAZEPINE oral

Prescription under medical supervision



## Therapeutic action

- Antiepileptic

### **Indications**

- Epilepsy (except absence seizures)
- Neuropathic pain (alone or combined with amitriptyline)
- Prevention of recurrence of bipolar disorder

## Forms and strengths

- 200 mg tablet

## **Dosage**

- Epilepsy

Child 1 month and over: start with 5 mg/kg once daily or 2.5 mg/kg 2 times daily, then increase the dose every week by 2.5 to 5 mg/kg, up to 5 mg/kg 2 or 3 times daily (max. 20 mg/kg daily)

Adult: start with 100 to 200 mg once daily or 2 times daily, then increase the dose every week by 100 to 200 mg, up to 400 mg 2 to 3 times daily (max. 1600 mg daily)

- Neuropathic pain

Adult: 200 mg once daily at bedtime for one week, then 200 mg 2 times daily (morning and bedtime) for one week, then 200 mg 3 times daily

- Prevention of recurrence of bipolar disorder

Adult: start with 100 mg 2 times daily, then increase the dose every week by 200 mg if necessary up to 200 mg 2 or 3 times daily (max. 1200 mg daily).

#### **Duration**

- *Epilepsy, prevention of recurrence of bipolar disorder*: lifetime treatment. Do not stop treatment abruptly, even if changing treatment to another antiepileptic.
- *Neuropathic pain*: continue several months after pain relief is obtained, then attempt to stop treatment.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with atrioventricular block, history of bone marrow depression.
- Administer with caution to patients with glaucoma, urinary retention, hepatic or renal impairment, heart failure or blood disorders and to elderly patients.
- May cause:
- headache, dizziness, gastrointestinal and visual disturbances, rash, leucopenia, confusion and agitation in elderly patients, drowsiness (use with caution when driving or operating machinery);
- rarely: severe allergic reactions (Lyell's and Stevens-Johnson syndromes), agranulocytosis, anaemia, bone marrow depression, pancreatitis, hepatitis, cardiac conduction defect. In these cases, stop treatment.
- Do not drink alcohol during treatment.
- Do not combine or monitor the combination with:
- erythromycin, isoniazid, fluoxetine, valproic acid, etc. (increased carbamazepine plasma concentrations);
- rifampicin (reduced efficacy of carbamazepine);
- oral anticoagulants, contraceptives (oral and implants), corticosteroids, tricyclic antidepressants, neuroleptics, protease inhibitors, rifampicin, itraconazole, doxycycline, tramadol, etc. (reduced efficacy of these drugs).
- Pregnancy:
- Epilepsy and bipolar disorder: do not start treatment during the first trimester, except if vital and there is no alternative (risk of neural tube defects, facial and cardiac malformations, hypospadias). However, if treatment has been started before the pregnancy, do not stop treatment and use the minimal effective dose. Due to the risk of haemorrhagic disease of the newborn, administer vitamin K to the mother and the neonate. The administration of folic acid during the first trimester may reduce the risk of neural tube defects.
- Neuropathic pain: not recommended
- Breast-feeding: avoid

#### Remarks

- Also comes in 100 mg/5 ml oral solution, 100 mg tablet and 100 mg and 200 mg chewable tablets.
- Storage: below 25 °C ₩ 🖣

# **CEFALEXIN** oral

Prescription under medical supervision

## Therapeutic action

- First-generation cephalosporin antibacterial

#### **Indications**

– Skin infections due to staphylococci and/or streptococci: impetigo, furuncle, erysipelas and superficial cellulitis

# Forms and strengths

- 250 mg capsule
- 125 mg/5 ml powder for oral suspension, to be reconstituted with filtered water

#### **Dosage**

- Neonate under 7 days: 25 mg/kg 2 times daily
- Neonate 7 to 28 days: 25 mg/kg 3 times daily

The exact dose should be calculated according to the newborn's weight.

- Child 1 month to under 12 years: 12.5 to 25 mg/kg 2 times daily
- Child 12 years and over and adult: 1 g 2 times daily

Age	Weight	125 mg/5 ml oral susp.	250 mg capsule
1 to < 5 months	4 to < 7 kg	1 tsp x 2	-
5 months to < 3 years	7 to < 15 kg	1½ tsp x 2	-
3 to < 6 years	15 to < 20 kg	2 tsp x 2	-
6 to < 12 years	20 to < 40 kg	-	2 cap x 2
≥ 12 years and adult	≥ 40 kg	-	4 cap x 2

#### **Duration**

- Impetigo, furuncle: 7 days; erysipelas, cellulitis: 7 to 10 days

- Do not administer to patients with allergy to cephalosporin.
- Administer with caution to patients with allergy to penicillin (cross-sensitivity may occur) and severe renal impairment (reduce the dose).
- May cause: gastrointestinal disturbances (particularly diarrhoea), allergic reactions (skin eruption, fever, pruritus).

- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

- Take preferably between meals.
- Also comes in 250 mg/5 ml powder for oral suspension.
- Storage: below 25 °C 7 7

For the oral suspension (powder or reconstituted suspension): follow manufacturer's instructions.

# **CEFIXIME** oral

Prescription under medical supervision

## Therapeutic action

- Third-generation cephalosporin antibacterial

#### **Indications**

- Typhoid fever
- Acute cystitis in girls over 2 years, pregnant women and lactating women
- Acute pyelonephritis in adults
- Cervicitis and urethritis due to Neisseria gonorrhoeae (in combination with a treatment for chlamydia)

#### Forms and strengths

- 200 mg tablet
- 100 mg/5 ml powder for oral suspension, to be reconstituted with filtered water

## **Dosage**

- Typhoid fever

Child: 10 mg/kg 2 times daily (max. 400 mg daily)

Adult: 200 mg 2 times daily

- Acute cystitis in girls over 2 years

8 mg/kg once daily

Acute cystitis in pregnant and lactating women, acute pyelonephritis in adult
 200 mg 2 times daily

- Cervicitis and urethritis due to Neisseria gonorrhoeae

Child: 8 mg/kg single dose Adult: 400 mg single dose

#### **Duration**

- Typhoid fever: 7 days; acute cystitis: 3 days for girls and 5 days for adults; acute pyelonephritis: 10 to 14 days

## Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to cephalosporins.
- Administer with caution to penicillin-allergic patients (cross-sensitivity may occur) and in patients with severe renal impairment (reduce dosage).
- May cause: gastrointestinal disturbances (especially diarrhoea), headache, dizziness, allergic reactions (rash, pruritus, fever). In the event of allergic reaction, stop treatment immediately.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### **Remarks**

- Cefixime is also used in the second-line treatment of shigellosis (child: 8 mg/kg once daily; adult: 400 mg once daily) for 5 days.
- Also comes in 400 mg capsules.
- <u>Storage</u>: below 25 °C **∅ †**

For the oral suspension (powder or reconstituted suspension): follow manufacturer's instructions.

# **Activated CHARCOAL oral**

## Therapeutic action

Adsorbent

#### **Indications**

- Poisoning by drugs, in particular: paracetamol, aspirin, ibuprofen, chloroquine, quinine, dapsone, phenobarbital, carbamazepine, digoxin
- Poisoning by other toxic substances: certain plants (datura, lantana, etc.), certain domestic, industrial or agricultural chemicals

## Forms and strengths

- Granules for oral suspension, in 50 g bottle, to be reconstituted with 250 ml of water

## **Dosage and duration**

The dose of charcoal has to be administered as soon as possible (preferably within one hour after ingestion of the toxic compound) and swallowed within a limited period, e.g., in 15 to 20 minutes:

- Child under 1 year: 1 g per kg
- Child from 1 to 12 years: 25 g
- Child over 12 years and adult: 50 g

If the dose of charcoal is not entirely swallowed or the toxic substance was ingested in large quantities or over 2 hours beforehand: follow the treatment for 24 hours after poisoning, by administering half or a quarter of the initial dose of charcoal every 4 or 6 hours, depending on the tolerance and cooperation of the patient.

#### Contra-indications, adverse effects, precautions

- Do not administer in case of poisoning by caustic or foaming products, or hydrocarbons: risk of aggravation of lesions during vomiting (caustic products), aspiration pneumonia (foaming products, hydrocarbons), and airway obstruction due to foaming when vomiting (foaming products).
- The charcoal is ineffective in poisoning by: alcohols (ethanol, ethylene glycol, methanol, isopropyl alcohol, etc.), organophosphorus and carbamate insecticides, metals (lithium, iron salts, etc.).
- May cause: black colouring of stools (normal), constipation; vomiting in the event of rapid administration of large quantities.
- Do not administer charcoal simultaneously with other drugs by oral route. Administer 2 hours apart.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- To facilitate the administration of charcoal and avoid vomiting in children, mask the taste (mix with fruit juice, syrup) and administer the suspension slowly in small quantities.
- If there is a specific antidote to the drug ingested, use it in complement.
- Storage: below 25 °C ₹

# CHLORAMPHENICOL oral

Prescription under medical supervision



The use of chloramphenicol should be restricted to severe infections when other less toxic antibacterials are not effective or contra-indicated.

## Therapeutic action

- Phenicol antibacterial

#### **Indications**

- Alternative to first-line treatments of bubonic plague
- Typhoid fever if the strain is susceptible (recent drug susceptibility test)
- Completion treatment following parenteral therapy with chloramphenicol

## Forms and strengths

- 250 mg capsule

#### **Dosage**

- Child from 1 year to less than 13 years: 12.5 mg/kg 3 to 4 times daily; the dose should be doubled in severe infection (max. 3 g daily)
- Child ≥ 13 years and adult: 1 g 3 to 4 times daily

Age	Weight 25	0 mg capsule
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1 to < 4 years	10 to < 17 kg	1 cap x 3
4 to < 9 years	17 to < 30 kg	2 cap x 3
9 to < 13 years	30 to < 45 kg	3 cap x 3
≥ 13 years and adult	≥ 45 kg	4 cap x 3

#### **Duration**

- Plague: 10 days; typhoid fever: 7 days

## Contra-indications, adverse effects, precautions

- Do not administer to children under 1 year.
- Do not administer to patients with:
- history of allergic reaction or bone marrow depression during a previous treatment with chloramphenicol;
- G6PD deficiency.
- May cause:
- dose-related haematological toxicity (bone marrow depression, anaemia, leucopenia, thrombocytopenia), allergic reactions. In these events, stop treatment immediately;
- gastrointestinal disturbances, peripheral and optic neuropathies.
- Reduce dosage in patients with hepatic or renal impairment.
- Avoid or monitor combination with potentially haematotoxic drugs (carbamazepine, co-trimoxazole, flucytocine, pyrimethamine, zidovudine, etc.).
- <u>Pregnancy</u>: **CONTRA-INDICATED**, except if vital, if there is no therapeutic alternative. If used during the 3<sup>rd</sup> trimester, risk of grey syndrome in the newborn infant (vomiting, hypothermia, blue-grey skin colour and cardiovascular depression).
- Breast-feeding: CONTRA-INDICATED

#### Remarks

- Oral treatment is more effective than parenteral treatment: blood and tissue concentrations are higher when chloramphenical is given orally.
- Capsules can be opened and their content mixed into a spoon with food.
- Also comes in 150 mg/5 ml powder for oral suspension.
- Storage: below 25 °C -

# CHLOROQUINE sulfate or phosphate oral



Given that resistance of *P. falciparum* to chloroquine is widespread, this drug must not be used for the treatment of falciparum malaria.

# Therapeutic action

- Antimalarial

#### **Indications**

- Treatment of malaria due to P. vivax, P. ovale, P. malariae and P. knowlesi

## Forms and strengths

- 155 mg chloroquine base tablet

The dose written on the labels is sometimes in chloroquine salt and sometimes in chloroquine base which leads to frequent confusion. The WHO recommends prescriptions and labels in chloroquine base. 155 mg base = approx. 200 mg sulfate = approx. 250 mg phosphate or diphosphate.

## **Dosage and duration**

- Child and adult:

Day 1: 10 mg base/kg

Day 2: 10 mg base/kg

Day 3: 5 mg base/kg

## Contra-indications, adverse effects, precautions

- Do not administer to patients with retinopathy.
- May cause: gastrointestinal disturbances, headache, transitory pruritus (lasting 72 hours), allergic reactions (urticaria, angioedema), visual disturbances.
- If the patient vomits within 30 minutes after administration: re-administer the full dose. If the patient vomits between 30 minutes and 1 hour after administration, re-administer half of the dose.
- There is a narrow margin between the therapeutic and toxic dose. Doses of 20 mg base/kg in children and 2 g base in adults are considered toxic.
- Avoid combination with drugs that prolong QT interval: amiodarone, other antimalarials, antipsychotics, fluconazole, fluoroquinolones, hydroxyzine, macrolides, ondansetron, etc.
- Do not administer simultaneously with antacids (aluminium/magnesium hydroxide, etc.) or calcium carbonate: administer 2 hours apart.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Also comes in 100 mg chloroquine base tablet and 50 mg chloroquine base/5 ml syrup.
- Storage: below 25 °C W

# CHLORPHENAMINE = CHLORPHENIRAMINE oral

#### Therapeutic action

- Sedating H1 antihistamine

#### **Indications**

- Symptomatic treatment of minor allergic reactions (urticaria, allergic conjunctivitis, etc.)

## Forms and strengths

- 2 mg/5 ml oral solution
- 4 mg tablet

#### **Dosage**

- Child 1 to < 2 years: 1 mg 2 times daily
- Child 2 to < 6 years: 1 mg 4 to 6 times daily (max. 6 mg daily)
- Child 6 to < 12 years: 2 mg 4 to 6 times daily (max. 12 mg daily)
- Child ≥ 12 years and adult: 4 mg 4 to 6 times daily (max. 24 mg daily; max.12 mg daily in elderly patients)

Age	Weight	2 mg/5 ml oral solution	4 mg tablet
1 to < 2 years	10 to < 13 kg	2.5 ml x 2	-
2 to < 6 years	13 to < 21 kg	2.5 ml x 4	-
6 to < 12 years	21 to < 39 kg	5 ml x 4	½ tab x 4
≥ 12 years and adult	≥39 kg	-	1 tab x 4

#### **Duration**

- As short as possible (a few days).

# Contra-indications, adverse effects, precautions

- Administer with caution and monitor use:
- in children and elderly patients (risk of agitation, excitability);
- in patients with prostate disorders, closed-angle glaucoma, epilepsy, severe renal or hepatic impairment;
- in patients taking central nervous system depressants (opioid analgesics, antipsychotics, sedatives, antidepressants, etc.) or drugs known to have an anticholinergic effect (atropine, amitriptyline, chlorpromazine, etc.).
- May cause:
- drowsiness, dizziness, headache, confusion, hypotension, photosensitivity (protect skin from sun exposure); rarely: extrapyramidal syndrome, allergic reactions;
- anticholinergic effects (dry mouth, constipation, blurred vision, tachycardia, disorders of micturition).
- Avoid alcohol during treatment.
- Pregnancy and breast-feeding:
- Prefer loratadine as from the 2<sup>nd</sup> trimester of pregnancy and in lactating women.
- If no alternative is available and treatment is clearly needed, administer chlorphenamine for as short a time as possible. Monitor the child (risk of sedation and anticholinergic effects) if the mother was treated just before birth or if she is breast-feeding.

#### **Remarks**

- Chlorphenamine is less sedating than promethazine.
- Storage: below 25 °C ∅ Ť

# **CHLORPROMAZINE** oral

Prescription under medical supervision



## Therapeutic action

- Sedative antipsychotic

#### **Indications**

- Acute or chronic psychosis

## Forms and strengths

- 25 mg and 100 mg tablets

#### **Dosage**

- Adult: 25 to 75 mg once daily in the evening. Increase gradually up to 100 mg 3 times daily if necessary.
- Reduce the dose by half in elderly patients.
- Use the lowest effective dose, especially in the event of prolonged treatment.

#### **Duration**

– *Acute psychosis*: minimum 3 months; *chronic psychosis*: minimum one year. The treatment should be discontinued gradually (over 4 weeks). If signs of relapse occur, increase the dose.

- Do not administer to patients with cardiac disorders (heart failure, recent myocardial infarction, conduction disorders, bradycardia, etc.), dementia (e.g. Alzheimer's disease), closed-angle glaucoma, prostate disorders, Parkinson's disease and history of neuroleptic malignant syndrome.
- Administer with caution and carefully monitor use in elderly patients and patients with hypokalaemia, hypotension, renal or hepatic impairment, history of seizures.
- May cause:
- drowsiness, dyskinesia, extrapyramidal symptoms, weight gain, orthostatic hypotension, hyperprolactinaemia, anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation, tachycardia);
- hyperglycaemia, photosensitivity, impaired thermoregulation; agranulocytosis, neuroleptic malignant syndrome (unexplained hyperthermia with neuromuscular disorders), rare but requiring immediate treatment discontinuation.
- In the event of extrapyramidal symptoms, combine with biperiden or trihexyphenidyl.
- Avoid or monitor combination with:
- central nervous system depressants (opioid analgesics, sedatives, H1 antihistamines, etc.); drugs with anticholinergic effects (amitriptyline, atropine, clomipramine, promethazine, etc.), antidiabetics, lithium;
- antihypertensive drugs (risk of hypotension); drugs that prolong the QT interval (amiodarone, chloroquine, erythromycin, fluconazole, mefloquine, pentamidine, quinine, etc.).
- Avoid alcohol during treatment.
- <u>Pregnancy</u>: re-evaluate whether the treatment is still necessary; if it is continued, monitor the neonate for extrapyramidal and/or anticholinergic effects (tremor, abdominal distension, hyperexcitability, etc.) if

the mother was treated in the 3<sup>rd</sup> trimester.

- Breast-feeding: avoid

#### Remarks

- Do not crush tablets (risk of contact dermatitis).
- <u>Storage</u>: below 25 °C 🖊 🖣

# **CIMETIDINE** oral

Prescription under medical supervision

## Therapeutic action

- Antiulcer agent (histamine H2-receptor antagonist)

#### **Indications**

- Prophylaxis of acid pulmonary aspiration syndrome in anaesthesia:
- in patients with a full stomach (emergency caesarean section, etc.)
- when a difficult intubation is expected

## Forms and strengths

- 200 mg effervescent tabletAlso comes 800 mg effervescent tablet.

## Dosage and duration

- Adult: 200 to 400 mg single dose, if possible one hour before anaesthetic induction

# Contra-indications, adverse effects, precautions

- May cause: diarrhoea, headache, dizziness, skin rash, fever.
- Do not administer with an antacid (aluminium hydroxide, etc.).

#### Remarks

- Effervescent cimetidine can be replaced by effervescent ranitidine, another H2-receptor antagonist, as a single dose of 150 mg.
- The onset of acid inhibition with cimetidine non-effervescent tablets (200 mg, 400 mg and 800 mg film coated tablets) or ranitidine non-effervescent tablets (150 mg and 300 mg film coated tablets) occurs 30 minutes after administration. The effervescent tablets containing sodium citrate have a more rapid onset of action, and can thus be used for emergency surgery.
- Omeprazole, another antiulcer agent (proton pump inhibitor), is not compatible with emergency situations as it must be administered at least 4 hours before surgery.
- Cimetidine in film coated tablets is also used in the treatment of gastro-oesophageal reflux and peptic ulcer. Use by preference ranitidine or omeprazole for these indications.
- Storage: below 25 °C ₩ Ť

# **CIPROFLOXACIN** oral

Prescription under medical supervision

# Therapeutic action

- Fluoroquinolone antibacterial

#### **Indications**

- Shigellosis, typhoid fever, uncomplicated cutaneous anthrax
- Uncomplicated acute pyelonephritis, acute prostatitis, acute cystitis in non-pregnant women in the event of previous treatment failure

## Forms and strengths

- 250 mg and 500 mg tablets
- 250 mg/5 ml granules and solvent for oral suspension

#### **Dosage**

Shigellosis, typhoid fever, uncomplicated cutaneous anthrax
 Child over 1 month: 15 mg/kg 2 times daily (max. 1 g daily)

Adult: 500 mg 2 times daily

Age	Weight	250 mg/5 ml susp.	250 mg tablet	500 mg tablet
1 to < 3 months	4 to < 6 kg	1.5 ml x 2	-	-
3 to < 7 months	6 to < 8 kg	2 ml x 2	-	-
7 months to < 2 years	8 to < 12 kg	2.5 ml x 2	-	-
2 to < 3 years	12 to < 15 kg	4 ml x 2	-	-
3 to < 8 years	15 to < 26 kg	5 ml x 2	1 tab x 2	-
8 to < 11 years	26 to < 36 kg	8 ml x 2	-	-
≥11 years and adult	≥ 36 kg	-	2 tab x 2	1 tab x 2

Uncomplicated acute pyelonephritis, acute prostatitis, acute cystitis
 Adult: 500 mg 2 times daily

#### **Duration**

- Shigellosis: 3 days; cystitis: 5 days; typhoid fever, pyelonephritis: 7 days; cutaneous anthrax: 7 to 10 days; prostatitis: 14 days (if signs and symptoms are ongoing after 14 days, continue the same treatment for a further 14 days).

## Contra-indications, adverse effects, precautions

- Do not administer to patients with history of allergy or serious adverse effects due to a fluoroquinolone, e.g. tendinitis, tendon rupture.
- Administer with caution to epileptic patients (risk of seizures), elderly patients and patients with hypertension.
- Reduce the dose by half in patients with renal impairment.
- May cause: gastrointestinal disturbances, neurological disorders (headache, dizziness, confusion, hallucinations, seizures), allergic reaction, peripheral neuropathy, photosensitivity (protect skin from sun exposure), joint and muscle pain, tendinitis (especially Achilles tendinitis), QT interval prolongation, hypo/hyperglycaemia, haemolytic anaemia in patients with G6PD deficiency. In the event of allergic reaction, severe neurological disorders, peripheral neuropathy, joint or muscle pain or tendinitis, stop treatment immediately.
- Avoid combination with drugs that prolong the QT interval (amiodarone, chloroquine, co-artemether, fluconazole, haloperidol, mefloquine, ondansetron, pentamidine, quinine, etc.).
- Monitor patients taking glibenclamide (risk of hypoglycaemia).
- Do not administer simultaneously with:
- corticosteriods (increased risk of tendinitis);
- antacids (aluminium or magnesium hydroxide, etc.): take ciprofloxacin 2 hours before or 4 hours after antacids;
- iron salts, calcium, zinc sulfate: take 2 hours apart.
- Drink a lot of liquid during treatment (risk of crystalluria).
- <u>Pregnancy</u>: reserved for severe infections, when there is no therapeutic alternative.
- Breast-feeding: no contra-indication

#### Remarks

- <u>Storage</u>: below 25 °C - 🕢 - Ť

# **CLARITHROMYCIN** oral

Prescription under medical supervision

# Therapeutic action

- Macrolide antibacterial

#### **Indications**

- Eradication of *Helicobacter pylori*, in combination with omeprazole and amoxicillin

#### Forms and strengths

- 500 mg tablet

#### **Dosage and duration**

- Adult: 500 mg 2 times daily for 7 days

## Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to clarithromycin or another macrolide.
- May cause:
- headache, taste disturbances, insomnia, gastrointestinal disturbances, reversible hearing disorders;
- heart rhythm disorders (QT prolongation);
- hypersensitivity reactions sometimes severe (in this event, stop treatment immediately).
- Administer with caution and reduce dosage by half in patients with severe renal impairment.
- Avoid combination with drugs that prolong the QT interval: amiodarone, antimalarials, antipsychotics, efavirenz, fluconazole, fluoroquinolones, hydroxyzine, ondansetron, etc.
- Administer with caution and monitor combination with: oral antidiabetics, atorvastatin, carbamazepine, daclatasvir, digoxin, phenytoin, rifabutin (increased plasma concentrations of these drugs).
- <u>Pregnancy</u>: avoid (safety not established)
- Breast-feeding: no contra-indication

#### Remarks

- Clarithromycin is also used for the treatment of non-tuberculous mycobacterial infections.
- Storage: below 25 °C

# **CLINDAMYCIN** oral

Prescription under medical supervision



## Therapeutic action

- Lincosamide antibacterial

#### **Indications**

- Severe staphylococcal and/or streptococcal infections (e.g. erysipelas, cellulitis, cutaneous anthrax, pneumonia):
- in betalactam-allergic patients
- in infections due to methicillin-resistant Staphylococcus aureus
- Completion treatment following parental therapy with clindamycin

## Forms and strengths

- 150 mg and 300 mg capsules

#### **Dosage**

- Child: 10 to 13 mg/kg 3 times daily
- Adult: 600 mg 3 times daily

Age	Weight	150 mg capsule	300 mg capsule
1 to < 6 years	10 to < 20 kg	1 cap x 3	-

6 to < 9 years	20 to < 30 kg	_	1 cap x 3
9 to < 13 years	30 to < 45 kg	3 cap x 3	-
≥ 13 years and adult	≥ 45 kg	_	2 cap x 3

#### **Duration**

- *Erysipelas, cellulitis*: 7 to 10 days; *cutaneous anthrax*: 7 to 14 days depending on severity; *pneumonia*: 10 to 14 days

## Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to lincosamides or history of pseudomembranous colitis.
- Reduce dosage in patients with hepatic impairment.
- May cause: pseudomembranous colitis, rash, jaundice, severe allergic reactions. In these cases, stop treatment.
- In the event of pseudomembranous colitis, treat for *Clostridium difficile* infection (oral metronidazole).
- Do not administer simultaneously with antacids (aluminium or magnesium hydroxide, etc.). Administer 2 hours apart.
- <u>Pregnancy</u>: no contra-indication
- <u>Breast-feeding</u>: use only when there is no therapeutic alternative. Check infant's stools (risk of pseudomembranous colitis).

#### Remarks

- Capsules are not suitable for children under 6 years (risk of aspiration). Open the capsule and mix the content into a spoon with food or fruit juice to mask the unpleasant taste.
- Clindamycin is use in combination with quinine for the treatment of malaria in pregnant women (10 mg/kg 2 times daily for 7 days).
- Also comes in 75 mg/5 ml oral suspension.
- <u>Storage</u>: below 25 °C 💋 🖣

# **CLOXACILLIN** oral

Prescription under medical supervision

## Therapeutic action

- Penicillin antibacterial

#### **Indications**

- Impetigo (preferably use cefalexin for this indication)

#### Forms and strengths

- 250 mg and 500 mg capsules

#### **Dosage and duration**

- Child over 10 years: 15 mg/kg 3 times daily for 7 days (max. 3 g daily)
- Adult: 1 g 3 times daily for 7 days

Age	Weight	250 mg capsule	500 mg capsule
10 to < 13 years	30 to < 45 kg	2 cap x 3	1 cap x 3
13 to < 15 years	45 to < 55 kg	3 cap x 3	-
Adult	≥ 55 kg	4 cap x 3	2 cap x 3

## Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to penicillin.
- Administer with caution to patients with allergy to cephalosporins (cross-sensitivity may occur) or severe renal impairment (reduce the dosage).
- May cause: gastrointestinal disturbances (particularly diarrhoea), allergic reactions sometimes severe; rarely, haematological disorders.
- Do not combine with methotrexate (increased methotrexate toxicity).
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Take between meals.
- Dicloxacillin, flucloxacillin and oxacillin are antibacterials used for the same indication.
- Also comes in powder for oral solution 125 mg/5 ml and 1 g capsules.
- Storage: below 25 ℃ Ť

# **CO-AMOXICLAV** oral

See AMOXICILLIN/CLAVULANIC acid(see page 21) oral(see page 21)

## **CO-ARTEMETHER oral**

See ARTEMETHER/LUMEFANTRINE = AL(see page 23) oral(see page 23)

# **CODEINE** oral

Prescription under medical supervision



## Therapeutic action

- Opioid analgesic

#### **Indications**

- Moderate pain, alone or in combination with a non-opioid analgesic

## Forms and strengths

- 30 mg codeine phosphate tablet

#### Dosage

- Child over 12 years and adult: 30 to 60 mg every 4 to 6 hours; maximum 240 mg daily

#### **Duration**

- According to clinical evolution; as short as possible.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with acute respiratory depression or asthma attack.
- May cause:
- constipation, nausea, vomiting, drowsiness, dizziness;
- rarely: respiratory depression, allergic reactions, dependence, withdrawal syndrome.
- Do not combine with:
- other agonist opioids such as morphine (increased risk of respiratory depression);
- agonist-antagonist opioids such as buprenorphine, nalbuphine, pentazocine (competitive action).
- Reduce dosage in patients with renal or hepatic impairment and in elderly patients.
- Management of respiratory depression includes assisted ventilation and/or administration of naloxone.
- Pregnancy: no contra-indication. The newborn infant may develop withdrawal symptoms, respiratory depression and drowsiness in the event of prolonged administration of large doses at the end of the 3<sup>rd</sup> trimester. In this event, closely monitor the newborn infant.
- <u>Breast-feeding</u>: use with caution, for a short period (2-3 days), at the lowest effective dose. Monitor the mother and the infant: in the event of excessive drowsiness, stop treatment.

#### Remarks

- Administer an appropriate laxative (e.g. lactulose) if analgesic treatment continues more than 48 hours.
- In some countries, codeine is on the list of narcotics: follow national regulations.
- Storage: below 25 °C W

# COLECALCIFEROL = VITAMIN D3 oral

Prescription under medical supervision

## Therapeutic action

 Vitamin necessary for the intestinal absorption of calcium and phosphate and for normal bone calcification

#### **Indications**

- Prevention and treatment of vitamin D deficiencies (rickets, osteomalacia)

# Forms and strengths

- 10 000 IU/ml oral solution, in 10 ml vial
- 50 000 IU/ml oral solution, in 2 ml ampoule (100 000 IU)

#### **Dosage and duration**

Colecalciferol and ergocalciferol are used at the same doses:

- Prevention of vitamin D deficiencies
- Term neonate: 400 to 800 IU once daily until 6 months of age
- Term neonate in contexts of high prevalence of vitamin D deficiency: 600 to 1200 IU once daily until 6 months of age
- Pregnant woman: 100 000 IU single dose (one 2 ml ampoule) in the 6<sup>th</sup> or 7<sup>th</sup> month of pregnancy
- Treatment of vitamin D deficiencies

Child < 3 months: 2 000 IU once daily for 3 months

Child from 3 to < 12 months: 2 000 IU once daily for 3 months or 50 000 IU single dose

Child from 12 months to < 12 years: 3 000 to 6 000 IU once daily for 3 months or 150 000 IU single dose

Child ≥ 12 years and adult: 6 000 IU once daily for 3 months or 300 000 IU single dose

Then continue with preventive dose, as long as the situation requires:

Child < 12 months: 400 IU once daily

Child ≥ 12 months and adult: 600 IU once daily

- Do not exceed 600 000 IU yearly.

#### Contra-indications, adverse effects, precautions

- Do not administer to patients with hypercalcaemia, hypercalciuria, calcic lithiasis, severe renal impairment.
- Stop treatment if signs of overdosage occur: headache, anorexia, nausea, vomiting, increased thirst, polyuria.
- Avoid combination with thiazide diuretics, e.g. hydrochlorothiazide (decreased urinary calcium excretion).
- Monitor, if possible, calcaemia and calciuria during curative treatment.
- <u>Pregnancy</u>: no contra-indication
- <u>Breast-feeding</u>: no contra-indication. When curative treatment is being administered to the mother, do not give vitamin D to the child.

#### Remarks

- The number of IU per drop of oral solution varies according to manufacturers. Check instructions for
- Preferably use the vials of oral solution that, once opened, keep for 6 months.
- During the first 3 months of curative treatment, administer a supplement of 500 mg of calcium once

daily.

– Storage: below 25°C - 🌽

# CO-TRIMOXAZOLE = SULFAMETHOXAZOLE (SMX)/TRIMETHOPRIM (TMP) oral

Prescription under medical supervision

## Therapeutic action

 Combination of two antibacterials: a sulfonamide (sulfamethoxazole) and a diaminopyrimidine antifolate (trimethoprim)

#### **Indications**

- Treatment of cerebral toxoplasmosis, pneumocystosis, isosporiasis, cyclosporiasis and brucellosis
- Prophylaxis of pneumocystosis, toxoplasmosis and isosporiasis
- Second-line treatment of pertussis
- Typhoid fever if the strain is susceptible (recent drug susceptibility test)

## Forms and strengths

- 400 mg SMX + 80 mg TMP and 800 mg SMX + 160 mg TMP tablets
- 100 mg SMX + 20 mg TMP dispersible tablet for paediatric use

## **Dosage**

Treatment of cerebral toxoplasmosis
 Child > 1 month and adult: 25 mg SMX + 5 mg TMP/kg 2 times daily

Treatment of pneumocystosis
 Child > 1 month: 50 mg SMX + 10 mg TMP/kg 2 times daily
 Adult: 1600 mg SMX + 320 mg TMP 3 times daily

Treatment of isosporiasis and cyclosporiasis
 Adult: 800 mg SMX + 160 mg TMP 2 times daily

Prophylaxis of pneumocystosis, toxoplasmosis and isosporiasis
 Child > 1 month: 50 mg SMX + 10 mg TMP/kg once daily, as long as necessary
 Adult: 800 mg SMX + 160 mg TMP once daily, as long as necessary

Treament of pertussis, brucellosis and typhoid fever
 Child > 1 month: 20 mg SMX + 4 mg TMP/kg 2 times daily
 Adult: 800 mg SMX + 160 mg TMP 2 times daily

#### **Duration**

- Cerebral toxoplasmosis: 4 to 6 weeks; pneumocystosis: 21 days; isosporiasis: 7 to 10 days; cyclosporiasis, typhoid fever: 7 days; pertussis: 14 days; brucellosis: 6 weeks

## Contra-indications, adverse effects, precautions

- Do not administer to children under 1 month.
- Do not administer to sulfonamide-allergic patients; patients with severe renal or hepatic impairment.
- Do not combine with phenytoin (increased plasma concentrations of phenytoin).
- May cause:
- gastrointestinal disturbances, hepatic or renal disorders (crystalluria, etc.), metabolic disorders (hyperkalaemia, hypoglycaemia, hyponatraemia); neuropathy, photosensitivity, haemolytic anaemia in patients with G6PD deficiency;
- allergic reactions (fever, rash, etc.) sometimes severe (Lyell's and Stevens-Johnson syndromes, haematological disorders, etc.); agranulocytosis, megaloblastic anaemia due to folic acid deficiency. In these cases, stop treatment immediately.
- Adverse effects occur more frequently in patients with HIV infection.
- In the event of prolonged treatment, monitor blood count if possible.
- Avoid combination with drugs inducing hyperkalaemia: potassium salts, spironolactone, enalapril, NSAIDs, heparin (increased risk of hyperkalaemia).
- Monitor combination with: zidovudine (increased haematotoxicity), antidiabetics (increased risk of hypoglycaemia).
- Drink plenty of water during treatment to reduce risk of crystalluria.
- <u>Pregnancy</u>: avoid using during the first trimester (risk of malformation) and during the last month of pregnancy (risk of neonatal jaundice and haemolytic anaemia).
- <u>Breast-feeding</u>: avoid if premature neonate, jaundice, low-birth weight, during the first month of life. If co-trimoxazole is used, observe the child for signs of jaundice.

#### Remarks

- Preferably take during meals.
- Also comes in 200 mg SMX + 40 mg TMP/5 ml oral suspension.
- Storage: below 25 °C W

# **DACLATASVIR = DCV oral**

Prescription under medical supervision

#### Therapeutic action

- Direct-acting antiviral (NS5A inhibitor)

#### **Indications**

- Treatment of chronic hepatitis C, in combination with sofosbuvir

## Forms and strengths

- 30 mg and 60 mg tablets
- 60 mg breakable tablet

#### **Dosage and duration**

- Genotypes 1, 2, 4, 5, 6 without cirrhosis or with compensated cirrhosis and genotype 3 without cirrhosis Adult: 60 mg once daily (in combination with sofosbuvir) for 12 weeks
- Genotype 3 with compensated cirrhosis

Adult: 60 mg once daily (in combination with sofosbuvir) for 24 weeks

- Genotypes 1, 2, 3, 4, 5, 6 with decompensated cirrhosis

Adult: 60 mg once daily (in combination with sofosbuvir) for 24 weeks

## Contra-indications, adverse effects, precautions

- Do not use as monotherapy.
- Do not administer to patients with allergy to daclatasvir.
- May cause: fatigue, headache, insomnia, dizziness, gastrointestinal disturbances, arthralgia.
- Administer with caution to patients co-infected with HBV (risk of HBV reactivation).
- Do not combine with: carbamazepine, phenobarbital, phenytoin, rifampicin, rifabutin, rifapentine, systemic dexamethasone (decreased daclatasvir plasma concentrations); amiodarone (risk of severe bradycardia and heart block).
- Administer with caution and monitor combination with:
- efavirenz, etravirine, nevirapine (increase daclatasvir dose);
- clarithromycin, erythromycin, itraconazole, atazanavir/ritonavir (reduce daclatasvir dose);
- digoxin (increased digoxin plasma concentrations).
- Closely monitor blood glucose levels in diabetic patients (risk of hypoglycaemia); adjust the antidiabetic treatment if necessary.
- Provide effective contraception in women of childbearing age.
- <u>Pregnancy and breast-feeding</u>: **CONTRA-INDICATED** (safety not established)

#### Remarks

- Tablets have a bad taste, they should be swallowed whole (not crushed or chewed).
- If the patient misses a dose, the dose should be taken as soon as possible if remembered within 20 hours of the usual time. After 20 hours or more, the dose should be skipped, and the next dose taken at the usual time.
- Also comes as fixed-dose combination tablets containing daclatasvir 60 mg/sofosbuvir 400 mg.
- Storage: below 25 °C

# **DAPSONE** oral

Prescription under medical supervision



## Therapeutic action

- Sulfone antibacterial, antileprotic

#### **Indications**

– Prophylaxis of toxoplasmosis and pneumocystosis, in combination with pyrimethamine and folinic acid

- Treatment of pneumocystosis, in combination with trimethoprim
- Paucibacillary and multibacillary leprosy, in combination with rifampicin and clofazimine

#### Forms and strengths

- 25 mg and 50 mg tablets and 100 mg scored tablets

#### **Dosage**

- Prophylaxis of pneumocystosis only

Child: 2 mg/kg once daily (max. 100 mg daily)

Adult: 100 mg once daily

- Prophylaxis of toxoplasmosis and pneumocystosis

Child: 2 mg/kg once daily (max. 25 mg daily) Adult: 200 mg once weekly or 50 mg once daily

- Treatment of pneumocystosis

Child: 2 mg/kg once daily (max. 100 mg daily)

Adult: 100 mg once daily

- Paucibacillary and multibacillary leprosy

Child under 10 years: 2 mg/kg once daily

Child from 10 to 14 years: 50 mg once daily Child 15 years and over and adult: 100 mg once daily

#### **Duration**

- *Prophylaxis of toxoplasmosis and pneumocystosis*: as long as necessary; *treatment of pneumocystosis*: 21 days; *paucibacillary leprosy*: 6 months; *multibacillary leprosy*: 12 months

## Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to sulfones or severe anaemia (first treat anaemia).
- Administer with caution to patients with renal or hepatic impairment.
- May cause: haemolytic anaemia in patients with G6PD deficiency, dose-related haemolytic anaemia, neutropenia, methaemoglobinaemia, pruritus, rash, gastrointestinal disturbances, peripheral neuropathies, agranulocytosis; hypersensitivity reactions during the first month of treatment (fever, jaundice, hepatitis, adenopathy, exfoliative dermatitis, etc.) requiring permanent discontinuation of treatment.
- Monitor blood count and transaminases if possible.
- Monitor combination with zidovudine (increased haematological toxicity).
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

– <u>Storage</u>: below 25 ℃ - 🌽 - 🌴

# **DARUNAVIR = DRV**

Prescription under medical supervision

## Therapeutic action

- Antiretroviral, HIV protease inhibitor

#### **Indications**

- HIV infection, in combination with ritonavir (booster) and other antiretrovirals

# Forms and strengths

- 75 mg, 300 mg, 400 mg and 600 mg tablets

#### **Dosage**

Patients with no previous use of protease inhibitors
 Child 14 to < 35 kg: 600 mg once daily (+ 100 mg ritonavir once daily)</li>
 Child ≥ 35 kg and adult: 800 mg once daily (+ 100 mg ritonavir once daily)

Patients with previous use of protease inhibitors
 Child 14 to < 25 kg: 375 mg 2 times daily (+ 50 mg ritonavir 2 times daily)</li>
 Child 25 to < 35 kg: 400 mg 2 times daily (+ 100 mg ritonavir 2 times daily)</li>
 Child ≥ 35 kg and adult: 600 mg 2 times daily (+ 100 mg ritonavir 2 times daily)

#### **Duration**

- The duration of treatment depends on the efficacy and tolerance of darunavir and ritonavir.

# Contra-indications, adverse effects, precautions

- Do not administer in children under 3 years; in case of severe hepatic impairment, history of allergy to sulfonamides or in combination with rifampicin.
- Administer with caution and monitor use in patients with haemophilia (increased bleeding) or in patients with mild or moderate hepatic impairment.
- May cause:
- gastrointestinal disturbances, headache, insomnia, fatigue, dizziness, peripheral neuropathy, renal disorders, myocardial infarction, hypertension, tachycardia, hyperglycaemia, hyperlipidaemia, lipodystrophy;
- skin rash sometimes severe, hepatic disorders; in this event, stop treatment immediately.
- Darunavir in combination with ritonavir reduces the efficacy of oral contraceptives: use a non-hormonal contraception or injectable medroxyprogesterone or an oral contraceptive containing 50 micrograms of ethinylestradiol per tablet.
- Pregnancy: no contra-indication

#### **Remarks**

- Take with meals together with ritonavir.
- Storage: below 25 °C W

## **DESOGESTREL** oral

Prescription under medical supervision

## Therapeutic action

- Hormonal contraceptive, progestogen

#### **Indications**

- Oral contraception

## Forms and strengths

- 0.075 mg (75 micrograms) tablet

## **Dosage**

- One tablet daily to be taken at the same time each day, on a continuous basis, including during menstruation.
- Contraception may be started at any moment of the cycle if it is reasonably certain the woman is not pregnant, including when switching from another form of contraception. Contraception will be effective as of the 3<sup>rd</sup> tablet.

Use condoms for the first 2 days of the pack if the pill is started:

- more than 5 days after the start of menstruation;
- more than 28 days postpartum if not breastfeeding;
- more than 7 days after an abortion.
- If a pill is missed, it should be taken as soon as possible and usual treatment continued. The missed pill and next scheduled pill can be taken together.

If the missed pill is more than 12 hours overdue, the effectiveness of the contraceptive is reduced. Use:

- condoms for the following 2 days;
- emergency contraception if the woman has had intercourse in the 5 days preceding the missed pill.

#### **Duration**

– If there are no adverse effects, as long as this method of contraception is desired.

# Contra-indications, adverse effects, precautions

- Do not administer to women with breast cancer, severe or recent liver disease, unexplained vaginal bleeding, active thromboembolic disorders.
- May cause: amenorrhoea, menstrual disturbances, nausea, weight gain, breast tenderness, mood changes, acne, headache.
- Enzyme-inducing drugs (rifampicin, rifabutine, efavirenz, nevirapine, lopinavir, ritonavir, phenobarbital, phenytoin, carbamazepine, griseofulvin, etc.) reduce the effectiveness of the contraceptive.
- <u>Pregnancy</u>: **CONTRA-INDICATED**
- Breast-feeding: no contra-indication

#### Remarks

- Desogestrel is a possible alternative when oestroprogestogens are contra-indicated or poorly tolerated. It has a wider window for error and may therefore be is preferred to levonorgestrel which must be taken at strictly the exact same time daily.
- <u>Storage</u>: below 25 ℃ 🎾

# **DIAZEPAM** oral

Prescription under medical supervision



## Therapeutic action

- Anxiolytic, sedative, anticonvulsant, muscle relaxant

#### **Indications**

- Severe anxiety, insomnia and agitation

## Forms and strengths

- 2 mg and 5 mg tablets

## **Dosage and duration**

- Anxiety

Adult: 2.5 to 5 mg 2 times daily for 1 to 2 weeks max. reducing the dose by half the last days before stopping treatment

- Insomnia

Adult: 2 to 5 mg once daily at bedtime for 7 days max.

Agitation

Adult: 10 mg single dose

- Do not administer to patients with severe respiratory insufficiency or severe hepatic impairment.
- Administer with caution and reduce the dose by half in elderly patients and in patients with renal or hepatic impairment.
- May cause:
- drowsiness, impaired concentration, memory loss, confusion, muscle weakness;
- dependence and tolerance when used for more than 2 weeks;
- withdrawal syndrome or rebound effect if prolonged treatment is discontinued abruptly;
- ataxia, hypotonia, hypotension, confusion, lethargy, respiratory depression, coma in the event of overdose.
- Monitor combination with:
- drugs acting on the central nervous system: opioid analgesics, antipsychotics (chlorpromazine, haloperidol, etc.), antihistamines (chlorphenamine, promethazine), antidepressants (fluoxetine, etc.), phenobarbital, etc.;
- fluconazole, erythromycin, omeprazole, ritonavir, isoniazide (effect of diazepam increased);
- phenobarbital (effect of diazepam decreased).
- Avoid alcohol during treatment.
- Pregnancy and breast-feeding: avoid

- Diazepam is subject to international controls: follow national regulations.
- Diazepam is not a treatment for depression, chronic anxiety, post-traumatic stress disorder, psychosis.
- <u>Storage</u>: below 25 ℃ 🌽 Ť

# **DIETHYLCARBAMAZINE** oral

Prescription under medical supervision



## Therapeutic action

- Anthelminthic (antifilarial)

#### **Indications**

- Lymphatic filariasis

## Forms and strengths

- 100 mg breakable tablet

#### **Dosage**

- Child under 10 years: 0.5 mg/kg on D1, then increase the dose gradually over 3 days to 1 mg/kg 3 times daily
- Child over 10 years and adult: 1 mg/kg on D1, then increase the dose gradually over 3 days to 2 mg/kg 3 times daily

#### **Duration**

- W. bancrofti: 12 days; B. malayi, B. timori: 6 to 12 days

- Do not administer to patients with onchocerciasis or heavy *Loa loa* microfilareamia; to infants, elderly patients and patients with heart or renal diseases.
- Do not administer during acute attacks (risk of severe reactions).
- Administer with caution in patients with history of seizures.
- May cause:
- nausea, vomiting, headache, dizziness, drowsiness, fever, joint pain, urticaria, transient haematuria, subcutaneous nodules, lymphangitis, localized oedema;
- in patients with associated onchocerciasis: severe ocular damages (optic nerve lesions, retinal lesions);
- in patients with associated loiasis: encephalitis (potentially fatal) if Loa loa microfilaraemia is high.
- Reduce dosage in patients with renal impairment.
- <u>Pregnancy</u>: **CONTRA-INDICATED** (treatment may be deferred until after delivery)
- <u>Breast-feeding</u>: not recommended

- In countries with a national programme for the elimination of bancroftian filariasis, the combination diethylcarbamazine + albendazole is administered as a single annual dose for 4 to 6 years. This regimen is only suitable for countries that are free from *Onchocerca volvulus* and/or *Loa loa*.
- Diethylcarbamazine is included in the WHO complementary list of essential medicines.
- Storage: between 15 °C and 25 °C ₩

## **DIGOXIN** oral

Prescription under medical supervision



## Therapeutic action

- Cardiotonic

#### **Indications**

- Supraventricular arrhythmias (fibrillation, flutter, paroxysmal tachycardia)
- Heart failure

## Forms and strengths

- 250 micrograms (0.25 mg) tablet

#### **Dosage**

- Adult: 125 to 250 micrograms (0.125 to 0.25 mg) once daily
- Reduce the dose by half in elderly patients and in patients with renal impairment.

#### **Duration**

- According to clinical response

- Do not administer to patients with bradycardia, ill defined arrhythmia, coronary artery disease.
- It is essential to monitor pulse in the initial stage of treatment.
- Narrow margin between therapeutic and toxic dose.
- May cause in the event of overdose: gastrointestinal disturbances (nausea, vomiting, diarrhoea), blurred vision, headache, confusion, conduction and rhythm disorders. If so, reduce dose or stop treatment.
- Do not combine with calcium, particularly by IV route (serious arrhythmias).
- Monitor combination with:
- amiodarone, macrolides, itraconazole, quinine, chloroquine (increased digoxin concentration);
- potassium-depleting drugs: diuretics, corticoids, amphotericin B (increased risk of digoxin toxicity).
- Monitor if possible serum potassium level in patients taking potassium-depleting drugs and serum creatinine level in patients with renal impairment.
- Do not administer simultaneously with antacids such as aluminium hydroxide, etc., administer 2 hours apart.

- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

– <u>Storage</u>: below 25 ℃ - 🌽

# DIHYDROARTEMISININ/PIPERAQUINE = DHA/PPQ oral

Prescription under medical supervision

## Therapeutic action

- Antimalarial

#### **Indications**

- Treatment of uncomplicated falciparum malaria
- Treatment of uncomplicated malaria due to other Plasmodium species, when chloroquine cannot be used
- Completion treatment following parenteral therapy for severe malaria

## Forms and strengths

- Co-formulated tablets of dihydroartemisinin (DHA)/piperaquine (PPQ), in blister pack, for a complete treatment for one individual
- There are 5 different blister packs:
- 20 mg DHA/160 mg PPQ tablets blister pack of 3 tablets
- 40 mg DHA/320 mg PPQ tablets blister pack of 3 tablets
- 40 mg DHA/320 mg PPQ tablets blister pack of 6 tablets
- 40 mg DHA/320 mg PPQ tablets blister pack of 9 tablets
- 40 mg DHA/320 mg PPQ tablets blister pack of 12 tablets

#### **Dosage and duration**

- Child 5 to < 25 kg: 2.5 to 10 mg/kg daily of DHA + 20 to 32 mg/kg daily of PPQ
- Child 25 kg and over and adult: 2 to 10 mg/kg daily of DHA + 16 to 27 mg/kg daily of PPQ

Weight	20 mg/160 mg tablet	40 mg/320 mg tablet
5 to < 8 kg	1 tab	-
8 to < 11 kg	1½ tab	-
11 to < 17 kg	-	1 tab
17 to < 25 kg	-	1½ tab

25 to < 36 kg	_	2 tab
36 to < 60 kg	-	3 tab
60 to < 80 kg	-	4 tab
≥80 kg	-	5 tab

<sup>-</sup> Tablets are to be taken once daily for 3 days.

## Contra-indications, adverse effects, precautions

- Do not administer in the event of cardiac disorders (bradycardia, heart rhythm disorders, congestive heart failure).
- Do not combine with drugs that prolong the QT interval: amiodarone, other antimalarials, antipsychotics, fluconazole, fluoroquinolones, hydroxyzine, macrolides, ondansetron, etc.
- Administer with caution to patients > 60 years or with renal or hepatic impairment.
- May cause: cardiac disorders (QT prolongation, tachycardia); rarely, gastrointestinal disturbances, pruritus, hepatic disorders, joint and muscle pain.
- Monitor combination with: antiretrovirals (increased blood levels of these drugs), enzymes inducers such as rifampicin, carbamazepine, phenytoin, phenobarbital (reduced blood levels of DHA/PPQ).
- If the patient vomits within 30 minutes after administration, re-administer the full dose. If the patient vomits between 30 minutes and 1 hour after administration, re-administer half of the dose.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Take 3 hours before or after meals, with a glass of water.
- The tablets may be crushed and mixed with water.
- <u>Storage</u>: below 25 °C **//** <del>↑</del>

# ! Dipyrone oral

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see METAMIZOLE = DIPYRONE = NORAMIDOPYRINE oral(see page 326)

# **DOLUTEGRAVIR = DTG oral**

Prescription under medical supervision

## Therapeutic action

- Antiretroviral, inhibitor of HIV integrase

#### **Indications**

- HIV infection, in combination with other antiretrovirals

## Forms and strengths

- 50 mg tablet

Also comes in fixed-dose combinations containing dolutegravir.

#### **Dosage**

- Child 25 kg and over and adult: 50 mg once daily

#### **Duration**

- The duration of treatment depends on the efficacy and tolerance of dolutegravir.

# Contra-indications, adverse effects, precautions

- Do not administer simultaneously with antacids (aluminium or magnesium hydroxide, etc.), iron, calcium and zinc salts (effect of dolutegravir decreased). These drugs must be taken at least 6 hours before or 2 hours after dolutegravir.
- May cause:
- insomnia, depression, anxiety, dizziness, headache, skin rash, gastrointestinal disturbances (nausea, vomiting, diarrhoea, etc.);
- rarely: hepatotoxicity, hypersensitivity reactions.
- In patients taking metformin, reduce dosage to 1 g daily (effect of metformin increased).
- In patients taking enzyme-inducing drugs (rifampicin, carbamazepine, phenytoin, phenobarbital, efavirenz, nevirapine), increase dosage of dolutegravir to 50 mg 2 times daily (effect of dolutegravir decreased).
- In women of childbearing age, use hormonal or non-hormonal contraception.
- <u>Pregnancy</u>: **CONTRA-INDICATED** during the first 8 weeks: prefer efavirenz during this period.

#### Remarks

- <u>Storage</u>: below 25 °C - **∅** - <del>Ť</del>

# **DOXYCYCLINE** oral

Prescription under medical supervision

#### Therapeutic action

- Cycline antibacterial

#### **Indications**

- Cholera, louse-borne and tick-borne relapsing fevers, epidemic typhus and other rickettsioses, bubonic plague, brucellosis, leptospirosis, lymphogranuloma venereum
- Lymphatic filariasis, alternative to ivermectin in onchocerciasis
- Alternative to first-line treatments of treponematosis, atypical pneumonia (*Mycoplasma pneumoniae, Chlamydophila pneumoniae*), cervicitis and urethritis due to *Chlamydia trachomatis* (in combination with a treatment for gonorrhoea), donovanosis, syphilis, uncomplicated cutaneous anthrax (if antibiotic therapy is indicated)

## Forms and strengths

- 100 mg tablet

#### **Dosage**

Louse-borne relapsing fever, epidemic typhus, cholera
 Child under 8 years: 4 mg/kg (max. 100 mg) single dose
 Child 8 years and over: 100 mg single dose
 Adult: 200 mg (300 mg in cholera) single dose

- Other indications

Child 8 years and over: 50 mg 2 times daily or 100 mg once daily (up to 100 mg 2 times daily in severe infections); 1 to 2 mg/kg 2 times daily (max. 100 mg per dose) in brucellosis and leptospirosis Adult: 100 mg 2 times daily or 200 mg once daily

#### **Duration**

– Tick-borne relapsing fever, leptospirosis, rickettsiosis, cervicitis and urethritis due to C. trachomatis: 7 days; cutaneous anthrax: 7-10 days; bubonic plague: 10 days; atypical pneumonia: 10-14 days; early syphilis, bejel, pinta, lymphogranuloma: 14 days; filariasis: minimum 4 weeks; late latent syphilis: 30 days; brucellosis: 6 weeks; donovanosis: until complete healing of lesions.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to cyclines and to children under 8 years (may damage teeth) except for single dose treatment.
- Administer with caution to patients with hepatic or renal impairment.
- May cause: gastrointestinal disturbances, allergic reactions, photosensitivity (protect exposed skin from sun exposure), oesophageal ulcerations (take tablets during meals with a glass of water in an upright position and at least 1 hour before going to bed).
- Do not give simultaneously with ferrous salts, zinc sulfate, calcium carbonate, antiacids (aluminium/magnesium hydroxide, etc.): administer 2 hours apart.
- Monitor combination with hepatic enzyme inducers: rifampicin, phenobarbital, phenytoin, carbamazepine, etc. (reduction of the doxycycline efficacy).
- <u>Pregnancy</u>: **CONTRA-INDICATED** during the 2<sup>nd</sup> and 3<sup>rd</sup> trimester (except for single dose treatment)
- <u>Breast-feeding</u>: avoid (risk of infant teeth discoloration)

#### Remarks

- <u>Storage</u>: below 25 °C - **∅** - <del>Ť</del>

# **EFAVIRENZ = EFV = EFZ oral**

Prescription under medical supervision

## Therapeutic action

- Antiretroviral, HIV-1 non nucleoside reverse transcriptase inhibitor

#### **Indications**

- HIV-1 infection, in combination with other antiretroviral drugs

## Forms and strengths

- 200 mg breakable tablet, 200 mg capsule and 200 mg and 600 mg tablets

## **Dosage**

The dose is given once daily at bedtime.
Child 3 years and over and adult:

Weight	Dose	Tablets or capsules
10 to < 14 kg	200 mg	1 tablet 200 mg or 1 capsule 200 mg
14 to < 25 kg	300 mg	1 tablet 200 mg + ½ tablet 200 mg
25 to < 40 kg	400 mg	2 tablets 200 mg or 2 capsules 200 mg
≥ 40 kg	600 mg	1 tablet 600 mg

#### **Duration**

– Depending on the efficacy and tolerance of efavirenz.

- Do not administer to children under 3 years.
- Avoid administration in patients with severe hepatic impairment.
- Avoid combination with drugs that prolong QT interval: amiodarone, chloroquine, co-artemether, fluconazole, haloperidol, hydroxyzine, mefloquine, moxifloxacin, ondansetron, pentamidine, quinine, etc.
- Administer with caution to patients with psychiatric disorders (or history of) or epilepsy.
- Do not combine with amodiaquine.
- May cause:
- neurological disorders (dizziness, insomnia, drowsiness, abnormal dreaming, impaired concentration, seizures):
- psychiatric disorders (severe depression, suicidal ideation);
- raised liver enzymes (ALAT);
- skin reactions, possibly severe (Stevens-Johnson syndrome).
- Efavirenz reduces the efficacy of oral contraceptives: use a non-hormonal contraception or injectable

medroxyprogesterone or an oral contraceptive containing 50 micrograms ethinylestradiol per tablet.

- Pregnancy: no contra-indication

#### Remarks

- Storage: below 25 °C

# **ENALAPRIL** oral

Prescription under medical supervision

## Therapeutic action

- Angiotensin converting enzyme inhibitor (ACE)

#### **Indications**

- Hypertension
- Chronic heart failure

# Forms and strengths

- 5 mg and 20 mg tablets

# **Dosage**

- Hypertension
- Adult: start with 5 mg once daily, then increase the dose gradually every 1 to 2 weeks, according to blood pressure, up to 10 to 20 mg once daily (max. 40 mg daily)
- In elderly patients, patients taking a diuretic or patients with renal impairment: start with 2.5 mg once daily then adapt dose according to renal function.
- Chronic heart failure

Adult:

Week 1: 2.5 mg once daily for 3 days then 5 mg once daily

Week 2: 10 mg once daily for 3 days then 20 mg once daily

The usual dose is 10 to 20 mg once daily or 5 to 10 mg 2 times daily depending on tolerance (max. 40 mg daily).

Reduce dosage in patients with renal impairment.

#### **Duration**

- According to clinical response

- Do not administer to patients with history of enalapril-related angioedema.
- May cause:
- hypotension, dizziness, headache, gastrointestinal disturbances, dry cough, renal impairment, hyperkalaemia, hyponatraemia;
- allergic reactions, angioedema; hypoglycaemia, haematological disorders.

- Avoid or monitor combination with: potassium-sparing diuretics and/or potassium chloride (risk of hyperkalaemia); non steroidal anti-inflammatory drugs and/or diuretics (risk of renal impairment).
- Monitor combination with:
- other antihypertensive drugs (risk of hypotension);
- drugs that provoke hypotension (e.g. haloperidol, amitriptyline);
- oral antidiabetics and insulin (risk of hypoglycaemia).
- <u>Pregnancy</u>: **CONTRA-INDICATED**
- Breast-feeding: no contra-indication at recommended doses

– <u>Storage</u>: below 25 °C - 🌽

# **ERGOCALCIFEROL = VITAMIN D2 oral**

See COLECALCIFEROL = VITAMIN D3 oral(see page 52)

# **ERYTHROMYCIN** oral

Prescription under medical supervision

## Therapeutic action

- Macrolide antibacterial

#### **Indications**

- Neonatal conjonctivitis due to Chlamydia trachomatis
- Alternative to first-line antibacterials in the treatment of:
- Borreliosis (louse-borne and tick-borne relapsing fevers), leptospirosis
- Acute otitis media, tonsillitis and sinusitis; pertussis, pneumonia due to *Mycoplasma pneumoniae* and *Chlamydophila pneumoniae*
- Furuncle, leg ulcer
- Cervicitis and urethritis due to *Chlamydia trachomatis* (in combination with a treatment for gonorrhoea), donovanosis, chancroid, lymphogranuloma venereum, syphilis
- Completion treatment following parenteral therapy with erythromycin

#### Forms and strengths

- 250 mg and 500 mg tablets
- 125 mg/5 ml powder for oral suspension, to be reconstituted with filtered water

#### **Dosage**

Neonatal conjonctivitis due to C. trachomatis
 Neonate: 12.5 mg/kg 4 times daily

- Louse-borne relapsing fever

Child under 5 years: 250 mg single dose

Child 5 years and over and adult: 500 mg single dose

- Other indications

Child: 30 to 50 mg/kg daily

Age	Weight	125 mg/5 ml susp.	250 mg tablet	500 mg tablet
1 to < 2 months	4 to < 5 kg	½ tsp x 2	1/4 tab x 2	-
2 to < 12 months	5 to < 10 kg	1 tsp x 2	½ tab x 2	1/4 tab x 2
1 to < 3 years	10 to < 15 kg	2 tsp x 2	1 tab x 2	½ tab x 2
3 to < 8 years	15 to < 25 kg	2 tsp x 3	1 tab x 3	½ tab x 3
8 to < 11 years	25 to < 35 kg	-	2 tab x 2	1 tab x 2
11 to < 13 years	35 to < 45 kg	-	2 tab x 3	1 tab x 3

Adult: 1 g 2 to 3 times daily

#### **Duration**

– Tick-borne relapsing fever, leptospirosis, pertussis, cervicitis and urethritis, chancroid, leg ulcer: 7 days; sinusitis: 7 to 10 days; tonsillitis, otitis: 10 days; atypical pneumonia: 10 to 14 days; early syphilis, lymphogranuloma venereum, donovanosis, conjunctivitis due to C. trachomatis: 14 days; late latent syphilis: 30 days.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to erythromycin or another macrolide.
- Administer with caution to patients with renal impairment (max. 1.5 g daily for adult with severe renal impairment) or hepatic impairment.
- May cause: gastrointestinal disturbances, reversible hearing disorders, heart rhythm disorders (QT prolongation); allergic reactions sometimes severe. In the event of allergic reaction, stop treatment immediately.
- Avoid combination with drugs that prolong the QT interval (amiodarone, chloroquine, co-artemether, fluconazole, haloperidol, mefloquine, moxifloxacin, ondansetron, pentamidine, quinine, etc.).
- Administer with caution and monitor use in patients taking carbamazepine or digoxin (increased their plasma levels).
- Avoid use in neonates less than 2 weeks (risk of pyloric stenosis).
- <u>Pregnancy and breast-feeding</u>: no contra-indication

#### Remarks

- Take tablets preferably one hour before or 2 hours after a meal.
- <u>Storage</u>: below 25 °C 🖊 🖣

For the oral suspension (powder or reconstituted suspension): follow manufacturer's instructions.

# **ETHAMBUTOL** = **E** oral

Prescription under medical supervision

## Therapeutic action

- First line antituberculous antibacterial (bacteriostatic activity)

#### **Indications**

- Treatment of tuberculosis, in combination with other antituberculous antibacterials

## Forms and strengths

- 100 mg and 400 mg tablets

#### **Dosage**

- Child under 30 kg: 20 mg/kg (15 to 25 mg/kg daily) once daily
- Child over 30 kg and adult: 15 mg/kg (15 to 25 mg/kg daily) once daily
- Maximum dose: 1200 mg daily

#### **Duration**

- According to protocol

## Contra-indications, adverse effects, precautions

- Do not administer to patients with severe renal impairment or pre-existing optic neuritis (e.g. diabetic retinopathy).
- Reduce the dose in patients with renal impairment (15 to 25 mg/kg 3 times weekly).
- May cause: retrobulbar optic neuritis. Patients should be warned that they must immediately stop treatment and seek medical attention in the event of visual disturbances such as blurred vision, reduced visual acuity, blind spot (scotoma), green-red colour blindness. Visual alterations are usually reversible a few weeks after stopping ethambutol.
- The dosage must be carefully adjusted to the body weight (adverse effects are dose-dependant), especially for children under 5 years, as it is more difficult to detect visual alterations at this age.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- For patients sensitive to first-line antituberculous treatment, ethambutol is given as part of a fixed dose combination (isoniazid+rifampicin+pyrazinamide+ethambutol or isoniazid+ethambutol).
- Storage: below 25 °C 

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# ETHINYLESTRADIOL/LEVONORGESTREL oral

Prescription under medical supervision

## Therapeutic action

- Combined hormonal contraceptive, oestrogen-progestogen

#### **Indications**

- Oral contraception

## Forms and strengths

– 28-day pack: 21 active tablets of 0.03 mg (30 micrograms) ethinylestradiol + 0.15 mg (150 micrograms) levonorgestrel and 7 inactive tablets (ferrous salts)

#### **Dosage**

- One tablet daily, to be taken preferably at the same time each day, on a continuous basis, including during menstruation. Explain to the woman which are the active and inactive tablets. Careful not to start with inactive tablets.
- Contraception may be started at any moment of the cycle if it is reasonably certain the woman is not pregnant, including when switching from another form of contraception. Contraception will be effective as of the 8<sup>th</sup> tablet.

Use condoms for the first 7 days of the pack if the tablets are started:

- more than 5 days after the start of menstruation;
- more than 28 days postpartum if not breastfeeding;
- more than 7 days after an abortion.
- If one or two active tablets are missed, take one tablet as soon as possible and then continue treatment as usual. 2 tablets can be taken at the same time: the missed tablet and the daily tablet.
- If 3 or more successive active tablets are missed, contraceptive effectiveness is compromised. Take one tablet as soon as possible, then continue treatment as usual and use condoms for the next 7 days.
- if the tablets are missed during the 1<sup>st</sup> week of a pack (1<sup>st</sup> to 7<sup>th</sup> tablet) or if the woman has had intercourse in the 5 days before forgetting the tablets, use emergency contraception.
- if the tablets are missed during the 3<sup>rd</sup> week of the pack (15<sup>th</sup> to 21<sup>st</sup> tablet), finish all the active tablets and start a new pack the next day, without taking the inactive tablets. If it is not possible to start a new pack immediately, use condoms for the next 7 days.

#### **Duration**

– If there are no adverse effects, as long as this method of contraception is desired.

#### Contra-indications, adverse effects, precautions

– Do not administer to women with breast cancer, hypertension, uncontrolled or complicated diabetes, history of thromboembolic disorders, coronary insufficiency, valvular disease, stroke, severe or recent liver disease, unexplained vaginal bleeding, migraine with neurological signs, renal impairment, hyperlipidaemia, to women smokers over age 35.

- May cause: reduced menstrual flow, nausea, weight gain, breast tenderness, mood changes, acne and headache. Other rare and severe adverse effects require discontinuation of treatment: hypertension, cardiovascular and thromboembolic disorders, jaundice, migraine, visual disturbances.
- -- Enzyme-inducing drugs (rifampicin, rifabutine, efavirenz, nevirapine, lopinavir, ritonavir, phenobarbital, phenytoin, carbamazepine, griseofulvin, etc.) reduce the effectiveness of the contraceptive.
- Clinical examinations must be carried out before (blood pressure, breasts) and during treatment (blood pressure).
- <u>Pregnancy</u>: **CONTRA-INDICATED**
- <u>Breast-feeding</u>: **CONTRA-INDICATED** before 6 weeks postpartum; not recommended between 6 weeks and 6 months (except if it is the only available or acceptable contraceptive method); no contra-indication after 6 months.

- Oestrogen-progestogens are easier to take that progestogen-only tablets in that they do not requiring taking the tablet at an exact time of day. Taking ethinylestradiol/levonorgestrel at the same time every day helps avoid forgetting tablets.
- Also comes in packs with 21 active tablets of ethinylestradiol/levonorgestrel that require 7 days of interruption between two packs. 28-day packs help improve compliance.
- Storage: below 25 °C V

# **FERROUS** salts

# Therapeutic action

- Antianaemia drug

#### **Indications**

- Prevention of iron-deficiency
- Treatment of iron-deficiency anaemia

# Forms and strengths

- 140 mg/5 ml syrup of ferrous fumarate containing approximately 45 mg/5 ml of elemental iron
- 200 mg ferrous fumarate or sulfate tablet containing approximately 65 mg of elemental iron

# Dosage

(expressed as elemental iron)

Prevention of iron-deficiency
 Neonate: 4.5 mg once daily
 Child 1 month to < 12 years: 1 to 2 mg/kg once daily (max. 65 mg daily)</li>
 Child ≥ 12 years and adult: 65 mg once daily

Treatment of iron-deficiency anaemia
 Neonate: 1 to 2 mg/kg 2 times daily

Child 1 month to < 6 years: 1.5 to 3 mg/kg 2 times daily

Child 6 to < 12 years: 65 mg 2 times daily

Child ≥ 12 years and adult: 65 mg 2 to 3 times daily

Age	Weight	Prevention		Treatment	
		45 mg/5 ml syrup	65 mg tablet	45 mg/5 ml syrup	65 mg tablet
< 1 month	< 4 kg	0.5 ml	-	0.5 ml x 2	-
1 month to < 1 year	4 to < 10 kg	1 ml	-	1.5 ml x 2	-
1 to < 6 years	10 to < 20 kg	2.5 ml	-	2.5 ml x 2	-
6 to < 12 years	20 to < 40 kg	5 ml	-	_	1 tab x 2
≥ 12 years and adult	≥ 40 kg	-	1 tab	_	1 tab x 2 or 3

#### **Duration**

- Prevention: during risk period (pregnancy, malnutrition)
- Treatment: 3 months

# Contra-indications, adverse effects, precautions

- Do not administer to patients with other forms of anaemia.
- May cause: abdominal pain, nausea, vomiting, diarrhoea or constipation, black stools.
- Do not exceed recommended doses in children (risk of overdose). 20 mg/kg of elemental iron (60 mg/kg of ferrous fumarate or sulfate) is considered toxic.
- Do not give simultaneously with doxycycline, ciprofloxacin,
- dolutegravir, antacids (aluminium hydroxide or magnesium, etc.), levodopa or zinc sulfate (reduced absorption of both drugs). Administer each drug at least 2 hours apart.
- Adminstration in combination with ascorbic acid (vitamin C) increases iron absorption.
- Rince mouth or drink water after administration of syrup (risk of tooth staining).
- Pregnancy and breast-feeding: no contra-indication

#### Remarks

- To reduce gastrointestinal disturbances, take during meals and gradually increase dosage.
- For the prevention of iron-deficiency during pregnancy, preferably use tablets containing both ferrous salts and folic acid.
- Storage: below 25 °C //

# FERROUS salts/FOLIC acid oral

#### **Indications**

- Prevention of iron and folic acid deficiency, mainly during pregnancy
- Treatment of iron-deficiency anaemia

## Forms and strengths

– Tablet of 185 or 200 mg ferrous fumurate or sulfate (60 or 65 mg of elemental iron) + 400 micrograms folic acid (vitamin  $B_9$ )

## **Dosage**

- See adult dosage of ferrous salts

#### Remarks

- This fixed-dose combination is not effective for the treatment of folic acid deficiency because of its low dose.
- Storage: below 25 °C 🖊

# **FLUCONAZOLE** oral

Prescription under medical supervision

# Therapeutic action

- Antifungal

#### **Indications**

- Oesophageal candidiasis
- Moderate to severe oropharyngeal candidiasis
- Secondary prophylaxis of recurrent candidiasis in immunocompromised patients
- Cryptococcocal meningitis, after treatment with amphotericin B + flucytosine or in combination with amphotericin B or flucytosine
- Secondary prophylaxis of cryptococcocal infections

# Forms and strengths

- 50 mg, 100 mg and 200 mg capsules or tablets
- 50 mg/5 ml oral solution

# **Dosage and duration**

Oesophageal candidiasis, oropharyngeal candidiasis, secondary prophylaxis of candidiasis
 Child over 1 week: 3 to 6 mg/kg once daily

Adult: 50 to 200 mg once daily

These doses may be increased up to 400 mg daily if necessary. The treatment lasts 14 to 21 days for oesophageal candidiasis; 7 to 14 days for oropharyngeal candidiasis; as long as required for secondary prophylaxis.

- Cryptococcocal meningitis

After treatment with amphotericin B + flucytosine	Child > 1 week	12 mg/kg once daily (max. 800 mg daily) for 1 week then 6 to 12 mg/kg once daily for 8 weeks (max. 800 mg daily)
	Adult	1200 mg once daily for 1 week then 800 mg once daily for 8 weeks
or		

In combination with amphotericin B or flucytosine	Child > 1 week	12 mg/kg once daily (max. 800 mg daily) for 2 weeks (with amphotericin B or flucytosine) then 6 to 12 mg/kg once daily for 8 weeks (max. 800 mg daily)
, , , , , , , , , , , , , , , , , , , ,	Adult	1200 mg once daily for 2 weeks (with amphotericin B or flucytosine) then 800 mg once daily for 8 weeks

- Secondary prophylaxis of cryptococcocal infections

Child: 6 mg/kg once daily (max. 200 mg daily), as long as required

Adult: 200 mg once daily, as long as required

# Contra-indications, adverse effects, precautions

- Administer with caution to patients with hepatic or renal impairment, cardiac disorders (bradycardia, heart rhythm disorders, etc.). Reduce the dose by half in patients with renal impairment.
- May cause: gastrointestinal disturbances, headache, skin reactions sometimes severe, anaphylactic reactions; severe hepatic disorders, haematologic (leukopenia, thrombocytopenia) and cardiac disorders (QT-prolongation). Stop treatment in the event of anaphylactic reaction, hepatic disorders or severe skin reaction.
- In the event of prolonged treatment, monitor hepatic function.
- Do not administer simultaneously with rifampicin, administer 12 hours apart (rifampicin in the morning, fluconazole in the evening).
- Avoid or monitor combination with:
- drugs that prolong the QT interval (amiodarone, chloroquine, erythromycin, haloperidol, mefloquine, pentamidine, quinine);
- warfarin, carbamazepine, phenytoin, rifabutin, benzodiazepines, calcium-channel blockers, certain antiretrovirals (e.g. nevirapine, saquinavir, zidovudine): increased blood concentration of these drugs.
- <u>Pregnancy and breast-feeding</u>: to be used only in severe or life-threatening infections, particularly during the first trimester of pregnancy (risk of foetal malformations).

#### Remarks

- For the treatment of histoplasmosis, fluconazole is less effective than itraconazole. It should be used (child: 10 to 12 mg/kg once daily, max. 400 mg daily; adult: 400 mg on D1 then 200 to 400 mg once daily, for 6 to 12 weeks) only in patients unable to tolerate itraconazole.
- For the treatment of dermatophytosis of the scalp, fluconazole may be used as a secondary option (child: 6 mg/kg once daily, max. 200 mg daily; adult: 200 mg once daily, for 2 to 4 weeks) but itraconazole is preferred for this indication.
- For the treatment of genital candidiasis (vulvovaginitis, balanitis), fluconazole is only used if local treatment fails: 150 mg single dose in adults.
- Storage: below 25 °C W

Once reconstituted, oral solution keeps for 2 weeks.

# **FLUCYTOSINE** oral

Prescription under medical supervision

# Therapeutic action

- Antifungal

#### **Indications**

- Cryptococcocal meningitis (induction phase), in combination with amphotericin B or fluconazole

# Forms and strengths

– 500 mg capsule Also comes in 250 mg capsule and 500 mg tablet.

## **Dosage**

- Child over 1 week and adult: 25 mg/kg 4 times daily

#### **Duration**

- One week if in combination with amphotericin B; 2 weeks if in combination with fluconazole

# Contra-indications, adverse effects, precautions

- Administer with caution and monitor use in patients > 60 years or with renal impairment or haematological disorders.
- Reduce the dose by half (25 mg/kg 2 times daily) in patients with renal impairment.
- May cause: gastrointestinal disturbances, haematological disorders (leukopenia, thrombocytopenia, less frequently, agranulocytosis), increase in transaminase levels, allergic reactions sometimes severe; sometimes, confusion and hallucinations.
- Monitor blood count and liver and renal function until the end of treatment.
- <u>Pregnancy and breast-feeding</u>: flucytosine is generally not recommended. It is teratogenic in animals and its safety in pregnant or lactating women has not been established. However, taking into account the severity of the disease, the potential benefit of treatment for the mother and in the absence of a safer alternative, it may be used despite the potential risks for the child.

## Remarks

- For children, tablets may be crushed.
- Storage: below 25 °C 🖊

# **FLUOXETINE** oral

Prescription under medical supervision



# Therapeutic action

- Antidepressant, selective serotonin re-uptake inhibitor (SSRI)

#### **Indications**

- Major depression

# Forms and strengths

- 20 mg capsule

## **Dosage**

– Adult: 20 mg once daily in the morning. In case of insufficient response after 4 weeks, increase to 40 mg daily max.

#### **Duration**

– 9 months minimum. Treatment should be discontinued gradually (20 mg on alternate days for 4 weeks). If signs of relapse or withdrawal occur, increase the dose.

# Contra-indications, adverse effects, precautions

- Administer with caution and monitor use in patients with epilepsy, diabetes, hepatic impairment or severe renal impairment (administer 20 mg on alternate days); history of: gastrointestinal bleeding, bipolar disorders, suicidal ideation or closed-angle glaucoma.
- May cause:
- gastrointestinal disturbances, drowsiness, fatigue, headache, dizziness, seizures, sexual dysfunction, blurred vision, hyponatraemia especially in elderly patients;
- mental disorders: anxiety, insomnia, agitation, aggressive behaviour, suicidal ideation;
- withdrawal symptoms very frequent if discontinued abruptly: dizziness, paraesthesia, nightmares, anxiety, tremors and headaches.
- Avoid combination with:
- alcohol (risk of drowsiness); aspirin and NSAIDs (risk of bleeding);
- serotonergic drugs: other selective serotonin re-uptake inhibitors, tricyclic antidepressants (amitriptyline, clomipramine, imipramine), ondansetron, tramadol, etc. (risk of serotonin syndrome).
- Monitor combination with: carbamazepine, phenytoin, risperidone (increased plasma concentrations), drugs which lower the seizure threshold (antipsychotics, mefloquine, etc.).
- <u>Pregnancy</u>: re-evaluate whether the treatment is still necessary; if it is continued, observe the neonate (risk of agitation, tremors, hypotony, respiratory difficulties, sleeping disorders, etc.) if the mother was under treatment in the 3<sup>rd</sup> trimester.
- Breast-feeding: avoid. Prefer paroxetine.

#### Remarks

- Do not open the capsules.
- It is necessary to wait at least 2 to 3 weeks before assessing the antidepressant effect. This must be explained to the patient.
- <u>Storage</u>: below 25 °C **//** <del>↑</del>

# **FOLIC** acid = VITAMIN B9 oral

Prescription under medical supervision

## Therapeutic action

- Antianaemia drug

#### **Indications**

– Treatment of folate-deficient megaloblastic anaemias: severe malnutrition, repeated attacks of malaria, intestinal parasitosis, etc.

# Forms and strengths

- 5 mg tablet

# **Dosage and duration**

- Child under 1 year: 0.5 mg/kg once daily for 4 months
- Child over 1 year and adult: 5 mg once daily for 4 months; 15 mg once daily in malabsorption states

# Contra-indications, adverse effects, precautions

- Do not combine with sulfadiazine-pyrimethamine in patients with toxoplasmosis nor sulfadoxine-pyrimethamine in patients with malaria: folic acid reduces the efficacy of these treatments.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Folic acid must not be used for the treatment of anaemia due to antifolates (pyrimethamine, trimethoprim or methotrexate). Use folinic acid.
- Folic acid is also used for primary and secondary prophylaxis of neural tube defects and for prophylaxis of acute anaemia in patients with sickle-cell anaemia.
- Storage: below 25 °C 🖊

# FOSFOMYCIN TROMETAMOL oral

Prescription under medical supervision

# Therapeutic action

- Phosphonic acid derivative antibacterial

#### **Indications**

- Acute uncomplicated cystitis in women, without fever nor flank pain
- Asymptomatic bacteriuria in pregnant women

# Forms and strengths

- Granules for oral solution in 3 g sachet, to be dissolved in filtered water

# Dosage and duration

- 3 g single dose

# Contra-indications, adverse effects, precautions

- Do not administer to patients with severe renal impairment, allergy to fosfomycin.
- May cause: gastrointestinal disturbances, skin rash; rarely, allergic reactions.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- In the treatment of cystitis, symptoms should improve within 3 days of treatment. If not, the patient should consult again. Treatment failure may be due to the presence of naturally fosfomycin-resistant organisms (*Staphylococcus saprophyticus*).
- Take between meals or at bedtime (food decreases absorption).
- Fosfomycin is not included in the WHO list of essential medicines.
- Storage: below 25 °C 7 7

# **FUROSEMIDE** oral

Prescription under medical supervision

# Therapeutic action

- Loop diuretic

## **Indications**

- Oedema associated with renal, hepatic or congestive heart failure

# Forms and strengths

- 20 mg and 40 mg tablets

## **Dosage**

- Adult: start with 20 mg once daily. Increase, if necessary, according to clinical response up to 80 mg once daily or 2 times daily (max. 160 mg daily). Once oedema decrease, reduce to 20 to 40 mg once daily.

#### **Duration**

- According to clinical response

- Do not administer to patients with dehydration, severe hypokalaemia and hyponatraemia.
- May cause:
- dehydration, hypotension, hypokalaemia, hyponatraemia, hyperuricemia;

- renal impairment, deafness, photosensitivity.
- Avoid or monitor combination with NSAIDs, ACE inhibitors (risk of renal impairment); ototoxic drugs (e.g. aminoglycosides, quinine); lithium (increased plasma concentrations of lithium).
- Monitor combination with:
- drugs that provoke hypotension (e.g. haloperidol, amitriptyline) and antihypertensive drugs (risk of hypotension);
- potassium-depleting drugs (e.g. corticosteriods, laxatives, amphotericin B), sodium-depleting drugs (e.g. SSRI, carbamazepine);
- oral antidiabetics and insulin (risk of hyperglycaemia).
- <u>Pregnancy</u>: administer only if clearly needed
- Breast-feeding: **CONTRA-INDICATED** (excreted in milk and reduces milk production)

- Preferably take in the morning.
- A potassium-rich diet (dates, bananas, mangos, oranges, tomatoes, etc.) is recommended during treatment. If potassium level is < 3.5 mmol/litre, administer a sustained-release potassium supplement.
- Diuretics are not indicated in the treatment of nutritional oedema or oedema associated with preeclampsia.
- <u>Storage</u>: below 25°C 🖊

# **GLIBENCLAMIDE** oral

Prescription under medical supervision

# Therapeutic action

- Sulfonylurea antidiabetic

#### **Indications**

- Second-line treatment of type 2 diabetes, in patients under 60 years:
- as monotherapy, when metformin is not tolerated or contra-indicated
- in combination with metformin, when glycaemic control is inadequate with metformin alone

# Forms and strengths

- 5 mg scored tablet

# Dosage and duration

– Adult:

Week 1: 2.5 mg once daily in the morning

Week 2: 5 mg once daily in the morning

Increase if necessary in increments of 2.5 mg weekly, according to blood glucose levels.

The usual dose is 5 mg 2 times daily (max. 15 mg daily).

# Contra-indications, adverse effects, precautions

- Do not administer in the event of:
- allergy to sulfonamides;
- type 1 diabetes, juvenile diabetes, ketoacidosis;
- severe renal or hepatic impairment.
- May cause: hypoglycaemia, especially in patients over 60 years; gastrointestinal disturbances, weight gain; rarely, allergic reactions.
- Monitor combination with:
- diuretics, angiotensin-converting enzyme inhibitors, non-steroidal anti-inflammatory drugs, azole antifungals (fluconazole, miconazole), ciprofloxacin, erythromycin, co-trimoxazole (enhanced hypoglycaemic effect);
- rifampicin (decreased hypoglycaemic effect);
- drugs increasing blood glucose levels: corticosteroids, hydrochlorothiazide, salbutamol, chlorpromazine.
- Avoid combination with alcohol (antabuse reaction and risk of hypoglycaemia).
- <u>Pregnancy</u>: avoid. Insulin is the drug of choice for the treatment of type 2 diabetes in pregnant women (improved glycaemic control; reduced risk of foetal anomalies and neonatal complications).
- Breast-feeding: CONTRA-INDICATED

#### Remarks

- Take with meals.
- For doses greater than 5 mg/day, divide the daily dose into 2 doses.
- Storage: below 25 °C 🌽

# **GLICLAZIDE** oral

Prescription under medical supervision

# Therapeutic action

- Sulfonylurea antidiabetic

#### **Indications**

- Second-line treatment of type 2 diabetes, in patients over 60 years:
- as monotherapy, when metformin is not tolerated or contra-indicated
- in combination with metformin, when glycaemic control is inadequate with metformin alone

## Forms and strengths

- 80 mg scored tablet

# **Dosage and duration**

- Adult:

Weeks 1 and 2: 40 mg once daily in the morning

Increase if necessary in increments of 40 mg every 2 weeks, according to blood glucose levels (Weeks 3

and 4: 80 mg once daily in the morning). The usual dose is 80 to 160 mg daily (max. 240 mg daily).

## Contra-indications, adverse effects, precautions

- Do not administer in the event of:
- allergy to sulfonamides;
- type 1 diabetes, juvenile diabetes, ketoacidosis;
- severe renal or hepatic impairment.
- May cause: hypoglycaemia, gastrointestinal disturbances, weight gain; rarely, allergic reactions.
- Monitor combination with:
- diuretics, angiotensin-converting enzyme inhibitors, non-steroidal anti-inflammatories, azole antifungals (fluconazole, miconazole), ciprofloxacin, erythromycin, co-trimoxazole (enhanced hypoglycaemic effect);
- rifampicin (decreased hypoglycaemic effect);
- drugs increasing blood glucose levels: corticosteroids, hydrochlorothiazide, salbutamol, chlorpromazine.
- Avoid combination with alcohol (risk of hypoglycaemia).
- <u>Pregnancy</u>: avoid. Insulin is the drug of choice for the treatment of type 2 diabetes in pregnant women (improved glycaemic control; reduced risk of foetal anomalies and neonatal complications).
- Breast-feeding: CONTRA-INDICATED

#### Remarks

- Take with meals (reduced risk of gastrointestinal disturbances).
- For doses greater than 80 mg daily, divide the daily dose into 2 doses.
- Also comes in 30 and 60 mg modified release tablets.
- Storage: below 25 °C V

# **GLYCERYL TRINITRATE = NITROGLYCERIN =** TRINITRIN oral

Prescription under medical supervision

## Therapeutic action

- Vasodilator, antianginal

#### **Indications**

- Short-term prophylaxis and treatment of angina

# Forms and strengths

- 0.5 mg sublingual tablet

## Dosage

- Short-term prophylaxis of acute angina

Adult: 0.5 to 1 mg taken 5 to 10 minutes before a precipitating event (physical exertion, stress, etc.)

- Treatment of acute angina

Adult: 0.5 to 1 mg, to be repeated 1 to 3 times at 3-4 minute intervals

Do not exceed 3 mg daily.

#### **Duration**

- According to clinical response

# Contra-indications, adverse effects, precautions

- Do not administer to patients with obstructive cardiomyopathy, hypotension, shock.
- May cause: orthostatic hypotension (especially in elderly patients), headache, nausea, flushing of the face, haemolytic anaemia in patients with G6PD deficiency, severe hypotension with risk of circulatory collapse in the event of overdose.
- Use the lowest effective dose in patients taking another nitrate derivative, a vasodilator or an antihypertensive drug and in elderly patients.
- Combination with antihypertensive drugs, diuretics, vasodilators and alcohol enhances hypotensive effects.
- Do not combine with sildenafil (risk of acute coronary syndrome).
- Pregnancy: not recommended (safety is not established)
- <u>Breast-feeding</u>: not recommended (safety is not established)

#### **Remarks**

- Tablet must be crunched first, then slowly dissolved under the tongue.
- Antianginal effect appears within less than 5 minutes and persists for less than 1 hour.
- Sustained-release formulations are used for the long-term management of angina and the treatment of heart failure.
- <u>Storage</u>: below 25 °C, preferably in airtight glass container  $ilde{Z}$   $ilde{ au}$

# **GRISEOFULVIN** oral

Prescription under medical supervision

# Therapeutic action

- Antifungal

#### **Indications**

- Dermatophyte infections of the scalp (scalp ringworm)
- Dermatophyte infections of the skin and folds, in the event of extended lesions or if the topical treatment has failed

## Forms and strengths

- 125 mg and 500 mg tablets

## **Dosage**

- Child 1 to 12 years: 10 to 20 mg/kg once daily (max. 500 mg daily)
- Child 12 years and over and adult: 500 mg once daily; 1 g once daily in severe infections

Age	Weight	125 mg tablet	500 mg tablet
1 to < 2 years	10 to < 13 kg	1 tab	¼ tab
2 to < 7 years	13 to < 24 kg	2 tab	½ tab
7 to < 12 years	24 to < 35 kg	4 tab	1 tab
≥ 12 years and adult	≥ 35 kg	4 to 8 tab	1 to 2 tab

#### **Duration**

- Scalp: 6 weeks minimum
- Skin and folds: 4 to 6 weeks

# Contra-indications, adverse effects, precautions

- Do not administer to patients with hepatic impairment, lupus erythematous, porphyria (may trigger attacks of acute porphyria).
- May cause: gastrointestinal disturbances, headache, skin reactions (eruption, urticaria, etc.); photosensitivity (protect exposed skin from sun exposure).
- In women, use a non-hormonal contraception or injectable medroxyprogesterone during treatment and up to one month after the end of treatment.
- Monitor patients taking warfarin (anticoagulant effect decreased).
- Avoid alcohol during treatment (antabuse effect).
- <u>Pregnancy and breast-feeding</u>: **CONTRA-INDICATED**. Apply a topical treatment (miconazole 2% cream or Whitfield ointment) in order to limit the lesions until it is possible to use griseofulvin.

### Remarks

- Take with meals.
- For young children, crush the tablet and mix it with a liquid.
- Storage: below 25 °C

# **HALOPERIDOL** oral

Prescription under medical supervision



# Therapeutic action

- Antipsychotic

#### **Indications**

- Acute or chronic psychosis
- Acute moderate to severe manic episode

# Forms and strengths

- 0.5 mg and 5 mg tablets
- 2 mg/ml oral solution with pipette graduated in mg

## **Dosage**

- Acute or chronic psychosis

Adult: 0.5 to 1 mg 2 times daily. Gradually increased up to 10 mg daily if necessary (max. 20 mg daily). Once the patient is stable, the maintenance dose is administered once daily at bedtime.

- Acute manic episode

Adult: 2.5 mg 2 times daily. Gradually increase up to 10 mg daily if necessary (max. 15 mg daily).

- Reduce the dose by half in elderly patients (max. 5 mg daily).
- Use the lowest effective dose, especially in the event of prolonged treatment.

#### **Duration**

– *Acute psychosis*: minimum 3 months; *chronic psychosis*: minimum one year; *manic episode*: 3 to 6 weeks. The treatment should be discontinued gradually (over 4 weeks). If signs of relapse occur, increase the dose.

- Do not administer to patients with cardiac disorders (heart failure, recent myocardial infarction, conduction disorders, bradycardia, etc.), dementia (e.g. Alzheimer's disease), Parkinson's disease and history of neuroleptic malignant syndrome.
- Administer with caution and carefully monitor use in elderly patients and patients with hypokalaemia, hyperthyroidism, renal or hepatic impairment, history of seizures.
- May cause: drowsiness, extrapyramidal symptoms, early or tardive dyskinesia, anticholinergic effects (constipation, dry mouth), hyperprolactinaemia, sexual dysfunction, QT-prolongation, ventricular arrhythmia, orthostatic hypotension; neuroleptic malignant syndrome (unexplained hyperthermia with neuromuscular disorders), rare but requiring immediate treatment discontinuation.
- In the event of extrapyramidal symptoms, combine with biperiden or trihexyphenidyl.
- Avoid combination with:
- central nervous system depressants (opioid analgesics, sedatives, H1 antihistamines, etc.);
- fluoxetine, paroxetine, sertraline, promethazine, ritonavir (increased plasma concentrations of haloperidol);
- carbamazepine, rifampicin, phenobarbital, phenytoin (decreased plasma concentrations of haloperidol);
- antihypertensive drugs (risk of hypotension); drugs that prolong the QT interval (amiodarone, chloroquine, erythromycin, fluconazole, mefloquine, pentamidine, quinine, etc.).
- Avoid alcohol during treatment.
- <u>Pregnancy</u>: re-evaluate whether the treatment is still necessary; if it is continued, monitor the neonate the first few days (risk of hypertonia, tremors, sedation).
- Breast-feeding: if absolutely necessary, do not exceed 10 mg daily.

- <u>Storage</u>: below 25 °C - 🖊 - Ť

# HYDROCHLOROTHIAZIDE oral

Prescription under medical supervision

# Therapeutic action

- Thiazide diuretic

#### **Indications**

- Hypertension
- Oedema associated with renal, hepatic or congestive heart failure

# Forms and strengths

- 12.5 mg and 25 mg tablets

## **Dosage**

- Hypertension

Adult: 12.5 to 25 mg once daily in the morning (max. 25 mg daily)

Oedema associated with renal, hepatic or congestive heart failure
 Adult: 25 mg once daily in the morning or 25 mg 2 times daily (max. 100 mg daily)

#### **Duration**

- According to clinical response

- Do not administer to patients with severe renal failure.
- Administer with caution in patients with hypokalaemia, hyponatraemia and in elderly patients.
- May cause:
- dehydration, hypotension, hypokalaemia, hyponatraemia;
- gastrointestinal disturbances, headache, dizziness, skin rash, impotence, photosensitivity.
- Avoid or monitor combination with NSAIDs (risk of renal impairment); lithium (increased plasma concentrations of lithium).
- Monitor combination with:
- drugs that provoke hypotension (e.g. haloperidol, amitriptyline) and antihypertensive drugs (risk of hypotension);
- potassium-depleting drugs (e.g. corticosteriods, laxatives, amphotericin B), sodium-depleting drugs (e.g. SSRI, carbamazepine), drugs enhancing hypercalcemic effect (e.g. calcium, ergocalciferol);
- oral antidiabetics and insulin (risk of hyperglycaemia).
- Pregnancy: CONTRA-INDICATED
- Breast-feeding: CONTRA-INDICATED

- A potassium-rich diet (dates, bananas, mangos, oranges, tomatoes, etc.) is recommended during treatment. If potassium level is < 3.5 mmol/litre, administer a sustained-released potassium supplement.
- Diuretics are not indicated in the treatment of nutritional oedema.
- Storage: below 25 °C 🌽

# **HYDROXYZINE** oral

Prescription under medical supervision



# Therapeutic action

- Sedating H-1 antihistamine

## **Indications**

- Anxiety

# Forms and strengths

– 25 mg tablet

## Dosage

- Adult: 25 to 50 mg 2 times daily (max. 100 mg daily)
- Reduce the dose by half in elderly patients.

#### **Duration**

– As short as possible; do not exceed 2 weeks.

- Do not administer to patients with closed-angle glaucoma, prostate disorders, dementia, history of QT interval prolongation.
- Do not combine with drugs that prolong the QT interval (amiodarone, co-artemether, erythromycin, fluconazole, haloperidol, mefloquine, pentamidine, quinine, etc.).
- Administer with caution (max. 50 mg daily) and monitor use in patients with hepatic impairment or severe renal impairment.
- May cause:
- drowsiness, headache, dizziness;
- anticholinergic effects (dry mouth, constipation, blurred vision, tachycardia, disorders of micturition);
- rarely: seizures, QT interval prolongation, allergic reactions.
- Administer with caution and monitor combination with:
- central nervous system depressants (opioid analgesics, sedatives, etc.);
- anticholinergic drugs (atropine, amitriptyline, chlorpromazine, promethazine, etc.).
- Avoid alcohol during treatment.
- <u>Pregnancy and breast-feeding</u>: avoid

- <u>Storage</u>: below 25 °C - 🕖 - 🖣

# HYOSCINE BUTYLBROMIDE = BUTYLSCOPOLAMINE oral

Prescription under medical supervision

# Therapeutic action

- Antispasmodic

#### **Indications**

- Spasms of the gastrointestinal tract and genitourinary tract

# Forms and strengths

- 10 mg tablet

## **Dosage**

- Adult: 10 to 20 mg, to be repeated up to 3 or 4 times daily if necessary

## **Duration**

- According to clinical response; no prolonged treatment.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with urethro-prostatic disorders, cardiac disorders, closed-angle glaucoma.
- May cause: urinary retention, dryness of the mouth, constipation, blurred vision, tachycardia.
- Administer with caution and under close supervision to patients taking other anticholinergic drugs (antidepressants, antipsychotics, H-1 antihistamines, antiparkinsonians, etc.).
- Administer with caution to patients with fever (may affect thermoregulation).
- <u>Pregnancy</u>: no contra-indication; NO PROLONGED TREATMENT
- Breast-feeding: no contra-indication; NO PROLONGED TREATMENT

#### **Remarks**

- Oral antispasmodic drugs are not included in the WHO list of essential medicines.
- Storage: below 25 °C W 🖣

# **IBUPROFEN** oral

Prescription under medical supervision

# Therapeutic action

- Analgesic, antipyretic, non-steroidal anti-inflammatory (NSAID)

#### **Indications**

- Mild to moderate pain, fever, rheumatic diseases

# Forms and strengths

- 200 mg and 400 mg enteric-coated tablets
- 100 mg/5 ml oral suspension, with pipette graduated per kg of body weight (each kg graduation corresponds to 10 mg ibuprofen)

# **Dosage**

- Pain, fever

Child over 3 months: 5 to 10 mg/kg 3 to 4 times daily (max. 30 mg/kg daily)
Child 12 years and over and adult: 200 to 400 mg 3 to 4 times daily (max. 1200 mg daily)
In post-operative period, ibuprofen should be given on a regular basis, every 8 hours, rather than "as needed".

Age	Weight	100 mg/5 ml susp.	200 mg tablet	400 mg tablet
3 months to < 6 years	5 to < 20 kg	1 pipette filled up to the graduation corresponding to the child's weight x 3	-	-
6 to < 10 years	20 to < 30 kg	1 pipette filled up to the graduation corresponding to the child's weight x 3	1 tab x 3	-
10 to < 12 years	30 to < 40 kg	-	1 tab x 4	-
≥ 12 years and adult	≥ 40 kg	_	2 tab x 3 or 1 tab x 4	1 tab x 3

<sup>-</sup> Rheumatic diseases

Child: up to 40 mg/kg daily maximum Adult: up to 3200 mg daily maximum

#### **Duration**

- According to clinical response; post-operative pain: 8 days max.

# Contra-indications, adverse effects, precautions

- Do not administer to children under 3 months, patients with allergy to NSAID, peptic ulcer, coagulation defects, haemorrhage, surgery with risk of major blood loss, severe renal or hepatic impairment, severe heart failure, severe malnutrition, uncorrected dehydration or hypovolaemia, severe infection.
- May cause: allergic reactions, epigastric pain, peptic ulcer, haemorrhage, renal impairment.
- Administer with caution to elderly or asthmatic patients.
- Do not combine with: methotrexate, anticoagulants and other NSAIDs.
- Monitor combination with diuretics and angiotensin-converting enzyme inhibitors (drink plenty of fluids to avoid renal failure).
- <u>Pregnancy</u>: avoid. **CONTRA-INDICATED** from the beginning of the 6<sup>th</sup> month. Use paracetamol.
- <u>Breast-feeding</u>: no contra-indication (short term treatment)

#### Remarks

- Take with meals. Doses must be taken at least 4 hours apart.
- Clean the graduated pipette after use. Shake the bottle before use.
- If ibuprofen alone does not provide pain relief, combine with paracetamol and/or an opioid analgesic.
- Storage: below 25 °C W 🖣

Once opened, oral suspension must be stored between 8 °C and 15 °C.

# **IODIZED OIL oral**

# Therapeutic action

- Iodine supplementation

#### **Indications**

- Prevention and treatment of severe iodine deficiency

# Forms and strengths

- 190 mg capsule of iodine

# **Dosage and duration**

- Child under 1 year: 1 capsule (190 mg) once a year
- Child from 1 to < 6 years: 2 capsules (380 mg) once a year
- Child from 6 to 15 years: 3 capsules (570 mg) once a year
- Pregnant woman or women of childbearing age: 2 capsules (380 mg) once a year

- Do not administer to patients with allergy to iodine or hyperthyrodism.
- Do not administer to patients over 45 years.
- May cause: allergic reactions, dysthyroidism.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

- For young children, open the capsule and empty the contents into the child's mouth.
- Also comes in 10 ml ampoules containing 480 mg/ml to be administered by IM injection using a glass syringe.
- <u>Storage</u>: below 25 °C **∅** <del>↑</del>

# **IPRATROPIUM** bromide nebuliser solution

Prescription under medical supervision

# Therapeutic action

- Bronchodilator, anticholinergic drug

#### **Indications**

- Acute life-threatening asthma attack, in combination with salbutamol

# Forms and strengths

– Solution for inhalation, in unit dose vial of 0.25 mg in 1 ml (0.25 mg/ml) and 0.5 mg in 2 ml (0.25 mg/ml), to be administered via a nebuliser

## **Dosage and duration**

- Child 1 month to < 12 years: 0.25 mg per nebulisation, to be repeated every 20 to 30 minutes if necessary
- Child 12 years and over and adult: 0.5 mg per nebulisation, to be repeated every 20 to 30 minutes if necessary

# Contra-indications, adverse effects, precautions

- May cause:
- throat irritation, headache, cough, vomiting;
- anticholinergic effects: dryness of the mouth, constipation, dilation of the pupils, blurred vision, urinary retention, tachycardia.
- Administer with caution to elderly patients and patients with closed-angle glaucoma, benign prostatic hyperplasia, urinary retention.
- Avoid or monitor combination with drugs known to have anticholinergic effects: tricyclic antidepressants (amitriptyline, clomipramine), H-1 antihistamines (chlorphenamine, promethazine), antiparkinsonians (biperiden), antispasmodics (atropine, hyoscine butylbromide), neuroleptics (chlorpromazine), etc. (increased risk of adverse effects).
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

– Volumes of nebuliser solution to be administered are insufficient to obtain efficient nebulisation in most nebulisers: add ipratropium to salbutamol and then 0.9% sodium chloride to obtain a total volume

of 5 ml in the reservoir of the nebuliser. Stop the nebulisation when the reservoir is empty, after around 10 to 15 minutes.

– <u>Storage</u>: below 25 °C - 🌽

# ISONIAZID = H oral

Prescription under medical supervision

# Therapeutic action

- First line antituberculous antibacterial (bactericidal activity)

#### **Indications**

- Treatment of tuberculosis, in combination with other antituberculous antibacterials
- Prophylaxis of tuberculosis

# Forms and strengths

- 100 mg and 300 mg tablets
- 50 mg/5 ml oral solution

## **Dosage**

- Child under 30 kg: 10 mg/kg (7 to 15 mg/kg) once daily, on an empty stomach
- Child over 30 kg and adult: 5 mg/kg (4 to 6 mg/kg) once daily, on an empty stomach
- Do not exceed 300 mg daily.

#### **Duration**

- According to protocol

- Do not administer to patients with severe hepatic impairment.
- Mav cause:
- peripheral neuropathy, especially in malnourished, alcoholic, diabetic, HIV-infected patients; pregnant and breast-feeding women; patients with renal impairment or chronic hepatic disease and patients receiving high doses of isoniazid;
- hepatic disorders (jaundice), especially in alcoholic patients, patients receiving rifampicin, patients > 35 years;
- hypersensitivity reactions, psychotic reactions.
- If signs of hepatotoxicity (e.g. jaundice) develop, isoniazid should be discontinued until symptoms resolve.
- Administer with caution and closely monitor patients taking phenytoin, carbamazepine, benzodiazepines (risk of toxicity), warfarin (risk of bleeding), cycloserine (increased risk of peripheral neuropathy).
- Administer pyridoxine (vitamin B6) in patients at risk of peripheral neuropathy (child: 5 mg daily; adult: 10 mg daily).

- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication; supplement the infant with pyridoxine (5 mg daily).

- Prophylactic treatment should be considered only after excluding active tuberculosis.
- For patients sensitive to first-line antituberculous treatment, isoniazid is given as part of a fixed dose combination (isoniazid+rifampicin+pyrazinamide+ethambutol or isoniazid+rifampicin+pyrazinamide or isoniazid+rifampicin).
- <u>Storage</u>: below 25 ℃ 🚀 Ť

# ISOSORBIDE DINITRATE oral

Prescription under medical supervision

# Therapeutic action

- Vasodilator, antianginal

#### **Indications**

- Prophylaxis and treatment of acute angina
- Adjunctive therapy in left-sided heart failure

# Forms and strengths

- 5 mg sublingual tablet

## **Dosage**

- Short-term prophylaxis of acute angina (sublingually)
   Adult: 5 to 10 mg taken 10 minutes before a precipitating event (physical exertion, stress, etc.)
- Long-term prophylaxis of angina and treatment of heart failure (orally)
   Adult: 5 to 40 mg 2 to 3 times daily
   Gradually increase the dose until effective. Do not stop treatment abruptly.
- Treatment of acute angina (sublingually)
   Adult: 5 to 10 mg, to be repeated after 10 minutes if necessary

#### **Duration**

- According to clinical response

- Do not administer to patients with obstructive cardiomyopathy, hypotension, shock.
- May cause: orthostatic hypotension (especially in elderly patients), headache, nausea, flushing of the face, haemolytic anaemia in patients with G6PD deficiency, severe hypotension with risk of circulatory collapse in the event of overdose.
- Use the lowest effective dose in patients taking another nitrate derivative, a vasodilator or an antihypertensive drug and in elderly patients.

- Combination with antihypertensive drugs, diuretics, vasodilators and alcohol enhances hypotensive effects.
- Do not combine with sildenafil (risk of acute coronary syndrome).
- <u>Pregnancy</u>: not recommended (safety is not established)
- <u>Breast-feeding</u>: not recommended (safety is not established)

- Sublingual tablet must be crunched first, then slowly dissolved under the tongue. Oral tablet must be swallowed whole.
- By sublingual route, antianginal effect appears within less than 10 minutes and persists for 1 to 2 hours.
- Sustained-release formulations are used for the long-term management of angina and the treatment of heart failure. The time interval between each administration depends on the preparations.
- <u>Storage</u>: below 25 °C 🚀 Ť

# ITRACONAZOLE oral

Prescription under medical supervision

# Therapeutic action

- Antifungal

#### **Indications**

- Histoplasmosis and penicilliosis: treatment and secondary prophylaxis
- Dermatophytosis of the scalp (Tinea capitis)

# Forms and strengths

- 100 mg capsule
Also comes in 50 mg/5 ml oral solution.

# **Dosage and duration**

- Histoplasmosis (moderate symptoms)

Child: 5 mg/kg once daily for 6 to 12 weeks

Adult: 200 mg 3 times daily for 3 days then 200 mg 1 to 2 times daily for 6 to 12 weeks

- Histoplasmosis (severe symptoms, disseminated form)

Same treatment for 12 weeks, preceded by one to 2 weeks of treatment with amphotericin B

- Penicilliosis (moderate symptoms)

Adult: 200 mg 2 times daily for 8 weeks

Penicilliosis (severe symptoms)

Same treatment for 10 weeks, preceded by 2 weeks of treatment with amphotericin B

- Secondary prophylaxis of histoplasmosis and penicilliosis

Adult: 200 mg once daily as long as required

- Dermatophytosis of the scalp

Child: 3 to 5 mg/kg once daily for 4 weeks Adult: 200 mg once daily for 2 to 4 weeks

# Contra-indications, adverse effects, precautions

- Administer with caution and monitor use in patients > 60 years or with hepatic or renal impairment or congestive heart failure.
- May cause: gastrointestinal disturbances, headache, skin reactions sometimes severe, anaphylactic reaction, hepatic disorders sometimes severe, paraesthesia, oedema, cardiac failure. Stop treatment in the event of anaphylactic reaction, hepatic disorders or severe skin reaction.
- In case of prolonged treatment, monitor liver function.
- Do not combine with quinidine (risk of arrhythmia).
- Avoid or monitor combination with amiodarone, calcium-channel blockers, benzodiazepines, certain antiretrovirals (e.g. indinavir, ritonavir, saquinavir), corticosteroids (dexamethasone, prednisolone), warfarin, carbamazepine, digoxin: increased blood concentration of these drugs.
- Efficacy of itraconazole may be reduced when combined with: rifampicin, rifabutin, isoniazid, efavirenz, phenytoin, phenobarbital.
- Do not administer simultaneously with aluminium or magnesium hydroxide: administer 2 hours apart.
- <u>Pregnancy and breast-feeding</u>: avoid; for histoplasmosis, amphotericin B alone for 4 to 6 weeks is an alternative in pregnant women. Do not administer in the event of dermatophytosis of the scalp (apply a topical treatment until it is possible to use itraconazole).

#### Remarks

- Do not open the capsules; take with meals.
- Storage: below 25 °C

# **IVERMECTIN** oral

Prescription under medical supervision

# Therapeutic action

- Anthelminthic, scabicide

## **Indications**

- Onchocerciasis
- Scabies

## Forms and strengths

- 3 mg tablet

# **Dosage and duration**

- Onchocerciasis

Child over 15 kg and adult: 150 micrograms/kg single dose. A 2<sup>nd</sup> dose should be administered after 3

months if clinical signs persist. Repeat the treatment every 6 or 12 months to maintain the parasite load below the threshold at which clinical signs appear.

Height Weight	0 to < 90 cm < 15 kg	90 to < 120 cm 15 to < 25 kg	120 to < 140 cm 25 to < 45 kg	140 to < 160 cm 45 to < 65 kg	≥ 160 cm ≥ 65 kg
3 mg tablet	Do not administer	1 tab	2 tab	3 tab	4 tab

- Ordinary scabies

Child over 15 kg and adult: 200 micrograms/kg single dose. A single dose may be sufficient; a 2<sup>nd</sup> dose one week later reduces the risk of treatment failure.

- Crusted scabies

Child over 15 kg and adult: 2 doses of 200 micrograms/kg one week apart, in combination with a topical keratolytic and topical scabicide; additional doses may be necessary.

# Contra-indications, adverse effects, precautions

- May cause:
- increased itching;
- moderate reactions in patients with onchocerciasis: ocular irritation, headache, arthralgia, myalgia, lymphadenopathy, fever, oedema;
- severe reactions in patients co-infected with *Loa loa*: marked functional impairment if *Loa loa* microfilaraemia > 8,000 mf/ml; encephalopathy if *Loa loa* microfilaraemia > 30,000 mf/ml.
- Administer with caution in regions where loiasis is endemic:
- For symptomatic onchocerciasis:

Evaluate the severity of *Loa loa* microfilaraemia and manage accordingly: either treat as an out-patient under supervision, or hospitalise, or choose an alternative treatment (doxycycline).

If it is not possible to perform a thick film examination: ivermectin may be administered if the patient has no history of loiasis (migration of an adult worm under the conjunctiva or transient « Calabar » swellings), nor history of severe adverse reactions following a previous treatment with ivermectin. In other cases, it is wiser either to treat under supervision, or to choose an alternative treatment (doxycycline), or decide not to treat, according to the severity of the onchocerciasis and the previous history.

- For ordinary scabies: review the patient's history and if in doubt, topical scabicidal treatment is preferred.
- <u>Pregnancy</u>: avoid (safety is not established)
- Breast-feeding: no contra-indication

#### Remarks

- Take tablets on an empty stomach. Tablets may be crushed for administration to small children.
- Ivermectin is also used for the treatment of strongyloidiasis (200 micrograms/kg single dose) and cutaneous larva migrans (200 micrograms/kg daily for 1 to 2 days).
- Storage: below 25°C 🌽

# **LABETALOL** oral

Prescription under medical supervision



# Therapeutic action

- Non cardioselective beta-blocker

#### **Indications**

- Hypertension in pregnancy

# Forms and strengths

- 100 mg and 200 mg tablets

## **Dosage**

– 100 mg 2 times daily. Increase if necessary in 100 to 200 mg increments until an effective dose is reached, usually 400 to 800 mg daily (max. 2400 mg daily). If higher doses are required, give in 3 divided doses.

#### **Duration**

- According to clinical response. Do not stop treatment abruptly, decrease doses gradually.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with asthma, chronic obstructive bronchopneumonia, heart failure, severe hypotension, bradycardia < 50/minute, atrio-ventricular heart blocks, Raynaud's syndrome, hepatic impairment.
- May cause: bradycardia, hypotension, heart failure, bronchospasm, hypoglycaemia, gastro intestinal disturbances, dizziness, headache, weakness, urinary retention.
- Administer with caution to patients with diabetes (risk of hypoglycaemia).
- Reduce dosage in patients with renal impairment.
- In the event of anaphylactic shock, risk of resistance to epinephrine.
- Avoid or monitor combination with: mefloquine, digoxin, amiodarone, diltiazem, verapamil (risk of bradycardia); tricyclic antidepressants, neuroleptics, other anti-hypertensive drugs (risk of hypotension).
- Do not administer simultaneously with antacids (aluminium or magnesium hydroxide, etc.). Administer 2 hours apart.
- Monitor the newborn: risk of hypoglycaemia, bradycardia, respiratory distress occurring most often during the first 24 hours and until 72 hours after the birth.
- Breast-feeding: no contra-indication

## Remarks

– <u>Storage</u>: below 25 ℃ - 🎾 - Ť

# **LACTULOSE** oral

# Therapeutic action

- Osmotic laxative

#### **Indications**

- Prevention of constipation in patients taking opioid analgesics (e.g. codeine, morphine)

# Forms and strengths

- 10 g/15 ml oral solution

# **Dosage and duration**

- Child under 1 year: 5 ml daily (1 tsp daily)
- Child from 1 to 6 years: 5 to 10 ml daily (1 to 2 tsp daily)
- Child from 7 to 14 years: 10 to 15 ml daily (2 tsp or 1 ssp daily)
- Child over 14 years and adult: 15 to 45 ml daily (1 to 3 ssp daily)

consistency of stools) is essential in order to adjust dosage correctly.

Start lactulose when analgesic treatment continues more than 48 hours.

Lactulose must be taken daily, until the end of the opioid treatment. Regular follow up (frequency/

## Contra-indications, adverse effects, precautions

- Do not administer to patients with Crohn's disease, ulcerative colitis, intestinal obstruction, undiagnosed abdominal pain.
- May cause: abdominal discomfort, flatulence and diarrhoea.
- In the event of diarrhoea, exclude a faecal impaction and intestinal obstruction; reduce the dose.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### **Remarks**

- It may take up to 48 hours, or even longer, before the treatment is effective. Lactulose is not indicated in acute constipation where a rapid result is needed.
- If necessary, lactulose may be given in combination with a stimulant laxative (e.g. bisacodyl, senna).
- The oral solution may be taken undiluted, or diluted in water.
- The treatment should be accompanied by dietary measures (fluids and fibre).
- <u>Storage</u>: below 25 °C. Do not store in a refrigerator (cristallisation).

# **LAMIVUDINE = 3TC oral**

Prescription under medical supervision

## Therapeutic action

- Antiretroviral, HIV-1 and HIV-2 nucleoside reverse transcriptase inhibitor

#### **Indications**

- HIV-1 or HIV-2 infection, in combination with other antiretroviral drugs

## Forms and strengths

- 150 mg and 300 mg tablets
- 50 mg/5 ml oral solution

## **Dosage**

- Child under 1 month: 2 mg/kg 2 times daily
- Child from 1 month to 12 years: 4 mg/kg 2 times daily
- Adult: 300 mg once daily

Weight	10 mg/ml oral sol.	150 mg tablet	300 mg tablet
5 to 9 kg	2.5 ml x 2	-	-
10 to 14 kg	5 ml x 2	-	-
15 to 19 kg	7 ml x 2	½ tab x 2	-
20 to 24 kg	9 ml x 2	½ tab x 2	-
25 to 29 kg	11 ml x 2	2 tab	1 tab
≥30 kg	-	2 tab	1 tab

#### **Duration**

- The duration of treatment depends on the efficacy and tolerance of lamivudine.

# Contra-indications, adverse effects, precautions

- Administer with caution to patients with history of hepatic disorders.
- May cause: gastrointestinal disturbances (diarrhoea, nausea, vomiting, etc.) and possibly: haematological disorders, especially when combined with zidovudine (neutropenia, anaemia, thrombocytopenia), myopathy, hepatic or pancreatic disorders.
- Reduce dosage in patients with renal impairment.
- Pregnancy: no contra-indication

#### Remarks

- For prophylactic treatment to reduce mother-to-child HIV transmission, check national recommendations.
- Many fixed-dose combinations containing lamivudine are available.
- Storage: below 25 °C

Once opened, oral solution keeps for 30 days maximum.

# **LEVODOPA/CARBIDOPA** oral

Prescription under medical supervision



# Therapeutic action

- Antiparkinson drug

#### **Indications**

- Parkinson's disease and extrapyramidal disorders except those induced by antipsychotics

# Forms and strengths

- 100 mg levodopa + 10 mg carbidopa tablet
- 250 mg levodopa + 25 mg carbidopa tablet

## **Dosage**

(expressed in levodopa)

- Adult:
- Initial dose: 50 to 125 mg 3 times daily, immediately after meals. Increase by 50 to 125 mg every day or every 2 days until the optimal dose for the individual patient is reached.
- Maintenance dose usually: 250 to 500 mg 3 times daily, immediately after meals (max. 2 g daily)
- Reduce dosage in elderly patients.

#### **Duration**

- According to clinical response

# Contra-indications, adverse effects, precautions

- Do not administer in case of severe psychosis, confusion, closed-angle glaucoma, recent myocardial infarction, malignant melanoma.
- May cause:
- early in treatment, when dose is not adjusted: anorexia, vomiting, orthostatic hypotension, cardiac arrhythmia, agitation, insomnia or drowsiness, depression;
- frequent delayed adverse effects, signs of excessive dosage, mainly:
  - dyskinesia, tremor;
- psychiatric disorders more frequent in elderly patients: confusion, hallucinations, delirium, depression with or without suicidal tendencies;
- later in treatment: fluctuation of the effect during the day (daily dosage may be divided into smaller doses and taken more frequently); or reduction of the effect (progression of the disease).
- Administer with caution in psychiatric disorders, cardiac disease, gastro-duodenal ulcer.
- Do not administer simultaneously with MAOIs, antidepressants, antipsychotics, reserpine.
- Pregnancy: CONTRA-INDICATED
- Breast-feeding: CONTRA-INDICATED

#### **Remarks**

- Tablet must be swallowed whole. Do not chew or dissolve.
- Storage: below 25 °C -

# **LEVONORGESTREL** oral

Prescription under medical supervision

# Therapeutic action

- Hormonal contraceptive, progestogen

#### **Indications**

Oral contraception

# Forms and strengths

- 0.03 mg (30 micrograms) tablet

## **Dosage**

- One tablet daily to be taken at the same time each day, on a continuous basis, including during menstruation.
- Contraception may be started at any moment of the cycle if it is reasonably certain the woman is not pregnant, including when switching from another form of contraception. Contraception will be effective as of the 3<sup>rd</sup> tablet.

Use condoms for the first 2 days of the pack if the pill is started:

- more than 5 days after the start of menstruation;
- more than 28 days postpartum if not breastfeeding;
- more than 7 days after an abortion.
- If a pill is missed, it should be taken as soon as possible and usual treatment continued. The missed pill and next scheduled pill can be taken together.

If the missed pill is more than 3 hours overdue, the effectiveness of the contraceptive is reduced. Use:

- condoms for the following 2 days;
- emergency contraception if the woman has had intercourse in the 5 days preceding the missed pill.

#### **Duration**

- If there are no adverse effects, as long as this method of contraception is desired.

- Do not administer to women with breast cancer, severe or recent liver disease, unexplained vaginal bleeding, active thromboembolic disorders.
- May cause: amenorrhoea, menstrual disturbances, nausea, weight gain, breast tenderness, mood changes, acne, headache.
- Enzyme-inducing drugs (rifampicin, rifabutine, efavirenz, nevirapine, lopinavir, ritonavir, phenobarbital, phenytoin, carbamazepine, griseofulvin, etc.) reduce the effectiveness of the contraceptive.
- <u>Pregnancy</u>: **CONTRA-INDICATED**
- Breast-feeding: no contra-indication

- Levonorgestrel is a possible alternative when oestroprogestogens are contra-indicated or poorly tolerated. Its use requires taking pills at strictly the exact time daily, no more than 3 hours late.
- Storage: below 25 °C 🌽

# LEVONORGESTREL for emergency contraception

# Therapeutic action

- Hormonal contraceptive, progestogen

#### **Indications**

- Emergency contraception after unprotected or inadequately protected intercourse (e.g. forgotten pill or condom breaking)

# Forms and strengths

- 1.5 mg tablet

# **Dosage and duration**

- One 1.5 mg tablet, whatever the day of the cycle, as soon as possible after unprotected or inadequately protected intercourse and preferably within the first 72 hours as effectiveness decreases with time. It is however recommended to administer the treatment up to 120 hours (5 days) after unprotected intercourse.

# Contra-indications, adverse effects, precautions

- May cause: disturbance of next menstrual cycle, metrorrhagia, nausea, headache, dizziness.
- Re-administer treatment immediately if vomiting occurs within 2 hours of taking treatment.
- Double the dose (3 mg single dose) in women taking enzyme-inducing drugs (rifampicin, rifabutin, efavirenz, nevirapine, lopinavir, ritonavir, phenobarbital, phenytoin, carbamazepine, griseofulvin, etc.): can reduce the effectiveness of the contraceptive.
- <u>Pregnancy</u>: in the event of treatment failure (i.e. pregnancy develops) or if used during an undiagnosed pregnancy, there is no known harm for the foetus.
- Breast-feeding: no contra-indication

#### Remarks

- Emergency contraception is intended to prevent pregnancy; it cannot terminate an ongoing pregnancy.
- If hormonal contraception is started or resumed immediately after taking levonorgestrel as emergency contraception, use condoms during the first 7 days.
- There is a risk of treatment failure; carry out a pregnancy test if signs or symptoms of pregnancy (no menstruation, etc.) appear one month after taking levonorgestrel as emergency contraception.
- Storage: below 25 °C -

# **LOPERAMIDE** oral

Prescription under medical supervision

# Therapeutic action

- Opioid antidiarrhoeal

#### **Indications**

- Symptomatic treatment of persistent diarrhoea in HIV patients, in combination with rehydration

# Forms and strengths

- 2 mg capsule or tabletAlso comes in 1 mg/5 ml oral solution.

# **Dosage**

- Child from 2 to 5 years: 1 mg 3 times daily
- Child from 6 to 8 years: 2 mg 2 times daily
- Child over 8 years: 2 mg 3 times daily

Age Weight	0-2 years < 13 kg	_	6-8 years 20 - 30 kg	_
Oral solution	Do not administer	1 tsp x 3	2 tsp x 2	2 tsp x 3
Capsule		-	1 cap x 2	1 cap x 3

<sup>-</sup> Adult: 4 mg (2 capsules), then 2 mg (1 capsule) after each loose stool, without exceeding 16 mg daily (8 capsules daily)

#### **Duration**

- According to clinical response

- Do not exceed indicated doses.
- Do not administer to children under 2 years.
- Do not administer to patients with bloody diarrhoea, acute inflammatory bowel disease, diarrhoea due to antibiotics.
- May cause: constipation, allergic skin reactions, drowsiness, dizziness.
- In the event of overdosage, treat with naloxone.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

- Rehydration is essential and must be adapted to the severity of diarrhoea.
- Loperamide is not included in the WHO list of essential medicines.
- Storage: below 25 °C W

# LOPINAVIR/RITONAVIR = LPV/r oral

Prescription under medical supervision

# Therapeutic action

- Antiretrovirals, HIV protease inhibitors

#### **Indications**

- HIV infection, in combination with other antiretroviral drugs

# Forms and strengths

- 40 mg lopinavir/10 mg ritonavir capsule and sachet of oral pellets
- 100 mg lopinavir/25 mg ritonavir and 200 mg lopinavir/50 mg ritonavir film coated tablets
- 80 mg lopinavir/20 mg ritonavir per ml oral solution, containing 42% alcohol (v/v), with a graduated syringe for oral administration

## **Dosage**

- Child from 14 days to 6 months: 16/4 mg/kg 2 times daily
- Child over 6 months:
- 7 to < 15 kg: 12/3 mg/kg 2 times daily
- 15 to 35 kg: 10/2.5 mg/kg 2 times daily
- Child ≥ 35 kg and adult: 400/100 mg 2 times daily

Weight	80/20 mg/ml oral sol.	40/10 mg capsule or sachet of oral pellets	100/25 mg tablet	200/50 mg tablet
3 to < 6 kg	1 ml x 2	-	_	-
6 to < 10 kg	1.5 ml x 2	3 capsules or sachets x 2	_	-
10 to < 14 kg	2 ml x 2	4 capsules or sachets x 2	2 tab morning and 1 tab evening	-
14 to < 20 kg	2.5 ml x 2	5 capsules or sachets x 2	2 tab x 2	-
20 to < 25 kg	3 ml x 2	6 capsules or sachets x 2	2 tab x 2	_
25 to < 35 kg	_	-	3 tab x 2	-

≥ 35 kg – –	4 tab x 2	2 tab x 2	
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#### **Duration**

- The duration of treatment depends on the efficacy and tolerance of lopinavir and ritonavir.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with severe hepatic impairment or hypokalaemia.
- Do not administer oral solution to patients with renal or hepatic impairment and capsules to children under 3 months.
- Administer with caution and monitor use in patients with haemophilia (increased bleeding).
- May cause:
- gastrointestinal disturbances (mainly diarrhoea), skin rash, fatigue, headache, insomnia, paraesthesia, muscle pain, hypertriglyceridaemia, hypercholesterolemia, hyperglycaemia, conduction disorders, lipodystrophy;
- hepatic and pancreatic disorders; in this event, stop treatment immediately.
- Administer with caution and monitor combination with:
- drugs that prolong the QT interval (amiodarone, co-artemether, mefloquine, quinine, haloperidol, etc.);
- metronidazole when using LPV/r oral solution that contains alcohol (risk of antabuse reaction).
- LPV/r reduces the efficacy of oral contraceptives: use a non-hormonal contraception or injectable medroxyprogesterone or an oral contraceptive containing 50 micrograms ethinylestradiol per tablet.
- Avoid combination with rifampicin; preferably use rifabutin. If only rifampicin is available, adjust LPV/r dosage.
- Pregnancy: oral solution is CONTRA-INDICATED; no contra-indication for tablets and capsules

#### **Remarks**

- Tablets may be taken with meals or on an empty stomach. The oral solution must be taken with meals.
- The tablets must not be cut, crushed or chewed.
- Capsules or sachets must be opened then oral pellets must be poured into a small amount of breast milk or soft foods and administered to the child immediately. Pellets must not be stirred, crushed, dissolved/dispersed in food, or chewed.
- Storage:
- ullet Tablets, capsules and sachets of oral pellets: below 25  $^\circ$ C  $^\prime$ Z  $^\circ$ T
- Oral solution: between 2 °C and 8 °C. If refrigeration is not available, oral solution kept below 25 °C may be stored for 6 weeks maximum.

# LORATADINE oral

Prescription under medical supervision

## Therapeutic action

- H1 antihistamine

#### **Indications**

- Symptomatic treatment of minor allergic reactions (urticaria, allergic conjunctivitis, etc.)

# Forms and strengths

- 5 mg/5 ml oral solution
- 10 mg tablet

## **Dosage**

- Child over 2 years and under 30 kg: 5 mg (5 ml) once daily
- Child over 30 kg and adult: 10 mg (1 tab) once daily

#### **Duration**

- As short as possible (a few days).

# Contra-indications, adverse effects, precautions

- Administer with caution and reduce the dose (administer every other day) in patients with severe renal or hepatic impairment.
- May cause: headache, dizziness, drowsiness, nervousness, insomnia, increased appetite, rash.
- Monitor combination with:
- central nervous system depressants (opioid analgesics, antipsychotics, sedatives, antidepressants, etc.) and alcohol;
- erythromycin, fluconazole, fluoxetine, amiodarone, ritonavir, cimetidine (increased plasma concentrations of loratadine).
- <u>Pregnancy</u>: avoid during the first trimester (uncertain risk of hypospadias)
- Breast-feeding: no contra-indication

#### Remarks

- Less sedating than chlorphenamine and promethazine.
- Storage: below 25 °C -



# **MEBENDAZOLE** oral

Prescription under medical supervision

## Therapeutic action

- Anthelminthic

#### **Indications**

– Ascariasis (*Ascaris lumbricoides*), trichuriasis (*Trichuris trichiura*), hookworm infections (*Ancylostoma duodenale, Necator americanus*), enterobiasis (*Enterobius vermicularis*), trichinellosis (*Trichinella* sp)

## Forms and strengths

- 100 mg tablet

## **Dosage and duration**

Ascariasis, trichuriasis, hookworm infections
 Child over 6 months and adult: 100 mg 2 times daily for 3 days
 Child over 6 months but under 10 kg: 50 mg 2 times daily for 3 days

- Enterobiasis

Child over 6 months and adult: 100 mg single dose Child over 6 months but under 10 kg: 50 mg single dose A second dose may be given after 2 to 4 weeks.

- Trichinellosis

Child over 2 years: 2.5 mg/kg 2 times daily for 10 to 15 days

Adult: 200 mg 2 times daily for 10 to 15 days

# Contra-indications, adverse effects, precautions

- Do not administer to children under 6 months.
- May cause: gastrointestinal disturbances, headache, dizziness.
- <u>Pregnancy</u>: avoid during the first trimester
- Breast-feeding: no contra-indication

#### Remarks

- Use albendazole in preference to mebendazole: albendazole is easier to use and is preferred in mixed infections as it has a broader spectrum of activity.
- Tablets are to be chewed or crushed: follow manufacturer's instructions.
- Take tablets between meals.
- Storage: below 25 °C ₩ Ť

# !Mefloquine = MQ oral

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see MEFLOQUINE = MQ oral(see page 323)

# ! Metamizole oral

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see METAMIZOLE = DIPYRONE = NORAMIDOPYRINE oral(see page 326)

# **METFORMIN** oral

Prescription under medical supervision

## Therapeutic action

- Biguanide antidiabetic

#### **Indications**

– First-line treatment of type 2 diabetes, when diet and lifestyle measures alone are insufficient, as monotherapy or in combination with another antidiabetic

## Forms and strengths

– 500 mg tablet

## **Dosage and duration**

- Adult:

Week 1: 500 mg once daily in the morning

Week 2: 500 mg 2 times daily (morning and evening)

Increase if necessary in increments of 500 mg per week, according to blood glucose levels and as long as the drug is well tolerated, without exceeding 2 g daily (1 g morning and evening).

- Do not administer to patients with: ketoacidosis; cardiac, respiratory, hepatic or severe renal impairment.
- May cause:
- often: dose-related gastrointestinal disturbances (nausea, vomiting, diarrhoea, abdominal pain), loss of appetite, metallic taste in mouth;
- rarely: lactic acidosis (in the event of acute alcohol intoxication, dehydration, taking drugs that alter renal function, etc.); decreased absorption of vitamin  $B_{12}$  (risk of macrocytic anaemia).
- Reduce dose (max. 1 g daily) in case of moderate renal impairment.
- Monitor combination with:
- diuretics, angiotensin-converting enzyme inhibitors, non-steroidal anti-inflammatory drugs (risk of lactic acidosis due to altered renal function);
- drugs increasing blood glucose levels: corticosteroids, hydrochlorothiazide, salbutamol, chlorpromazine.
- Stop metformin before surgery or the injection of iodinated contrast agents. Resume treatment 48 hours later after checking renal function.
- <u>Pregnancy</u>: insulin is the drug of choice for type 2 diabetes in pregnant women (improved glycaemic control; reduced risk of foetal anomalies and neonatal complications). Nevertheless, metformin is not contra-indicated.
- Breast-feeding: no contra-indication

#### Remarks

- To reduce gastrointestinal intolerance, gradually increase the dose and take tablets with meals.
- Storage: below 25 °C 🖊

## **METHYLDOPA** oral

Prescription under medical supervision



## Therapeutic action

- Centrally acting antihypertensive

#### **Indications**

- Hypertension in pregnancy

## Forms and strengths

- 250 mg tablet

## **Dosage**

– Initially 250 mg 2 to 3 times daily for 2 days, then increase gradually if necessary by 250 mg every 2 to 3 days, until the optimal dose is reached, usually 1.5 g daily. Do not exceed 3 g daily.

#### **Duration**

- According to clinical response. Do not stop treatment abruptly; reduce doses gradually.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with active liver disease, history of drug-induced hepatitis, severe depression.
- Administer with caution to patients with hepatic impairment, and reduce doses in patients with renal impairment.
- May cause:
- orthostatic hypotension, drowsiness, headache, gastrointestinal disturbances, dry mouth;
- rarely: haematological, hepatic, psychical disorders; allergic reactions.
- Stop treatment in the event of haemolytic anaemia or jaundice.
- In the event of unexplained fever during treatment, check blood count and transaminases for possible hepatitis due to methyldopa.
- Monitor combination with lithium (risk of lithium overdose), antidepressants (enhanced hypotensive effect), CNS depressants (increased sedation).
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Storage: below 25 °C

# **METOCLOPRAMIDE** oral

Prescription under medical supervision

## Therapeutic action

- Antiemetic (dopamine antagonist)

#### **Indications**

- Symptomatic treatment of nausea and vomiting in adults

## Forms and strengths

- 10 mg tablet

## **Dosage**

- Adult under 60 kg: 5 mg 3 times daily
- Adult over 60 kg: 10 mg 3 times daily

The interval between each dose should be at least 6 hours (even in the event of vomiting).

#### **Duration**

- A few days

## Contra-indications, adverse effects, precautions

- Do not administer to children < 18 years and to patients with gastrointestinal haemorrhage, obstruction or perforation.
- Reduce the dose by half in patients with severe renal impairment.
- Administer with caution and monitor use in patients > 60 years and patients with epilepsy or Parkinson's disease.
- May cause: drowsiness (caution when driving/operating machinery), dizziness, confusion, extrapyramidal symptoms, seizures (especially in epileptics), allergic reactions; neuroleptic malignant syndrome (unexplained hyperthermia with neuromuscular disorders), exceptional but requiring immediate treatment discontinuation.
- Do not combine with levodopa (antagonism).
- Avoid combination with CNS depressants (opioid analgesics, antipsychotics, sedatives, antidepressants, antihistamines, etc.).
- Avoid alcohol during treatment.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- <u>Storage</u>: below 25 °C - **∅** - Ť

# **METRONIDAZOLE** oral

Prescription under medical supervision

## Therapeutic action

- Antiprotozoal, antibacterial (group of nitroimidazoles)

#### **Indications**

- Amoebiasis, giardiasis, trichomoniasis
- Bacterial vaginitis, infections due to anaerobic bacteria (e.g. *Clostridium* sp, *Bacteroides* sp, etc.)

# Forms and strengths

- 250 mg and 500 mg tablets
- 200 mg/5 ml oral suspension

## **Dosage and duration**

- Amoebiasis

Child: 15 mg/kg 3 times daily Adult: 500 mg 3 times daily

The treatment lasts 5 days in intestinal amoebiasis and 5 to 10 days in hepatic amoebiasis.

- Giardiasis

Child: 30 mg/kg once daily for 3 days Adult: 2 g once daily for 3 days

- Trichomoniasis and bacterial vaginitis

Adult: 2 g single dose

In the event of trichomoniasis, also treat sexual partner.

- Infections due to anaerobic bacteria

Child: 10 mg/kg 3 times daily Adult: 500 mg 3 times daily

According to indication, metronidazole may be used in combination with other anti bacterials; treatment duration depends on indication.

- Do not administer to patients with hypersensitivity to metronidazole or another nitroimidazole (tinidazole, secnidazole, etc.).
- May cause: gastrointestinal disturbances; rarely: allergic reactions, brownish urine, headache, dizziness. Risk of antabuse reaction when combined with alcohol.
- Administer with caution in patients taking oral anticoagulants (risk of haemorrhage), lithium, phenytoin, ergometrine (increased plasma concentrations of these drugs).
- Reduce total daily dose to one third and give once daily to patients with severe hepatic impairment.
- <u>Pregnancy</u>: no contra-indication; divide into smaller doses, avoid prolonged use.
- <u>Breast-feeding</u>: significantly excreted in milk (risk of gastrointestinal disturbances in breastfed infants); divide into smaller doses, avoid prolonged use.

### Remarks

- Storage: below 25 °C - ✓

For the oral suspension: follow manufacturer's instructions.

# **MICONAZOLE** oral gel

Prescription under medical supervision

## Therapeutic action

- Antifungal

#### **Indications**

- Mild oropharyngeal candidiasis

## Forms and strengths

- 2% oral gel (24 mg/ml) together with, depending on the manufacturer:
- a 2.5 ml measuring spoon with 1.25 ml and 2.5 ml graduation or
- a 5 ml measuring spoon with 2.5 ml and 5 ml graduation

## **Dosage**

- Child from 6 months to 2 years: 1.25 ml 4 times daily
- Child over 2 years and adult: 2.5 ml 4 times daily

The oral gel should be kept in the mouth 2 to 3 minutes and then swallowed, or in young children, applied to the tongue and inside of each cheek.

#### **Duration**

- 7 days; 14 days of treatment may be necessary.

- Do not administer:
- to children under 6 months or patients with swallowing difficulties (risk of suffocation due to oral gel form):
- in patients with hepatic impairment.
- Do not combine with antivitamin K agents (risk of haemorrhage), glibenclamide (increased hypoglycaemic effect), phenytoin (increased plasma concentration of phenytoin).
- May cause: nausea, taste disturbances.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Use the measuring spoon provided and check the graduation.
- Administer between meals (preferably after meals).
- In patients with dentures, clean dentures with oral gel when removed.
- In the event of moderate or severe oropharyngeal candidiasis, use oral fluconazole.
- Miconazole oral gel is not included in the WHO list of essential medicines.
- Storage: below 25 °C //

# MIFEPRISTONE oral

Prescription under medical supervision

## Therapeutic action

- Antiprogestogen

#### **Indications**

– Termination of intra-uterine pregnancy up to 22 weeks after the last menstrual period, in combination with misoprostol

## Forms and strengths

- 200 mg tablet

## **Dosage and duration**

- 200 mg single dose, followed by the administration of misoprostol 1 to 2 days later

# Contra-indications, adverse effects, precautions

- Do not administer to patients with chronic adrenal failure or severe uncontrolled asthma.
- May cause: gastrointestinal disturbances, vaginal bleeding, uterine contractions, headache.
- <u>Breast-feeding</u>: no contra-indication for a single dose; to be avoided if multiple doses

#### Remarks

- Do not use mifepristone in ectopic or molar pregnancy.
- Storage: below 25 °C 🖊 🕆

# MISOPROSTOL oral

Prescription under medical supervision

## Therapeutic action

- Oxytocic drug, prostaglandin analogue

#### **Indications**

- Incomplete abortion
- Termination of intra-uterine pregnancy, preferably in combination with mifepristone
- Induction of labour
- Treatment of post-partum haemorrhage due to uterine atony, when injectable oxytocics are not available or ineffective
- Cervical dilation before aspiration or curettage

## Forms and strengths

- 25 micrograms and 200 micrograms tablets

## Dosage and duration

- Incomplete abortion
- up to 13 weeks since the last menstrual period: 400 micrograms single dose sublingually or 600 micrograms single dose orally
- from 13 to 22 weeks since the last menstrual period: 400 micrograms sublingually every 3 hours
- Termination of pregnancy
- up to 13 weeks since the last menstrual period: 800 micrograms single dose sublingually or vaginally. If expulsion has not occurred within 24 hours administer a 2<sup>nd</sup> dose of 800 micrograms.
- from 13 to 22 weeks since the last menstrual period: 400 micrograms single dose sublingually or vaginally every 3 hours
- Induction of labour
- 25 micrograms orally every 2 hours, or if not possible, vaginally every 6 hours, until labour starts (max. 200 micrograms per 24 hours)
- Treatment of post-partum haemorrhage
   800 micrograms single dose sublingually
- Cervical dilation before aspiration or curettage
- 400 micrograms single dose sublingually 1 to 3 hours before the procedure or vaginally 3 hours before the procedure

- For induction of labour if the foetus is viable:
- Do not administer in the event of previous caesarean section.
- Administer with caution in case of grand multiparity or overdistention of the uterus (risk of uterine rupture).
- Monitor the intensity and frequency of contractions as well as foetal heart rate after administration of misoprostol.
- Do not administer simultaneously with oxytocin. At least 4 hours must have elapsed since the last administration of misoprostol before oxytocin can be given.
- For incomplete abortion or termination of pregnancy after 13 weeks since the last menstrual period: reduce the dose by half in the event of 2 or more previous caesarean sections.
- May cause: dose-dependent diarrhoea, vomiting, uterine hypertony, headache, fever, chills, foetal

heart rhythm disorders, foetal distress.

- Breast-feeding: no contra-indication

#### Remarks

- Do not use misoprostol in ectopic or molar pregnancy.
- Rectal route is used for the treatment of post-partum haemorrhage when the sublingual route cannot be used.
- Storage: below 25 °C ₩ Ť

# **MORPHINE immediate-release (MIR) oral**

Prescription under medical supervision



## Therapeutic action

- Centrally acting opioid analgesic

#### **Indications**

- Severe pain

## Forms and strengths

- 10 mg immediate-release tablet
- 10 mg/5 ml oral solution, for pediatric use

## **Dosage**

There is no standard dose. The optimal dose is that which provides efficient pain relief to the patient. It is adjusted in relation to the regular assessment of pain intensity and the incidence of adverse effects.

- Day 1:
  - Start with a scheduled treatment (scheduled doses):
     Child over 6 months: 0.15 mg/kg every 4 hours
     Adult: 10 mg every 4 hours
  - Adjust the treatment if pain persists by administering "rescue" doses between the scheduled doses. The rescue doses administered are the same as the scheduled doses.
- Then, adjust scheduled treatment every 24 hours according to the total dose given the day before (i.e. total scheduled doses + total rescue doses).

For example, Day 1, for a dose of 60 mg, i.e. 10 mg every 4 hours:

Hours	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	0	1	2	3	4	5	6	7
Scheduled doses	10 mg				10 mg				10 mg				10 mg				10 mg				10 mg			
Example simple verbal scale	severe pain		moderate pain		mild pain		moderate pain		mild pain		mild pain		mild pain		moderate pain		mild pain				mild pain			
Example rescue doses			10 mg				10 mg								10 mg									

In this example, the scheduled treatment on Day 2 is 90 mg, i.e. 60 mg (total scheduled doses on Day 1) + 30 mg (total rescue doses on Day 1), i.e. 15 mg every 4 hours.

- Scheduled doses must be administered at regular time intervals and not on demand, even at night, unless the patient is abnormally drowsy (in this event, delay the administration).
- Reduce the dose by half in elderly patients and patients with renal or hepatic impairment.

#### **Duration**

- Once the pain is controlled, change to sustained-release morphine.

## Contra-indications, adverse effects, precautions

- See sustained-release oral morphine (MSR)(see page 117).

#### Remarks

- Administer an appropriate laxative (e.g. lactulose) if analgesic treatment continues more than 48 hours.
- The morphine dose in tablets is not suitable for young children. Use oral solution instead. If this is not available, use injectable morphine by the oral route: dilute an ampoule of 10 mg/ml (1 ml) with 9 ml of water to obtain a solution containing 1 mg/ml.
- Morphine is on the list of narcotics: follow national regulations.
- Storage: below 25°C 🌽

# **MORPHINE** sustained-release (MSR) oral

Prescription under medical supervision



## Therapeutic action

- Centrally acting opioid analgesic

## **Indications**

- Severe and persistent pain, especially cancer pain

## Forms and strengths

- 10 mg, 30 mg and 60 mg sustained-release capsules or tablets

## **Dosage**

- Usually, the effective daily dose is determined during the initial treatment with immediate-release morphine (MIR). When changing from MIR to MSR, the daily dose remains the same. For example, if the effective dose of MIR is 20 mg every 4 hours (120 mg daily), the dose of MSR is 60 mg every 12 hours (120 mg daily).
- If treatment is initiated directly with MSR:
- Child over 6 months: initially 0.5 mg/kg every 12 hours
- Adult: initially 30 mg every 12 hours

Adjust the dose if necessary, increasing the dose by 50% per day until pain relief is obtained.

– Patients stabilized on MSR may require rescue doses of MIR in the event of episodic (breakthrough) pain. A rescue dose corresponds to 10% of the daily MSR dose. If a patient regularly requires more than 3 rescue doses per day, increase the daily MSR dose by the sum of rescue doses.

#### **Duration**

– According to clinical response. Do not stop long-term treatment abruptly. Decrease doses progressively to avoid withdrawal symptoms.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with severe respiratory impairment or decompensated hepatic impairment.
- Do not initiate treatment with the sustained-release formulation in elderly patients or those with renal or hepatic impairment. Begin treatment with the immediate release formulation (MIR).
- May cause:
- dose-related sedation and respiratory depression, nausea, vomiting, constipation, urinary retention, confusion, raised intracranial pressure, pruritus;
- in the event of overdose: excessive sedation, respiratory depression, coma.
- Management of respiratory depression includes assisted ventilation and/or administration of naloxone. Monitor patient closely for several hours.
- Administer with caution to patients with respiratory impairment, head injury, raised intracranial pressure, uncontrolled epilepsy or urethroprostatic disorders.
- Do not combine with opioid analgesics with mixed agonist-antagonist activity such as buprenorphine, nalbuphine, pentazocine (competitive action).
- Increased risk of sedation and respiratory depression, when combined with alcohol and drugs acting on the central nervous system: benzodiazepines (diazepam, etc.), neuroleptics (chlorpromazine, haloperidol, etc.), antihistamines (chlorphenamine, promethazine), phenobarbital, etc.
- <u>Pregnancy and breast-feeding</u>: no contra-indication. The child may develop withdrawal symptoms, respiratory depression and drowsiness when the mother receives morphine at the end of the 3<sup>rd</sup> trimester and during breast-feeding. In these situations, administer with caution, for a short period, at the lowest effective dose, and monitor the child.

## Remarks

- Administer an appropriate laxative (e.g. lactulose) if analgesic treatment continues more than 48 hours.
- Do not crush or chew capsules. They can be opened and emptied into food.
- Morphine is on the list of narcotics: follow national regulations.
- Storage: below 25 °C ₩ 🕆

# **MULTIVITAMINS - VITAMIN B COMPLEX oral**

## Therapeutic action

- Vitamin supplementation

#### **Indications**

- Few indications: this drug has no effect in case of real vitamin deficiency. Nevertheless, vitamin supplementation helps to prevent some deficiencies in people at risk (e.g. pregnant women).

## Forms and strengths

– Tablet. Composition varies in quality and quantity, with manufacturers. Examples of composition per tablet:

	Multivitamins	B complex	Daily needs (adult)
Vitamin A	2500 IU	/	2500 IU
Vitamin B <sub>1</sub>	1 mg	1 mg	0.9 to 1.3 mg
Vitamin B <sub>2</sub>	0.5 mg	1 mg	1.5 to 1.8 mg
Vitamin B <sub>3</sub> (= PP)	7.5 mg	15 mg	15 to 20 mg
Vitamin C	15 mg	/	10 mg
Vitamin D <sub>3</sub>	300 IU	/	100 to 200 IU

## **Dosage**

Child under 5 years: 1 tablet dailyChild over 5 years: 2 tablets daily

- Adult: 3 tablets daily

#### **Duration**

- Depending on situation

## Contra-indications, adverse effects, precautions

- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Specific vitamin deficiency states require appropriate doses of vitamins.
- Multivitamins are not included in the WHO list of essential medicines.
- Storage: keep in a cool place (8 °C to 15 °C) W

# **NEVIRAPINE = NVP oral**

Prescription under medical supervision

# Therapeutic action

- Antiretroviral, HIV-1 non nucleoside reverse transcriptase inhibitor

### **Indications**

- HIV-1 infection, in combination with other antiretroviral drugs

## Forms and strengths

- 50 mg dispersible tablet
- 200 mg tablet
- 50 mg/5 ml oral suspension

## **Dosage**

- Child from 2 months to 8 years: 4 mg/kg once daily for 14 days, then 7 mg/kg 2 times daily from the  $15^{th}$  day
- Child over 8 years: 4 mg/kg once daily for 14 days, then 4 mg/kg 2 times daily from the 15<sup>th</sup> day (max. 400 mg daily)
- Adult: 200 mg once daily for 14 days, then 200 mg 2 times daily from the 15<sup>th</sup> day

		l oral suspension	200 mg tablet			
Weight	Initial	Maintenance	Initial	Maintenance		
5 to < 10 kg	3 ml	6 ml x 2	Use oral	-		
10 to < 15 kg	5 ml	10 ml x 2	suspension	½ tab x 2		
15 to < 20 kg	7 ml	14 ml x 2	½ tab	1 tab AM and ½ tab PM		
20 to < 25 kg	< 8 years: 16 ml x 10 ml 2		½ tab	< 8 years: 1 tab AM and ½ tab PM		
		> 8 years: 10 ml x		> 8 years: ½ tab x 2		
25 to < 30 kg	12 ml	< 8 years: 20 ml x 2	½ tab	< 8 years: 1 tab x 2		
		> 8 years: 12 ml x		> 8 years: ½ tab x 2		
30 to < 40 kg	14 ml	14 ml x 2	1 tab	1 tab AM and ½ tab PM		

40 to < 50 kg	_	-	1 tab	1 tab x 2
≥ 50 kg	_	-	1 tab	1 tab x 2

#### **Duration**

– The duration of treatment depends on the efficacy and tolerance of nevirapine.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with severe hepatic impairment, history of severe intolerance to nevirapine that led to permanent discontinuation of treatment.
- May cause:
- cutaneous reactions sometimes severe (Stevens-Johnson and Lyell syndromes), hepatic disorders possibly severe (fulminant hepatitis). In these cases, stop taking nevirapine immediately and permanently;
- gastrointestinal disturbances, headache, myalgia.
- Nevirapine reduces the efficacy of oral contraceptives: use a non-hormonal contraception or injectable medroxyprogesterone or an oral contraceptive containing 50 micrograms ethinylestradiol per tablet.
- Avoid combination with rifampicin (decreases the efficacy of nevirapine). Use rifabutin if possible. If rifabutin is not available, use efavirenz rather than nevirapine.
- Monitor liver enzyme level (ALAT) during the first 2 months, then every 3 to 6 months. If the enzyme level reaches 5 times the normal level, stop nevirapine immediately.
- <u>Pregnancy</u>: no contra-indication

#### Remarks

- For prophylactic treatment to reduce mother-to-child transmission, check national recommendations.
- To improve tolerance, respect the initial 14-day phase of treatment. In the event of restarting treatment after having stopped for more than 7 days, recommence initial 14-day phase.
- Tablets are not scored. When half a tablet is required, use a cutter to cut the tablet into two equal parts.
- Also comes in fixed-dose combination tablets incorporating nevirapine-lamivudine-zidovudine.
- Storage: below 25 °C

Once opened, oral suspension keeps for 2 months maximum.

# **NICLOSAMIDE** oral

## Therapeutic action

- Anthelminthic (taenicide)

#### **Indications**

– Taeniasis: beef tapeworm (*Taenia saginata*), pork tapeworm (*Taenia solium*), dwarf tapeworm (*Hymenolepis nana*) and fish tapeworm (*Diphyllobothrium latum*)

# Forms and strengths

- 500 mg chewable tablet

## **Dosage and duration**

T. saginata, T. solium and D. latum
 Child under 2 years: 500 mg single dose
 Child from 2 to 6 years: 1 g single dose
 Child over 6 years and adult: 2 g single dose

– H. nana

Child under 2 years: 500 mg on D1, then 250 mg once daily for 6 days Child from 2 to 6 years: 1 g on D1, then 500 mg once daily for 6 days Child over 6 years and adult: 2 g on D1, then 1 g once daily for 6 days

## Contra-indications, adverse effects, precautions

- May cause: gastrointestinal disturbances.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Chew or crush the tablets before swallowing with water.
- In the event of vomiting, the single dose may be divided in 2 doses taken with an interval of one hour.
- As niclosamide is a taenicide not a taenifuge, do not expect the patient to expel the worm, portions are voided in a partially digested form.
- Niclosamide is not active against the larval form of *T. solium* (cysticercosis).
- Storage: below 25 °C W

# NICOTINAMIDE = VITAMIN PP = VITAMIN B3 oral

## Therapeutic action

- Vitamin

#### **Indications**

- Treatment of pellagra

# Forms and strengths

- 100 mg tablet

## **Dosage and duration**

- Child and adult: 100 mg 3 times daily, with a diet rich in protein, until the patient is fully cured

## Contra-indications, adverse effects, precautions

- <u>Pregnancy and breast-feeding</u>: avoid, except if clearly needed (safety is not established)

#### Remarks

- Nicotinamide is also called niacinamide.
- Vitamin PP deficiency is common when diet is almost entirely based on sorghum, millet or maize.
- Vitamin PP deficiency often occurs in association with other vitamin B-complex deficiency (thiamine, pyridoxine), especially in alcoholic patients.
- Vitamin PP is usually one of the components of multivitamin preparations and B-complex (7.5 mg to 15 mg per tablet).
- Nicotinic acid has a similar action to nicotinamide, but is no longer used because of its adverse effects, especially its vasodilator action.
- Storage: below 25°C 🌽

# **NIFEDIPINE** oral

Prescription under medical supervision



## Therapeutic action

- Uterine relaxant

#### **Indications**

- Threatened premature labour

## Forms and strengths

- 10 mg immediate-release soft capsule or tablet

## Dosage and duration

 $-\,10$  mg by oral route, to be repeated every 15 minutes if uterine contractions persist (max. 4 doses or 40 mg), then 20 mg by oral route every 6 hours

The total duration of treatment is 48 hours.

- Do not administer to patients with severe cardiac disease (recent myocardial infarction, unstable angina).
- Do not administer if systolic blood pressure is below 90 mmHg.
- May cause:
- headache, flushing, peripheral oedema (common adverse effects at the start of treatment);
- dizziness, hypotension, tachycardia, nausea, gingival hyperplasia, rash.
- Stop nifedipine if ischaemic chest pain occurs or existing pain increases after starting treatment.
- Do not combine with magnesium sulphate, salbutamol IV, and other calcium channel blockers.
- Monitor combination with cimetidine (enhances hypotensive effects), phenytoin (risk of phenytoin overdose), rifampicin (efficacy of nifedipine diminished), itraconazole (increased risk of oedema), beta-blockers (increased adverse cardiac effects).
- <u>Pregnancy</u>: **CONTRA-INDICATED** during the first trimester. Never administer sublingually (risk of foetal death from placental hypoperfusion).
- Breast-feeding: avoid

#### Remarks

- Nifedipine is a calcium channel blocker that is also used in the management of hypertension at doses of 10 to 40 mg 2 times daily or 20 to 90 mg once daily, depending on the sustained-release form used. Immediate-release forms of nifedipine should not be used in either long-term treatment of hypertension or treatment of hypertensive crisis (risk of excessive fall in blood pressure and cerebral or myocardial ischaemia in patients with coronary artery disease).
- Storage: below 25 °C W

# **NITROFURANTOIN** oral

Prescription under medical supervision

## Therapeutic action

- Antibacterial (group of nitrofuranes)

#### **Indications**

- Uncomplicated cystitis, without fever or lower back pain, when no other antibiotic can be used

## Forms and strengths

– 100 mg tablet

## Dosage and duration

- Adult: 100 mg 3 times daily for 5 to 7 days

# Contra-indications, adverse effects, precautions

- Do not administer to patients with renal impairment, G6PD deficiency or allergy to nitrofurantoin.
- May cause:
- nausea, vomiting, headache, dizziness, brownish urine;
- haemolytic anaemia in patients with G6PD deficiency, pulmonary and hepatic disorders, allergic reactions
- Do not administer simultaneously with antacids (aluminium or magnesium hydroxide, etc.). Administer doses at least 2 hours apart.
- <u>Pregnancy</u>: **CONTRA-INDICATED** during the last month of pregnancy (risk of haemolysis in the newborn)
- Breast-feeding: avoid during the first month

## **Remarks**

- Take during meals.
- Do not use nitrofurantoin to prevent cystitis.
- Also comes in modified release capsules to be administered 2 times daily.
- Storage: below 25 °C 7 7

# NITROGLYCERIN oral

See GLYCERYL TRINITRATE oral(see page 83)

# ! Noramidopyrine oral

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see METAMIZOLE = DIPYRONE = NORAMIDOPYRINE oral(see page 326)

## **NYSTATIN** oral

## Therapeutic action

- Antifungal

#### **Indications**

- Mild oropharyngeal candidiasis

## Forms and strengths

– 100 000 IU/ml oral suspension, bottle with calibrated dropper

## **Dosage and duration**

– Child and adult: 100 000 IU 4 times daily (1 ml of the oral suspension 4 times daily) for 7 days The oral suspension should be retained in the mouth for a few minutes before swallowing, or, in young children, applied to the tongue and the inside of the cheeks.

## Contra-indications, adverse effects, precautions

- Take between meals (e.g. at least 30 minutes before eating).
- Shake oral suspension well before using.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Nystatin also comes in:
- 100 000 IU lozenge for the treatment of oropharyngeal candidiasis;
- 100 000 IU and 500 000 IU film coated tablets for the treatment of oesophageal candidiasis.
- For the treatment of moderate to severe oropharyngeal candidiasis and oesophageal candidiasis, oral

fluconazole is the first-line treatment.

- Storage: below 25 °C

# **OLANZAPINE** oral

Prescription under medical supervision



## Therapeutic action

- Atypical antipsychotic

#### **Indications**

- Chronic psychosis, in the event of intolerance or treatment failure with other antipsychotics

## Forms and strengths

- 2.5 mg and 5 mg tablets

## **Dosage**

- Adult: 5 mg once daily. Increase up to 10 mg daily if necessary (max. 20 mg daily).
- Reduce the dose by half in elderly patients (max. 10 mg daily).

### **Duration**

– Minimum one year. The treatment should be discontinued gradually (over 4 weeks). If signs of relapse occur, increase the dose.

- Do not administer to patients with cardiac disorders (heart failure, recent myocardial infarction, conduction disorders, bradycardia, etc.), dementia (e.g. Alzheimer's disease), Parkinson's disease, history of neuroleptic malignant syndrome and closed-angle glaucoma.
- Administer with caution and carefully monitor use in elderly patients and patients with hypokalaemia, hypotension, prostate disorders, renal or hepatic impairment, history of seizures.
- May cause: orthostatic hypotension, drowsiness,
- extrapyramidal symptoms, hyperprolactinaemia, weight gain, hyperlipidaemia,
- hyperglycaemia, anticholinergic effects (constipation, dry mouth), headache, insomnia, dizziness, sexual dysfunction; neuroleptic malignant syndrome (unexplained hyperthermia with neuromuscular disorders), rare but requiring immediate treatment discontinuation.
- In the event of extrapyramidal symptoms, combine with biperiden or trihexyphenidyl.
- Avoid or monitor combination with:
- central nervous system depressants (opioid analgesics, sedatives, H1 antihistamines, etc.);
- ciprofloxacin (increased plasma concentrations of olanzapine);
- carbamazepine, rifampicin, phenobarbital, phenytoin, ritonavir (decreased plasma concentrations of olanzapine);
- antihypertensive drugs (risk of hypotension); drugs that prolong the QT interval (amiodarone, chloroquine, erythromycin, fluconazole, mefloquine, pentamidine, quinine, etc.).
- Avoid alcohol during treatment.

- <u>Pregnancy</u>: re-evaluate whether the treatment is still necessary; if it is continued, monitor the neonate the first few days (risk of hypertonia, tremors, sedation).
- Breast-feeding: if absolutely necessary, do not exceed 10 mg daily.

#### Remarks

− <u>Storage</u>: below 25 °C -

# **OMEPRAZOLE** oral

Prescription under medical supervision

## Therapeutic action

- Antiulcer and gastric antisecretory agent (proton pump inhibitor)

#### **Indications**

- Gastro-oesophageal reflux
- Gastric and duodenal ulcers in adult

## Forms and strengths

- 10 mg dispersible gastro-resistant tablet
- 20 mg gastro-resistant capsule

## **Dosage**

- Gastro-oesophageal reflux

Child under 5 kg: 0.7 to 1.4 mg/kg (max. 2.8 mg/kg daily) once daily in the morning

Child 5 to 10 kg: 5 mg once daily in the morning Child 10 to 20 kg: 10 mg once daily in the morning

Child over 20 kg and adult: 20 mg once daily in the morning

Age	Weight	1 mg/ml sol.*	10 mg tablet**	20 mg capsule
< 2 months	< 5 kg	3 ml	-	-
2 months to < 1 year	5 to < 10 kg	5 ml	-	-
1 to < 6 years	10 to < 20 kg	-	1 tab	-
≥6 years and adult	≥ 20 kg	-	-	1 cap

<sup>\*</sup> In a syringe, dissolve a ½ dispersible tablet (5 mg) in 5 ml of water to obtain a solution of 1 mg/ml.

- Gastric and duodenal ulcers

Adult: 20 mg once daily in the morning

In severe or recurrent cases, dose can be increased if necessary to 40 mg once daily.

<sup>\*\*</sup> Dissolve 1 dispersible tablet in half a glass of water.

#### **Duration**

- Gastro-oesophageal reflux: 3 days (short-term relief of symptoms) or 4 to 8 weeks (long-term treatment); gastric and duodenal ulcers: 7 to 10 days or up to 8 weeks (severe or recurrent cases).

## Contra-indications, adverse effects, precautions

- Do not exceed 0.7 mg/kg daily (max. 20 mg daily) in patients with severe hepatic impairment.
- May cause: headache, diarrhoea, constipation, nausea, vomiting, abdominal pain, dizziness, skin rash, fatigue.
- Monitor combination with:
- atazanavir, itraconazole (decreased efficacy of these drugs);
- diazepam, phenytoin, digoxin, raltegravir (increased toxicity of these drugs).
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Do not open capsules.
- Omeprazole is also used in combination with 2 antibacterial drugs for cure of *Helicobacter pylori* infection, at a dosage of 20 mg 2 times daily for 7 days.
- Storage: below 25 °C 🖊

Once dissolved, dispersible tablets should be administered within 30 minutes.

## ORAL REHYDRATION SALTS = ORS

#### **Indications**

- Prevention and treatment of dehydration from acute diarrhoea, cholera, etc.

## Forms and strengths

- Sachet of powder to be diluted in 1 litre of clean water.
- WHO formulation:

	grams/litre		mmol/litre
sodium chloride	2.6	sodium	75
glucose	13.5	chloride	65
potassium chloride	1.5	glucose	75
trisodium citrate	2.9	potassium	20
		citrate	10
Total weight	20.5	Total osmolarity	245

## **Dosage**

- Prevention of dehydration (WHO - Treatment plan A)

Child under 24 months: 50 to 100 ml after each loose stool (approximately 500 ml daily)
Child from 2 to 10 years: 100 to 200 ml after each loose stool (approximately 1000 ml daily)
Child over 10 years and adult: 200 to 400 ml after each loose stool (approximately 2000 ml daily)

Treatment of moderate dehydration (WHO - Treatment plan B)
 Child and adult:

Over the first four hours:

Age	under 4 months	4 to 11 months	12 to 23 months	2 to 4 years	5 to 14 years	15 years and over
Weight	under 5 kg	5 to 7.9 kg	8 to 10.9 kg	11 to 15.9 kg	16 to 29.9 kg	30 kg and over
ORS in ml	200 to 400	400 to 600	600 to 800	800 to 1200	1200 to 2200	2200 to 4000

#### After four hours:

If there are no signs of dehydration: follow *Treatment plan A.* 

If there are signs of moderate dehydration: repeat Treatment plan B.

If there are signs of severe dehydration: start IV therapy (*Treatment plan C*).

- Treatment of severe dehydration (WHO - Treatment plan C)

In combination with IV therapy and only to a conscious patient:

Child and adult: 5 ml/kg per hour

After 3 hours (6 hours in infants), reassess and choose the appropriate plan A, B or C.

#### **Duration**

- As long as diarrhoea and signs of dehydration persist.

## Contra-indications, adverse effects, precautions

- If the eyelids become puffy during the treatment: stop ORS, give plain water then, resume ORS according to Treatment plan A when the puffiness is gone.
- If case of vomiting, stop ORS for 10 min and then resume at a slower rate (very small, frequent, amounts); do not stop rehydration.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- A special ORS-formula, ReSoMal, is used under medical supervision, for severely malnourished children only. However, in malnourished children with cholera, standard ORS- formula is used instead of ReSoMal.
- Storage: below 25 °C ₹

Do not use the powder if it has turned into a yellow-brownish sticky substance.

Once prepared, the solution must be used within 24 hours.

# PARACETAMOL = ACETAMINOPHEN oral

## Therapeutic action

- Analgesic, antipyretic

#### **Indications**

- Mild pain
- Fever

## Forms and strengths

- 100 mg and 500 mg tablets
- 120 mg/5 ml oral suspension

## **Dosage**

- Child under 1 month: 10 mg/kg 3 or 4 times daily, if necessary (max. 40 mg/kg daily)
- Child 1 month and over: 15 mg/kg 3 or 4 times daily, if necessary (max. 60 mg/kg daily)
- Adult: 1 g 3 or 4 times daily, if necessary (max. 4 g daily)

Age	Weight	120 mg/5 ml susp.	100 mg tablet	500 mg tablet
< 1 month	< 4 kg	1.5 ml x 3	-	-
1 to < 3 months	4 to < 6 kg	2.5 ml x 3	½ tab x 3	-
3 months to < 1 year	6 to < 10 kg	4 ml x 3	1 tab x 3	-
1 to < 3 years	10 to < 15 kg	6 ml x 3	1½ tab x 3	-
3 to < 5 years	15 to < 20 kg	8 ml x 3	2 tab x 3	-
5 to < 9 years	20 to < 30 kg	12 ml x 3	3 tab x 3	-
9 to < 14 years	30 to < 50 kg	-	-	1 tab x 3
≥ 14 years and adult	≥ 50 kg	-	-	2 tab x 3

#### **Duration**

- According to clinical response

# Contra-indications, adverse effects, precautions

- Administer with caution to patients with hepatic impairment.
- Do not exceed indicated doses, especially in children and elderly patients. Paracetamol intoxications are severe (hepatic cytolysis).
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

## Remarks

- For mild pain, paracetamol is used alone or in combination with an NSAID.
- For moderate pain, paracetamol is used in combination with an NSAID and codeine or tramadol.
- For severe pain, paracetamol is used in combination with an NSAID and morphine.
- Paracetamol is particularly recommended for patients allergic to aspirin, patients with a history of gastric problems and for pregnant and breast-feeding women and children.
- Paracetamol has no anti-inflammatory properties.
- Storage: below 25 °C ₩

# **PAROXETINE** oral

Prescription under medical supervision



## Therapeutic action

- Antidepressant, selective serotonin re-uptake inhibitor (SSRI)

#### **Indications**

- Major depression
- Generalised anxiety
- Severe post-traumatic stress disorders (PTSD)

## Forms and strengths

- 20 mg scored tablet

## **Dosage**

- Depression

Adult: 20 mg once daily at bedtime. In case of insufficient response after 4 weeks, increase up to 40 mg daily max.

- Generalised anxiety, PTSD

Adult: 10 to 20 mg once daily at bedtime

#### **Duration**

- *Depression*: at least 9 months. The treatment should be discontinued gradually (10 mg daily for 2 weeks then, 10 mg on alternate days for 2 weeks). If signs of relapse or withdrawal occur, increase the dose.
- Generalised anxiety, PTSD: 2 to 3 months after symptoms resolve. The treatment should be discontinued gradually (over at least 2 weeks).

- Administer with caution and monitor use in patients with epilepsy, diabetes, hepatic or renal impairment (max. 20 mg daily); history of: gastrointestinal bleeding, bipolar disorders, suicidal ideation or closed-angle glaucoma.
- May cause:
- gastrointestinal disturbances, drowsiness, fatigue, headache, dizziness, seizures, sexual dysfunction, blurred vision, hyponatraemia especially in elderly patients;
- mental disorders: anxiety, insomnia, agitation, aggressive behaviour, suicidal ideation;
- frequent withdrawal symptoms if discontinued abruptly: dizziness, paraesthesia, nightmares, anxiety, tremors and headaches.
- Avoid combination with:
- alcohol (risk of drowsiness); aspirin and NSAIDs (risk of bleeding);
- serotonergic drugs: other selective serotonin re-uptake inhibitors, tricyclic antidepressants (amitriptyline, clomipramine, imipramine), ondansetron, tramadol, etc. (risk of serotonin syndrome).
- Monitor combination with: risperidone (increased plasma concentration), drugs which lower the

seizure threshold (antipsychotics, mefloquine, etc.).

- <u>Pregnancy</u>: re-evaluate whether the treatment is still necessary; if it is continued, avoid paroxetine and use sertraline.
- Breast-feeding: no contra-indication

#### Remarks

- It is necessary to wait at least 2 to 3 weeks before assessing the antidepressant effect. This must be explained to the patient.
- <u>Storage</u>: below 25 °C **//** <del>↑</del>

# **PHENOBARBITAL** oral

Prescription under medical supervision



## Therapeutic action

- Anticonvulsant, sedative and hypnotic

#### **Indications**

- Epilepsy: tonic-clonic (grand mal) and partial (focal) seizures

## Forms and strengths

- 50 mg and 60 mg tablets

## **Dosage**

Follow national protocol.

For information:

- Child: initial dose of 3 to 4 mg/kg once daily or 1.5 to 2 mg/kg 2 times daily, increase to 8 mg/kg daily if necessary
- Adult: initial dose of 2 mg/kg once daily at bedtime (max. 100 mg daily), then, increase gradually if necessary, to the maximum dose of 3 mg/kg 2 times daily or 2 mg/kg 3 times daily

## **Duration**

- According to clinical response

- Do not administer in respiratory depression.
- May cause: drowsiness, depression of the central nervous system.
- Do not stop treatment abruptly.
- Risk of increased sedation when combined with alcohol and drugs acting on the central nervous system such as diazepam, chlorphenamine, chlorpromazine, etc.
- Phenobarbital reduces the effectiveness of implants and oral contraceptives: use an intrauterine device (copper or levonorgestrel) or a progestogen-only injectable (medroxyprogesterone).

- Pregnancy: avoid
- Breast-feeding: avoid

#### Remarks

- Phenobarbital is subject to international controls: follow national regulations.
- Plasma-concentrations are stable after 2 to 3 weeks. Caution: risk of accumulation.
- If necessary, phenytoin may be combined with phenobarbital.
- Also comes in 15 mg to 100 mg tablets.
- Storage: below 25 °C V

# PHENOXYMETHYLPENICILLIN = PENICILLIN V oral

Prescription under medical supervision

## Therapeutic action

- Penicillin antibacterial

## **Indications**

- Streptococcal tonsillitis, scarlet fever
- Completion treatment following parenteral therapy with penicillin

## Forms and strengths

- 250 mg tablet (400 000 IU)
- Powder for oral suspension, 125 mg/5 ml (200 000 IU/5 ml), to be reconstituted with filtered water

## **Dosage**

- Child under 1 year: 125 mg 2 times daily
- Child 1 to < 6 years: 250 mg 2 times daily
- Child 6 to < 12 years: 500 mg 2 times daily
- Child 12 years and over and adult: 1 g 2 times daily

Age	Weight	125 mg/5 ml oral susp.	250 mg tablet
< 1 year	< 10 kg	1 tsp x 2	-
1 to < 6 years	10 to < 21 kg	2 tsp x 2	-
6 to < 12 years	21 to < 39 kg	4 tsp x 2	2 tab x 2
≥ 12 years and adult	≥ 39 kg	-	4 tab x 2

#### **Duration**

- Streptococcal tonsillitis, scarlet fever. 10 days

## Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to penicillin.
- Administer with caution to patients with allergy to cephalosporin (cross-sensitivity may occur) or severe renal impairment (reduce dose).
- May cause: diarrhea, nausea; allergic reactions sometimes severe.
- Do not combine with methotrexate.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Take between meals.
- Also comes in 250 mg/5 ml (400 000 IU/5 ml) oral solution.
- <u>Storage</u>: below 25 °C  **7** − <del>↑</del>

For the oral suspension (powder or reconstituted suspension): follow manufacturer's instructions.

# **PHENYTOIN** oral

Prescription under medical supervision



## Therapeutic action

- Anticonvulsant

## **Indications**

- Epilepsy, except absence seizure (petit mal)

## Forms and strengths

- 100 mg tablet

## **Dosage**

- Child 1 month to < 12 years: initially 1.5 to 2.5 mg/kg 2 times daily. According to response, increase up to 2 to 4 mg/kg 2 times daily (max. 7.5 mg/kg 2 times daily or 300 mg daily).
- Child 12 years and over: initially 75 to 150 mg 2 times daily. According to response, increase up to 150 to 200 mg 2 times daily (max. 300 mg 2 times daily).
- Adult: initially 75 to 150 mg 2 times daily. According to response, increase up to 200 to 500 mg daily (max. 600 mg daily).

### **Duration**

- According to clinical response

## Contra-indications, adverse effects, precautions

- Do not administer in case of hypersensitivity to phenytoin.
- May cause:
- gastro-intestinal disturbances: gingival hypertrophy, nausea, vomiting;
- blood disorders: monitor blood counts if possible and administer folic acid in case of prolonged use;
- neurological disorders: dizziness, visual disturbances, mental confusion;
- allergic reactions: cutaneous eruption, fever, adenopathy.
- Do not stop treatment abruptly, decrease daily doses gradually.
- It is not recommended to combine phenytoin with oral contraceptives, sulphonamides or chloramphenicol. Combination with many other drugs must be closely monitored (diazepam, phenobarbital, digoxin, corticosteroids, etc.).
- Pregnancy: avoid
- Breast-feeding: avoid

#### Remarks

- <u>Storage</u>: below 25 °C - **//** Never use phenytoin after expiry date (risk of underdosage).

# POTASSIUM CHLORIDE immediate-release oral

Prescription under medical supervision



## Therapeutic action

- Potassium supplement, when immediate effect is required

### **Indications**

- Treatment of moderate hypokalaemia

## Forms and strengths

- 7.5% potassium chloride syrup (1 mmol of K<sup>+</sup>/ml)

## Dosage

- Child under 45 kg: 2 mmol/kg (2 ml/kg) daily (see table below)
- Child 45 kg and over and adult: 30 mmol (30 ml) 3 times daily

Age	Weight	7.5% syrup	
< 2 months	< 5 kg	4 ml x 2	
2 months to < 1 year	5 to < 10 kg	6 ml x 2	

1 to < 3 years	10 to < 15 kg	12 ml x 2
3 to < 5 years	15 to < 20 kg	20 ml x 2
5 to < 7 years	20 to < 25 kg	25 ml x 2
7 to < 9 years	25 to < 30 kg	20 ml x 3
9 to < 13 years	30 to < 45 kg	25 ml x 3
≥ 13 years and adult	≥ 45 kg	30 ml x 3

#### **Duration**

– According to clinical response. Treatment of 1 to 2 days is typically sufficient when the patient is fully able to drink oral rehydration solution and can eat.

## Contra-indications, adverse effects, precautions

- Reduce dosage in elderly patients and patients with renal impairment (risk of hyperkalaemia).
- Do not combine with spironolactone and angiotensin-converting-enzyme inhibitors (e.g. enalapril).
- May cause: gastrointestinal ulcerations, diarrhoea, nausea and vomiting, rarely hyperkalaemia.
- Administer with caution in patients with gastrointestinal ulcer (risk of gastrointestinal ulcerations).
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Take with or at the end meals in order to reduce the risk of gastrointestinal ulcerations.
- Hypokalaemia is defined as a serum potassium concentration below 3.5 mmol/litre.
- Storage: below 25 °C

# POTASSIUM CHLORIDE sustained-release oral

Prescription under medical supervision

## Therapeutic action

- Potassium supplement

## **Indications**

- Hypokalaemia induced by:
- thiazide diuretics (e.g. hydrochlorothiazide)
- loop diuretics (e.g. furosemide)

## Forms and strengths

- 600 mg potassium chloride sustained-release tablet (8 mmol of K<sup>+</sup>)

## **Dosage**

- Adult: 15 to 25 mmol daily = 1 tablet 2 to 3 times daily
- Do not exceed indicated doses if potassium serum levels cannot be measured.

#### **Duration**

- According to clinical response and duration of diuretic treatment

## Contra-indications, adverse effects, precautions

- Administer with caution and reduce dosage in elderly patients and in patients with renal impairment (risk of hyperkalaemia).
- Do not combine with spironolactone and angiotensin-converting-enzyme inhibitors (e.g. enalapril).
- May cause: hyperkalaemia, gastroduodenal ulcerations, diarrhoea, nausea and vomiting.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Take with or at the end meals in order to reduce the risk of gastrointestinal ulcerations.
- Hypokalaemia is defined as a serum potassium concentration below 3.5 mmol/litre.
- If tablets are not available, a lack of potassium may be corrected by a diet rich in dates, bananas, mangos, oranges, tomatoes, etc.
- <u>Storage</u>: below 25 °C Ţ

# **PRAZIQUANTEL** oral

Prescription under medical supervision

## Therapeutic action

- Anthelminthic

## **Indications**

- Urinary (*S. haematobium*) and intestinal (*S. mansoni, S. japonicum, S. mekongi, S. intercalatum*) schistosomiasis
- Taeniasis (T. saginata, T. solium, D. latum, H. nana)
- Pulmonary (P. westermani), hepatobiliary (O. felineus, O. viverrini, C. sinensis) and intestinal (F. buski, H. heterophyes, M. yokogawai) flukes

## Forms and strengths

- 600 mg breakable tablet

## Dosage and duration

Child 4 years and over and adult:

- Schistosomiasis
- *S. haematobium, S. mansoni, S. intercalatum*: 40 mg/kg single dose or 2 doses of 20 mg/kg administered 4 hours apart
- S. japonicum, S. mekongi: 2 doses of 30 mg/kg or 3 doses of 20 mg/kg administered 4 hours apart
- Taeniase
- T. saginata, T. solium, D. latum: 5 to 10 mg/kg single dose
- H. nana: 15 to 25 mg/kg single dose
- Fluke infections
- lung and hepatobiliary: 25 mg/kg 3 times daily for 2 days
- intestinal: 25 mg/kg 3 times daily, 1 day

## Contra-indications, adverse effects, precautions

- Do not administer to patients with ocular cysticercosis.
- May cause:
- drowsiness, headache, gastrointestinal disturbances, dizziness; rarely: allergic reactions;
- neurological disorders (headache, seizures) in patients with undiagnosed neuro cysticercosis.
- <u>Pregnancy</u>: no contra-indication for the treatment of schistosomiasis and taeniasis. If immediate treatment not considered essential for fluke infections, it should be delayed until after delivery.
- Breast-feeding: no contra-indication

#### Remarks

- Do not chew the tablets due to their bitter taste. Take during meals.
- Praziquantel is not active against certain liver flukes (*Fasciola hepatica* and *gigantica*). For this indication, use triclabendazole.
- Storage: below 30 °C ✓

## PREDNISOLONE and PREDNISONE oral

Prescription under medical supervision

## Therapeutic action

- Steroidal anti-inflammatory drug (corticosteroid)

### **Indications**

- Symptomatic treatment of allergic and inflammatory diseases or reactions, e.g.:
- Pneumocystis carinii (jiroveci) pneumonia with severe hypoxia
- Certain severe forms of extra-pulmonary tuberculosis
- Severe immune reconstitution syndrome, following initiation of antiretroviral or anti tuberculous treatment
- Leprosy reactions
- Severe persistent asthma, in the event of treatment failure with high doses of inhaled corticoids

- Prevention of inflammatory reaction triggered by antiparasitic treatment (e.g. trichinellosis)

## Forms and strengths

- 5 mg tablet

## **Dosage**

The dose depends on indication, patient's response and tolerance. If treatment lasts over 10 days, a high initial dose should be reduced as quickly as possible to the lowest effective maintenance dose.

- Child:
- Initial dose: 0.5 to 2 mg/kg once daily
- Maintenance dose: 0.25 to 0.5 mg/kg once daily
- Adult:
- Initial dose: 20 to 70 mg once daily
- maintenance dose: 5 to 15 mg once daily
- Administer preferably in the morning, with food.

#### **Duration**

– According to indication and clinical response. If the treatment lasts more than 3 weeks: do not stop abruptly, reduce the daily dose gradually.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with active peptic ulcer (except if ulcer under treatment); infections not controlled by a specific treatment; acute viral infection (e.g. hepatitis, herpes simplex or zoster).
- May cause (prolonged treatment with high doses): adrenal suppression, muscle atrophy, growth retardation, increased susceptibility to infections, hypokalaemia, sodium and water retention (oedema and hypertension), osteoporosis.
- In the event of acute adrenal failure, use IV hydrocortisone.
- <u>Pregnancy</u>: no contra-indication
- <u>Breast-feeding</u>: no contra-indication; take tablets just after a feed and wait 4 hours before the next feed if possible.

#### Remarks

- 5 mg of prednisolone has the same anti-inflammatory activity as 5 mg of prednisone, 0.75 mg of dexamethasone and 20 mg of hydrocortisone.
- Storage: below 25 °C V

# **PROMETHAZINE** oral

Prescription under medical supervision

## Therapeutic action

- Sedating H1 antihistamine

#### **Indications**

- Insomnia

## Forms and strengths

- 25 mg tablet

## **Dosage**

- Adult: 25 mg once daily at bedtime

#### **Duration**

- As short as possible (max. 10 days)

## Contra-indications, adverse effects, precautions

- Administer with caution and monitor use:
- in elderly patients;
- in patients with prostate disorders, closed-angle glaucoma, epilepsy, orthostatic hypotension, severe renal or hepatic impairment;
- in patients taking central nervous system depressants (opioid analgesics, antipsychotics, sedatives, antidepressants, etc.) or drugs known to have an anticholinergic effect (atropine, amitriptyline, chlorpromazine, etc.).
- May cause:
- drowsiness, dizziness, headache, confusion, hypotension, photosensitivity (protect skin from sun exposure);
- anticholinergic effects (dry mouth, constipation, blurred vision, tachycardia, disorders of micturition);
- rarely: seizures, extrapyramidal symptoms, neuroleptic malignant syndrome (unexplained hyperthermia with neuromuscular disorders), allergic reactions.
- Avoid alcohol during treatment.
- Pregnancy and breast-feeding: avoid

#### Remarks

- Storage: below 25 °C - ✓ - 🗍

# **PYRANTEL** oral

# Therapeutic action

Anthelminthic

## **Indications**

- Ascariasis
- Enterobiasis
- Ancylostomiasis
- Trichinellosis

## Forms and strengths

- 250 mg pyrantel embonate chewable tablet
- Oral suspension, 50 mg pyrantel embonate per ml

## **Dosage and duration**

– Ascariasis

Child and adult: 10 mg/kg single dose

- Enterobiasis

Child and adult: 10 mg/kg single dose followed by a second dose after 2 to 4 weeks

- Ancylostomiasis

Child and adult: 10 mg/kg single dose; in severe infection, 10 mg/kg once daily for 4 days

- Trichinellosis

Child and adult: 10 mg/kg once daily for 5 days

## Contra-indications, adverse effects, precautions

- May cause: gastrointestinal disturbances, headache, dizziness, drowsiness, skin rash.
- Reduce dosage in patients with hepatic impairment.
- <u>Pregnancy</u>: avoid during the first trimester
- Breast-feeding: no contra-indication

#### Remarks

- Preferably use albendazole or mebendazole for these indications. However, when these drugs are contra-indicated, e.g. in children under one year, pyrantel is an alternative.
- Storage: below 25 °C ₩

# **PYRAZINAMIDE** = **Z** oral

Prescription under medical supervision

## Therapeutic action

- First line antituberculous antibacterial (sterilising and bactericidal activity)

## **Indications**

- Tuberculosis, in combination with other antituberculous antibacterials

## Forms and strengths

- 400 mg tablet

## **Dosage**

- Child under 30 kg: 35 mg/kg (30 to 40 mg/kg) once daily
- Child over 30 kg and adult: 25 mg/kg (20 to 30 mg/kg) once daily
- Maximum dose: 2 g daily

#### **Duration**

- According to protocol

## Contra-indications, adverse effects, precautions

- Do not administer to patients with hypersensitivity to pyrazinamide, severe hepatic impairment or severe gout.
- Reduce the dose in patients with renal impairment (25 mg/kg/dose 3 times weekly).
- May cause: gout and arthralgias, hepatic disorders (jaundice), photosensitivity (limit sun exposure), rash, gastrointestinal disturbances, hypersensitivity reactions.
- If signs of hepatotoxicity (e.g. jaundice) develop, pyrazinamide should be discontinued until symptoms resolve.
- <u>Pregnancy</u>: safety of pyrazinamide in the first trimester is not definitely established. However, given the severity of the disease, it may be used during pregnancy.
- Breast-feeding: no contra-indication

#### Remarks

- For patients on first-line antituberculous treatment, pyrazinamide is given as part of a fixed dose combination (isoniazid+rifampicin+pyrazinamide+ethambutol or isoniazid+ rifampicin+ pyrazinamide).
- Storage: below 25 °C ♥ Ť

# **PYRIDOXINE = VITAMIN B6 oral**

## Therapeutic action

- Vitamin

## **Indications**

- Prevention and treatment of isoniazid-induced peripheral neuropathy

# Forms and strengths

- 25 mg tabletAlso comes in 10 mg and 50 mg tablets.

## Dosage

Prevention of isoniazid neuropathy
 Child under 5 kg: 5 mg once daily
 Child over 5 kg and adult: 10 mg once daily

- Treatment of isoniazid neuropathy

Child: 50 mg once daily Adult: 50 mg 3 times daily

#### **Duration**

- Prevention: as long as treatment with isoniazid continues.
- *Treatment*: according to clinical response (in general, ≤ 3 weeks) then, preventive dose, as long as treatment with isoniazid continues.

## Contra-indications, adverse effects, precautions

- No contra-indication.
- May cause: peripheral neuropathy in the event of prolonged use with doses ≥ 200 mg daily.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- In children receiving isoniazid prophylaxis or treatment for tuberculosis: concomitant administration of pyridoxine at preventive dosage is recommended for children under 5 years and all children infected with HIV.
- Pyridoxine is also used for the prevention and treatment of cycloserin-induced neuropathy (150 to 200 mg daily in adults, in divided doses).
- <u>Storage</u>: below 25 °C 🖊

# **PYRIMETHAMINE** oral

Prescription under medical supervision



## Therapeutic action

- Antiprotozoal

## **Indications**

- Treatment and secondary prophylaxis of toxoplasmosis in immunodeficient patients, in combination with sulfadiazine or clindamycin
- Primary prophylaxis of toxoplasmosis in immunodeficient patients, in combination with dapsone (only if co-trimoxazole cannot be used)
- Second-line treatment of isosporiasis in immunodeficient patients (only if co-trimoxazole cannot be used)

## Forms and strengths

- 25 mg tablet

## **Dosage and duration**

- Treatment of toxoplasmosis

Adult: 2 doses of 100 mg on D1, then 75 to 100 mg once daily for at least 6 weeks

- Secondary prophylaxis of toxoplasmosis

Adult: 25 to 50 mg once daily, as long as necessary

- Primary prophylaxis of toxoplasmosis

Adult: 50 to 75 mg once weekly, as long as necessary

- Treatment of isosporiasis

Adult: 50 to 75 mg once daily for 10 days

# Contra-indications, adverse effects, precautions

- Do not administer to patients with severe renal or hepatic impairment.
- May cause: gastrointestinal disturbances, seizures, leucopenia, thrombocytopenia, megaloblastic anaemia due to folic acid deficiency.
- Administer calcium folinate to prevent folic acid deficiency.
- Avoid if possible combination with other folate antagonists: co-trimoxazole, methotrexate (increased risk of folic acid deficiency).
- Monitor combination with zidovudine (increased risk of zidovudine-associated haematotoxicity).
- <u>Pregnancy</u>: **CONTRA-INDICATED** during the first trimester
- <u>Breast-feeding</u>: no contra-indication; however avoid concomitant administration of other folate antagonists.

#### Remarks

- The combination of sulfadoxine/pyrimethmine is used for the treatment of uncomplicated falciparum malaria.
- Storage: below 25 °C

# **QUININE** oral

Prescription under medical supervision

## Therapeutic action

- Antimalarial

## **Indications**

- Treatment of uncomplicated falciparum malaria, when artemisinin-based combinations cannot be used
- Completion treatment following parenteral therapy with quinine for severe falciparum malaria, when artemisinin-based combinations cannot be used

# Forms and strengths

- 300 mg quinine sulfate tablet

# Dosage and duration

Dosage is expressed in terms of salt. Except for quinine bisulfate, the dosage is the same for all quinine salts (sulfate, hydrochloride, dihydrochloride):

- Child and adult < 50 kg: 10 mg/kg 3 times daily at 8-hour intervals for 7 days
- Adult ≥ 50 kg: 600 mg 3 times daily at 8-hour intervals for 7 days

Age	Weight	300 mg tablet
5 months to < 2 years	7 to < 12 kg	1/4 tab x 3
2 to < 8 years	12 to < 25 kg	½ tab x 3
8 to < 11 years	25 to < 35 kg	1 tab x 3
11 to < 14 years	35 to < 50 kg	1½ tab x 3
≥ 14 years	≥ 50 kg	2 tab x 3

# Contra-indications, adverse effects, precautions

- May cause: headache, skin rash; visual, auditory and gastrointestinal disturbances.
- Do not exceed indicated doses: risk of toxicity in the event of overdose.
- Avoid combination with drugs that prolong QT interval: amiodarone, other antimalarials, antipsychotics, fluconazole, fluoroquinolones, hydroxyzine, macrolides, ondansetron, etc.
- If the patient vomits within 30 minutes after administration, re-administer the full dose. If the patient vomits between 30 minutes and 1 hour after administration, re-administer half of the dose.
- <u>Pregnancy</u>: no contra-indication; it is recommended to administer quinine in combination with clindamycin if possible.
- Breast-feeding: no contra-indication

#### Remarks

- 10 mg of quinine sulfate or hydrochloride or dihydrochloride = 8 mg of quinine base; 14 mg of quinine bisulfate = 8 mg of quinine base.
- Storage: below 25 °C 7

# ReSoMal (REhydration SOlution for MALnutrition) oral

Prescription under medical supervision

# Therapeutic action

- Oral rehydration salts with high potassium and low sodium contents

## **Indications**

- Prevention and treatment of dehydration, in patients suffering from complicated acute malnutrition only

# Forms and strengths

– Sachet containing 84 g of powder, to be diluted in 2 litres of clean, boiled and cooled water Composition for one litre:

	mmol/litre	mmol/litre		
Glucose	55	Citrate	7	
Saccharose	73	Magnesium	3	
Sodium	45	Zinc	0.3	
Potassium	40	Copper	0.045	
Chloride	70	Osmolarity	294 mEq/litre	

# **Dosage and duration**

- Prevention of dehydration

Child under 2 years: 50 to 100 ml after each loose stool as long as diarrhoea persists Child over 2 years: 100 to 200 ml after each loose stool as long as diarrhoea persists Adult: 200 to 400 ml after each loose stool as long as diarrhoea persists

- Treatment of dehydration

Child and adult: 5 ml/kg every 30 minutes over the first 2 hours, then 5 to 10 ml/kg/hour for the next 4 to 10 hours, until dehydration is corrected.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with cholera or uncomplicated acute malnutrition: use standard ORS instead.
- May cause: heart failure when administered too rapidly. During treatment, closely monitor the rate of administration in order to avoid overhydration. Increase in respiratory and pulse rates and appearance or increase of oedema are signs of over rapid rehydration. In this event, stop ReSoMal for one hour then reassess the patient's condition.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

## Remarks

- <u>Storage</u>: below 25 °C - N -  $\tilde{T}$ Do not use the powder if it has turned sticky. Once prepared, the solution should be used within 24 hours.

# **RETINOL = VITAMIN A oral**

# Therapeutic action

- Vitamin

## **Indications**

- Prevention of vitamin A deficiency
- Treatment of vitamin A deficiency (xerophthalmia)

# Forms and strengths

- 200 000 IU capsule, i.e. about 8 drops (1 drop = 25 000 IU)

# **Dosage and duration**

- Prevention of vitamin A deficiency

Child under 6 months: 50 000 IU single dose

Child from 6 to 12 months: one dose of 100 000 IU every 4 to 6 months

Child over 1 year: one dose of 200 000 IU every 4 to 6 months

- Treatment of vitamin A deficiency

Child under 6 months: 50 000 IU once daily on D1, D2 and D8 (or D15) Child from 6 to 12 months: 100 000 IU once daily on D1, D2 and D8 (or D15) Child over 1 year and adult: 200 000 IU once daily on D1, D2 and D8 (or D15)

	200 000 IU capsule		
Age	Prevention	Treatment	
< 6 months	2 drops	2 drops	
6 months to < 1 year	4 drops	4 drops	
1 to < 5 years	1 cap	1 cap	
≥5 years and adult	-	1 сар	

# Contra-indications, adverse effects, precautions

- Do not exceed indicated doses.
- Overdosage may cause: gastrointestinal disturbances, headache, raised intracranial pressure (bulging fontanelle in infants); foetal abnormalities.
- Pregnancy:

Prevention: after delivery only, 200 000 IU single dose

Treatment: dosage depends on severity of eye lesions:

- Night blindness and Bitot's spots: 10 000 IU once daily or 25 000 IU once weekly for at least 4 weeks
- Corneal lesion: 200 000 IU once daily on D1, D2 and D8 (or D15)
- <u>Breast-feeding</u>: no contra-indication at recommended doses

- Do not swallow the capsule. Cut open the end of the capsule and squeeze the dose directly into the mouth.
- Administer routinely 2 doses (on D1 and D2) to children suffering from measles to prevent the complications of measles.
- Storage: below 25°C 🌽

# **RIFAMPICIN** = R oral

Prescription under medical supervision

# Therapeutic action

- Antibacterial, first line antituberculous antibacterial (sterilising and bactericidal activity), antileprotic antibacterial (bactericidal activity)

## **Indications**

- Tuberculosis, in combination with other antituberculous antibacterials
- Paucibacillary and multibacillary leprosy, in combination with dapsone and clofazimine
- Brucellosis, in combination with another antibacterial

# Forms and strengths

- 150 mg and 300 mg tablets or capsules

## **Dosage**

- Tuberculosis

Child under 30 kg: 15 mg/kg (10 to 20 mg/kg) once daily, on an empty stomach Child over 30 kg and adult: 10 mg/kg (8 to 12 mg/kg) once daily, on an empty stomach (max. 600 mg daily)

- Paucibacillary and multibacillary leprosy

Child under 10 years: 10 mg/kg once monthly, on an empty stomach Child from 10 to 14 years: 450 mg once monthly, on an empty stomach Child 15 years and over and adult: 600 mg once monthly, on an empty stomach

- Brucellosis

Child: 15 to 20 mg/kg once daily, on an empty stomach (max. 600 mg daily) Adult: 600 to 900 mg once daily, on an empty stomach

## **Duration**

- *Tuberculosis*: according to protocol; *paucibacillary leprosy*: 6 months; *multibacillary leprosy*: 12 months; *brucellosis*: 6 weeks

# Contra-indications, adverse effects, precautions

- Do not administer to patients with jaundice, hypersensitivity to rifamycins or history of severe haematological disorders (thrombocytopenia, purpura) during a previous treatment with rifamycins.
- Avoid or administer with caution to patients with hepatic impairment (do not exceed 8 mg/kg daily).
- May cause:
- orange-red discoloration of body secretions (urine, tears, saliva, sputum, sweat, etc.), normal, harmless;
- gastrointestinal disturbances, headache, drowsiness, hepatic disorders;
- influenza-like symptoms (more frequent when treatment is not taken regularly);
- thrombocytopenia, hypersensitivity reactions.
- If signs of hepatotoxicity (e.g. jaundice) develop, rifampicin should be discontinued until symptoms resolve.

- In patients taking nevirapine, indinavir, nelfinavir, lopinavir/ritonavir, atazanavir/ritonavir, use rifabutin in place of rifampin.
- Rifampicin reduces the effect of many drugs (antimicrobials, some hormones, antidiabetics, corticoids, phenytoin, etc.):
- In women, use a non-hormonal contraception or injectable medroxyprogesterone or, as a last resort, use an oral contraceptive containing 50 micrograms ethinylestradiol per tablet.
- In the event of concomitant fluconazole administration, administer each drug 12 hours apart (rifampicin in the morning, fluconazole in the evening).
- For the other drugs, adjust dosage if necessary.
- <u>Pregnancy</u>: no contra-indication. Risk of maternal and neonatal bleeding disorders when the mother receives rifampicin in late pregnancy: administer phytomenadione (vitamin K) to the mother and the newborn to reduce the risk.
- Breast-feeding: no contra-indication

#### Remarks

- For patients sensitive to first-line antituberculous treatment, rifampicin is given as part of a fixed dose combination (isoniazid + rifampicin + pyrazinamide + ethambutol or isoniazid + rifampicin + pyrazinamide or isoniazid + rifampicin).
- Storage: below 25 °C ₩ 🕆

# **RISPERIDONE** oral

Prescription under medical supervision



# Therapeutic action

- Atypical antipsychotic

## **Indications**

- Acute or chronic psychosis
- Acute moderate to severe manic episode

## Forms and strengths

- 1 mg and 2 mg tablets

## **Dosage**

- Acute or chronic psychosis

Adult: 1 mg 2 times daily. Gradually increase up to 3 mg 2 times daily if necessary (max. 10 mg daily).

- Acute moderate to severe manic episode

Adult: 2 mg once daily; increase in increments of 1 mg daily if necessary (max. 6 mg daily).

- Reduce the doses by half (initial dose and increments) in elderly patients and in patients with hepatic or renal impairment (max. 4 mg daily).

#### **Duration**

– *Acute psychosis*: minimum 3 months; *chronic psychosis*: minimum one year; *manic episode*: 3 to 6 weeks. The treatment should be discontinued gradually (over 4 weeks). If signs of relapse occur, increase the dose.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with cardiac disorders (heart failure, recent myocardial infarction, conduction disorders, bradycardia, etc.), dementia (e.g. Alzheimer's disease), Parkinson's disease and history of neuroleptic malignant syndrome.
- Administer with caution and carefully monitor use in elderly patients, patients with hypokalaemia, hypotension, renal or hepatic impairment, history of seizures.
- May cause: drowsiness, insomnia, headache, extrapyramidal symptoms, agitation, anxiety, orthostatic hypotension, weight gain, hyperprolactinaemia, sexual dysfunction; neuroleptic malignant syndrome (unexplained hyperthermia with neuromuscular disorders), rare but requiring immediate treatment discontinuation.
- In the event of extrapyramidal symptoms, combine with biperiden or trihexyphenidyl.
- Avoid or monitor combination with:
- central nervous system depressants (opioid analgesics, sedatives, H1 antihistamines, etc.);
- fluoxetine, paroxetine, sertraline, verapamil (increased plasma concentrations of risperidone);
- carbamazepine, rifampicin, phenobarbital, phenytoin (decreased plasma concentrations of risperidone);
- antihypertensive drugs (risk of hypotension); drugs that prolong the QT interval (amiodarone, chloroquine, erythromycin, fluconazole, mefloquine, pentamidine, quinine, etc.).
- Avoid alcohol during treatment.
- <u>Pregnancy</u>: re-evaluate whether the treatment is still necessary; if it is continued, monitor the neonate the first few days (risk of hypertonia, tremors, sedation).
- Breast-feeding: if absolutely necessary, do not exceed 6 mg daily.

#### Remarks

− <u>Storage</u>: below 25 °C -

# RITONAVIR = RTV oral

Prescription under medical supervision

## Therapeutic action

- Antiretroviral, HIV protease inhibitor

## **Indications**

– Booster for protease inhibitors (atazanavir, darunavir, etc.) in HIV infection. Ritonavir should not be used alone.

# Forms and strengths

- 25 mg and 100 mg tablets
- 80 mg/ml oral solution, containing 43% alcohol (v/v), with a graduated syringe for oral administration Also comes in fixed dose combinations containing ritonavir.

## **Dosage**

Dosage depends on the administration schedule of the boosted protease inhibitor.

- Child 10 to < 14 kg: 40 mg 2 times daily
- Child 14 to < 25 kg: 50 mg 2 times daily or 100 mg once daily
- Child ≥ 25 kg and adult: 100 mg once or 2 times daily

Weight	80 mg/ml oral sol.*	25 mg tab	100 mg tab
10 to < 14 kg	0.5 ml x 2	-	-
14 to < 25 kg	0.6 ml x 2 or 1.25 ml x 1	2 tab x 2 or 4 tab x 1	-
≥ 25 kg and adult	-	_	1 tab x 1 or 2

<sup>\*</sup> For doses less than 0.8 ml, use a 1 ml syringe graduated 0.01 ml.

## **Duration**

– The duration of treatment depends on the efficacy and tolerance of the boosted protease inhibitor and ritonavir.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with severe hepatic impairment.
- Administer with caution and monitor use in patients with haemophilia (increased bleeding).
- The adverse effects of ritonavir as a booster are also dependent on the boosted protease inhibitor.
- May cause:
- gastrointestinal disturbances, fatigue, headache, dizziness, paraesthesia, joint and muscle pain, hyperglycaemia, lipodystrophy, conduction disorders;
- pancreatitis, hepatic disorders, skin rash sometimes severe; in this event, stop treatment immediately.
- Administer with caution and monitor combination with metronidazole when using oral solution of ritonavir that contains alcohol (risk of antabuse reaction).
- Ritonavir reduces the efficacy of oral contraceptives.
- Pregnancy: CONTRA-INDICATED for oral solution; no contra-indication for tablets

## **Remarks**

- Take with meals.
- The oral solution has a bitter taste.
- Storage: below 25 °C ₩ Ť

Do not refrigerate or freeze the oral solution.

# SALBUTAMOL = ALBUTEROL aerosol

Prescription under medical supervision

# Therapeutic action

- Short-acting bronchodilator

## **Indications**

- Symptomatic treatment of asthma attack

# Forms and strengths

- Solution for inhalation in pressurised metered dose inhaler, 100 micrograms/puff

## **Dosage**

Dosage depends on the severity of attack and patient's response. For information :

- 2 to 4 puffs (up to 10 puffs depending on severity) every 10 to 30 minutes

# Administration technique

- Shake the inhaler.
- Breathe out as completely as possible. Place the lips tightly around the mouthpiece. Inhale deeply while activating the inhaler. Hold breath 10 seconds before exhaling.
- Co-ordination between the hand and inhalation is very difficult in children under 6 years, elderly patients and patients with severe dyspnoea. Use a spacer to facilitate administration and improve the efficacy of treatment.

## Contra-indications, adverse effects, precautions

- May cause: headache, tremor and tachycardia.
- In the event of bronchial infection, administer simultaneously with appropriate antibacterial treatment.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

- Clean the mouthpiece before and after each use.
- Do not pierce or incinerate used aerosol containers. Empty all residual gas, then bury.
- Storage: below 25°C 🌽

# SALBUTAMOL = ALBUTEROL nebuliser solution

Prescription under medical supervision

# Therapeutic action

- Short-acting bronchodilator

## **Indications**

- Symptomatic treatment of severe acute bronchospasm, e.g. in severe acute asthma attack

# Forms and strengths

- Solution for inhalation, in unit dose vial of 5 mg in 2.5 ml (2 mg/ml), to be administered via a nebuliser

# **Dosage and duration**

- Child under 5 years or under 15 kg: 2.5 mg (1.25 ml) per nebulisation, to be repeated every 20 to 30 minutes if necessary
- Child 5 years and over and adult: 2.5 to 5 mg (1.25 to 2.5 ml) per nebulisation, to be repeated every 20 to 30 minutes if necessary

# Contra-indications, adverse effects, precautions

- May cause: headache, tremor, tachycardia, hyperglycaemia; hypokalaemia (after large doses).
- Never use nebuliser solution by the parenteral route.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Nebulised salbutamol should be reserved for severe acute asthma attacks. Otherwise, salbutamol should be delivered via a metered-dose inhaler with a spacer: administration is easier and faster, the treatment is as effective, or even more effective, than with a nebuliser and causes fewer adverse effects.

   Volumes of nebuliser solution to be administered are insufficient to obtain efficient nebulisation in
- Volumes of nebuliser solution to be administered are insufficient to obtain efficient nebulisation in most nebulisers: dilute salbutamol solution with 0.9% sodium chloride to obtain a total volume of 4 ml in the reservoir of the nebuliser. Stop the nebulisation when the reservoir is empty (± 10-15 minutes).
- <u>Storage</u>: below 25 °C 🎾

# SERTRALINE oral

Prescription under medical supervision



# Therapeutic action

- Antidepressant, selective serotonin re-uptake inhibitor (SSRI)

## **Indications**

- Major depression, if fluoxetine or paroxetine poorly tolerated or contra-indicated
- Severe post-traumatic stress disorder (PTSD)

# Forms and strengths

- 50 mg and 100 mg tablets

## **Dosage**

– Adult: 50 mg once daily with a meal. If case of insufficient response after 4 weeks, increase to 100 mg daily max.

## **Duration**

- *Depression*: at least 9 months. Treatment should be discontinued gradually (50 mg on alternate days for 4 weeks). If signs of relapse or withdrawal occur, increase the dose.
- *PTSD*: 2 to 3 months after symptoms resolve. Stop gradually (over at least 2 weeks).

# Contra-indications, adverse effects, precautions

- Do not administer to patients with severe hepatic impairment. Reduce the dose by half in patients with mild to moderate hepatic impairment.
- Administer with caution and monitor use in patients with epilepsy, diabetes; history of: gastrointestinal bleeding, bipolar disorders, suicidal ideation, or closed-angle glaucoma.
- May cause:
- gastrointestinal disturbances, drowsiness, fatigue, headache, dizziness, seizures, sexual dysfunction, blurred vision, hyponatraemia especially in elderly patients;
- mental disorders: anxiety, insomnia, agitation, aggressive behaviour, suicidal ideation;
- withdrawal symptoms very frequent if discontinued abruptly: dizziness, paraesthesia, nightmares, anxiety, tremors and headaches.
- Avoid combination with:
- alcohol (risk of drowsiness); aspirin and NSAIDs (risk of bleeding);
- serotonergic drugs: other selective serotonin re-uptake inhibitors, tricyclic antidepressants (amitriptyline, clomipramine, imipramine), ondansetron, tramadol, etc. (risk of serotonin syndrome).
- Monitor combination with: risperidone (increased plasma concentration), drugs which lower the seizure threshold (antipsychotics, mefloquine, etc.).
- <u>Pregnancy</u>: re-evaluate whether the treatment is still necessary; if it is continued, observe the neonate (risk of agitation, tremors, hypotony, respiratory difficulties, sleeping disorders, etc.) if the mother was under treatment in the 3<sup>rd</sup> trimester.
- Breast-feeding: no contra-indication. Prefer paroxetine.

- It is necessary to wait at least 2 to 3 weeks before assessing the antidepressant effect. This must be explained to the patient.
- <u>Storage</u>: below 25 °C 💋 🖣

# SODIUM VALPROATE oral

See VALPROIC acid oral(see page 167)

# SOFOSBUVIR = SOF oral

Prescription under medical supervision

# Therapeutic action

- Direct-acting antiviral (NS5B polymerase inhibitor)

#### **Indications**

- Treatment of chronic hepatitis C, in combination with daclastasvir or other antivirals

# Forms and strengths

- 400 mg tablet

# **Dosage and duration**

- Genotypes 1, 2, 4, 5, 6 without cirrhosis or with compensated cirrhosis and genotype 3 without cirrhosis Adult: 400 mg once daily (in combination with daclatasvir) for 12 weeks
- Genotype 3 with compensated cirrhosis

Adult: 400 mg once daily (in combination with daclatasvir) for 24 weeks

- Genotypes 1, 2, 3, 4, 5, 6 with decompensated cirrhosis

Adult: 400 mg once daily (in combination with daclatasvir) for 24 weeks

# Contra-indications, adverse effects, precautions

- Do not use as monotherapy.
- Do not administer to patients with allergy to sofosbuvir.
- May cause: fatigue, headache, insomnia, nausea.
- Administer with caution to patients co-infected with HBV (risk of HBV reactivation).
- Do not combine with: carbamazepine, phenobarbital, phenytoin, rifampicin, rifapentine (decreased sofosbuvir plasma concentrations); amiodarone (risk of severe bradycardia and heart block).
- Closely monitor blood glucose levels in diabetic patients (risk of hypoglycaemia); adjust the antidiabetic treatment if necessary.
- <u>Pregnancy and breast-feeding</u>: **CONTRA-INDICATED** (safety not established)

- Tablets have a bitter taste, they should be swallowed whole (not crushed or chewed), with meals.
- If the patient vomits within 2 hours after administration, take the same dose.
- If the patient misses a dose, the dose should be taken as soon as possible if remembered within 18 hours of the usual time. After 18 hours or more, the dose should be skipped, and the next dose taken at the usual time.

- Also comes in fixed-dose combination tablets containing sofosbuvir/daclatasvir, and sofosbuvir/velpatasvir.
- <u>Storage</u>: below 30 ℃ Ť

# SOFOSBUVIR/VELPATASVIR = SOF/VEL oral

Prescription under medical supervision

# Therapeutic action

– Combination of two direct-acting antivirals: a NS5B polymerase inhibitor (sofosbuvir) and a NS5A inhibitor (velpatasvir)

## **Indications**

- Treatment of chronic hepatitis C

# Forms and strengths

- 400 mg sofosbuvir/100 mg velpatasvir co-formulated tablet

# **Dosage and duration**

- Genotypes 1, 2, 3, 4, 5, 6 with no cirrhosis or compensated cirrhosis Adult: one tablet once daily for 12 weeks
- Genotypes 1, 2, 3, 4, 5, 6 with decompensated cirrhosis Adult: one tablet once daily for 24 weeks

# Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to sofosbuvir or velpatasvir.
- May cause: fatigue, headache, insomnia, nausea, rash.
- Administer with caution to patients co-infected with HBV (risk of HBV reactivation).
- Do not combine with: carbamazepine, phenobarbital, phenytoin, rifampicin, rifabutin, rifapentine, efavirenz, nevirapine, etravirine (decreased sofosbuvir and/or velpatasvir plasma concentrations); amiodarone (risk of severe bradycardia and heart block)
- Administer with caution and monitor combination with: tenofovir, atorvastatin, digoxin (increased plasma concentration of these drugs)
- Do not administer simultaneously with:
- omeprazole: take sofosbuvir/velpatasvir 4 hours before omeprazole, with food;
- antacids (aluminium/magnesium hydroxide, etc.), calcium carbonate: take 4 hours apart.
- Closely monitor blood glucose levels in diabetic patients (risk of hypoglycemia); adjust the antidiabetic treatment if necessary.
- <u>Pregnancy and breast-feeding</u>: **CONTRA-INDICATED** (safety not established)

- Tablets have a bitter taste, they should be swallowed whole (not crushed or chewed), with meals.
- If the patient vomits within 3 hours after administration: take the same dose.
- If the patient misses a dose, the dose should be taken as soon as possible if remembered within 18

hours of the usual time. After 18 hours or more, the dose should be skipped, and the next dose taken at the usual time.

- Storage: below 30 °C - Ť

# SPIRONOLACTONE oral

Prescription under medical supervision

# Therapeutic action

- Potassium-sparing diuretic, antagonist of aldosterone

## **Indications**

- Oedema associated with heart failure, hepatic cirrhosis and nephrotic syndrome

# Forms and strengths

- 25 mg tablet

## **Dosage**

Adjunctive therapy in heart failure
 Adult: 25 mg once daily

Ascites in hepatic cirrhosis
 Adult: 100 to 400 mg daily.

When weight is stable, administer the lowest possible maintenance dose, in order to prevent adverse effects.

- Oedema in nephrotic syndrome

Adult: 100 to 200 mg daily

The daily dose can be administered in 2 to 3 divided doses or once daily.

## **Duration**

- According to clinical response; avoid prolonged use.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with severe renal impairment, anuria, hyperkalaemia > 5 mmol/litre, hyponatraemia.
- Do not combine with potassium salts, potassium-sparing diuretics; lithium (risk of lithium toxicity).
- Avoid or closely monitor combination with angiotensin-converting enzyme inhibitors (risk of severe, potentially fatal hyperkalaemia), digoxin (risk of digoxin toxicity) and reduce dosages.
- May cause:
  - hyperkalaemia (especially in elderly or diabetics patients, patients with renal impairment or patients taking NSAIDs), hyponatraemia; metabolic acidosis (in patients with decompensated cirrhosis);

- gynecomastia, metrorrhagia, impotence, amenorrhoea, gastrointestinal disturbances, headache, skin rash, drowsiness.
- Administer with caution in patients with hepatic or renal impairment or diabetes.
- Monitor regularly plasma-potassium levels.
- <u>Pregnancy</u>: avoid, use only if clearly needed (risk of feminisation of foetus); spironolactone is not indicated in the treatment of pregnancy-related oedema.
- Breast-feeding: no contra-indication

## **Remarks**

- In children with oedema, the daily dose is 1 to 3 mg/kg once daily or 0.5 to 1.5 mg/kg 2 times daily.
- Spironolactone is also used for the diagnosis and treatment of primary hyperaldosteronism.
- Storage: below 25°C 🌽

# **SULFADIAZINE** oral

Prescription under medical supervision

# Therapeutic action

- Sulfonamide antibacterial

## **Indications**

– Treatment and secondary prophylaxis of toxoplasmosis in immunodeficient patients, in combination with pyrimethamine

# Forms and strengths

- 500 mg tablet

# **Dosage and duration**

Treatment of toxoplasmosis
 Adult: 2 g 2 to 3 times daily for 6 weeks minimum

Secondary prophylaxis of toxoplasmosis
 Adult: 1 to 1.5 g 2 times daily, as long as necessary

## Contra-indications, adverse effects, precautions

- Do not administer to sulfonamide-allergic patients; patients with severe renal or hepatic impairment.
- May cause:
- gastrointestinal disturbances, renal disorders (crystalluria, etc.), photosensitivity, megaloblastic anaemia due to folic acid deficiency; haemolytic anaemia in patients with G6PD deficiency;
- allergic reactions (fever, rash, etc.) sometimes severe (Lyell's and Stevens-Johnson syndromes, haematological disorders, etc.). In these cases, stop treatment immediately.
- Adverse effects occur more frequently in patients with HIV infection.
- Monitor blood count if possible.
- Reduce the dose by half in patients with renal impairment.
- Do not combine with methotrexate and phenytoin.

- Administer calcium folinate systematically to prevent folic acid deficiency.
- Drink a lot of liquid during treatment.
- <u>Pregnancy</u>: no contra-indication. However, avoid using during the last month of pregnancy (risk of jaundice and haemolytic anaemia in the newborn infant).
- <u>Breast-feeding</u>: avoid if preterm infant, jaundice, low-birth weight, infant under one month of age. If sulfadiazine is used, observe the infant for signs of jaundice.

## Remarks

– <u>Storage</u>: below 25°C - 🖊

# **SULFADOXINE/PYRIMETHAMINE = SP oral**

Prescription under medical supervision

# Therapeutic action

- Antimalarial

## **Indications**

– Intermittent preventive treatment of malaria in pregnancy (IPTp-SP), as of the second trimester, in areas with moderate to high malaria transmission in Africa

# Forms and strengths

– Sulfadoxine 500 mg/pyrimethamine 25 mg co-formulated tablet

# Dosage and duration

- 3 tablets single dose for each treatment, starting as early as possible in the second trimester
 Each treatment should be given at least one month apart and at least 3 doses should be given during pregnancy.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to sulfonamides.
- Do not administer to HIV-infected women taking co-trimoxazole prophylaxis.
- May cause: gastrointestinal disturbances, skin reactions, sometimes severe (toxic epidermal necrolysis and Stevens-Johnson syndrome); anaemia, leukopenia, agranulocytosis, thrombocytopenia, haemolytic anaemia in patients with G6PD deficiency.
- Do not use in combination with co-trimoxazole.
- Do not give folic acid on the same day SP is administered, or within 2 weeks thereafter.
- <u>Pregnancy</u>: **CONTRA-INDICATED** during the first trimester (risk of neural tube defects)

## Remarks

– Also comes as co-packaged dispersible tablets for seasonal malaria chemoprevention in children: amodiaquine 153 mg + sulfadoxine/pyrimethamine 500 mg/25 mg and amodiaquine 76.5 mg +

– <u>Storage</u>: below 25 °C - 🌽

# SULFAMETHOXAZOLE (SMX)/TRIMETHOPRIM (TMP) oral

See CO-TRIMOXAZOLE oral(see page 54)

# TENOFOVIR DISOPROXIL FUMARATE = TDF oral

Prescription under medical supervision

# Therapeutic action

- Antiretroviral, HIV nucleotide reverse transcriptase inhibitor

## **Indications**

- HIV infection, in combination with other antiretrovirals
- Post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP), in combination with lamivudine
   (3TC) or emtricitabine (FTC)

# Forms and strengths

– 300 mg tablet, equivalent to 245 mg of tenofovir disoproxil Also comes in fixed-dosed combinations containing tenofovir for HIV treatment.

## **Dosage**

- Child 35 kg and over and adult: 300 mg once daily

## **Duration**

- The duration of treatment depends on the efficacy and tolerance of tenofovir.

# Contra-indications, adverse effects, precautions

- Administer with caution in patients with renal impairment.
- Monitor renal function. In the event of deterioration of renal function, switch to another antiretroviral.
- Avoid combination (or monitor renal function in the event of combination) with nephrotoxic drugs: aminoglycosides (e.g. gentamicin, streptomycin), amphotericin B, pentamidine, etc.
- May cause:
- gastrointestinal disturbances (nausea, vomiting, diarrhoea, etc.), dizziness, fatigue, skin rash;
- renal impairment, bone loss (osteoporosis, fractures), pancreatitis.

- Administer with caution and monitor use with NSAID (addition of nephrotoxic activity).
- Pregnancy: no contra-indication

#### Remarks

- Tenofovir disoproxil is used alone for the treatment of chronic hepatitis B.
- <u>Storage</u>: below 25 °C 💋 🖣

# THIAMINE = VITAMIN B1 oral

# Therapeutic action

- Vitamin

#### **Indications**

- Vitamin B<sub>1</sub> deficiencies: beriberi, alcoholic neuritis

# Forms and strengths

- 50 mg tablet

Also comes in 10 mg and 25 mg tablets.

# **Dosage and duration**

- Infantile beriberi

10 mg once daily, until complete recovery (3 to 4 weeks)

– Acute beriberi

50 mg 3 times daily for a few days, until symptoms improve, then 10 mg once daily until complete recovery (several weeks)

- Mild chronic deficiency

10 to 25 mg once daily

# Contra-indications, adverse effects, precautions

- No contra-indication, or adverse effects with oral thiamine.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

- In the treatment of severe cases, the use of injectable thiamine is justified to correct the disorder as rapidly as possible, but is no longer justified when symptoms have improved.
- Vitamin B<sub>1</sub> deficiency often occurs in association with other vitamin B-complex deficiencies, especially in alcoholic patients.
- Thiamine is also called aneurine.
- <u>Storage</u>: in airtight non-metallic container **//**

# **TINIDAZOLE** oral

Prescription under medical supervision

# Therapeutic action

- Antiprotozoal, antibacterial (group of nitroimidazoles)

## **Indications**

- Amoebiasis, giardiasis, trichomoniasis
- Bacterial vaginitis, infections due to anaerobic bacteria (e.g. Clostridium sp, Bacteroides sp)

# Forms and strengths

- 500 mg tablet

# Dosage and duration

- Amoebiasis

Child: 50 mg/kg once daily (max. 2 g daily)

Adult: 2 g once daily

The treatment lasts 3 days in intestinal amoebiasis; 5 days in hepatic amoebiasis.

- Giardiasis, trichomoniasis and bacterial vaginitis

Child: 50 mg/kg single dose (max. 2 g)

Adult: 2 g single dose

In the event of trichomoniasis, also treat sexual partner.

- Infections due to anaerobic bacteria

Child over 12 years and adult: 2 g on D1 then 1 g once daily or 500 mg 2 times daily According to indication, tinidazole may be used in combination with other antibacterials; treatment duration depends on indication.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to tinidazole or another nitroimidazole (metronidazole, secnidazole, etc.).
- May cause: gastrointestinal disturbances; rarely: allergic reactions, brownish urine, headache, dizziness. Risk of antabuse reaction when combined with alcohol.
- Administer with caution in patients taking oral anticoagulants (risk of haemorrhage), lithium, phenytoin (increased plasma concentrations of these drugs).
- <u>Pregnancy</u>: no contra-indication; divide into smaller doses, avoid prolonged use.
- <u>Breast-feeding</u>: significantly excreted in milk (risk of gastrointestinal disturbances in breastfed infants); divide into smaller doses, avoid prolonged use.

## Remarks

- Storage: below 25 °C - W

# **TRAMADOL** oral

Prescription under medical supervision



# Therapeutic action

- Opioid analgesic

## **Indications**

- Moderate pain, alone or in combination with a non-opioid analgesic

# Forms and strengths

- 50 mg capsule
- 100 mg/ml oral solution (1 drop = 2.5 mg)

## **Dosage**

- Child over 12 years and adult: 50 to 100 mg every 4 to 6 hours (max. 400 mg daily)

## **Duration**

- According to clinical evolution; as short as possible. In the event of prolonged treatment, do not stop abruptly, reduce doses progressively.

# Contra-indications, adverse effects, precautions

- Do not administer in the event of severe respiratory depression and to patients that risk seizures (e.g. epilepsy, head injury, meningitis).
- May cause:
- dizziness, nausea, vomiting, drowsiness, dry mouth, sweating:
- rarely: allergic reactions, seizures, confusion; withdrawal symptoms; respiratory depression in the event of overdosage.
- Do not combine with opioid analgesics, including codeine.
- Avoid combination with carbamazepine, fluoxetine, chlorpromazine, promethazine, clomipramine, haloperidol, digoxin.
- Reduce doses by half and administer every 12 hours in elderly patients and in patients with severe renal or hepatic impairment (risk of accumulation).
- <u>Pregnancy</u>: no contra-indication. The neonate may develop withdrawal symptoms, respiratory depression and drowsiness in the event of prolonged administration of large doses at the end of the  $3^{rd}$  trimester. In this event, closely monitor the neonate.
- <u>Breast-feeding</u>: use with caution, for a short period (2-3 days), at the lowest effective dose. Monitor the mother and the child: in the event of excessive drowsiness, stop treatment.

- Tramadol is approximately 10 times less potent than morphine.
- In some countries, tramadol is on the list of narcotics: follow national regulations.

- Tramadol is not included in the WHO list of essential medicines.
- <u>Storage</u>: below 25 °C **¼** <del>†</del>

# TRANEXAMIC acid oral

Prescription under medical supervision

# Therapeutic action

- Antifibrinolytic

## **Indications**

- Metrorrhagia (especially functional uterine bleeding) and menorrhagia

# Forms and strengths

- 500 mg tablet

## **Dosage**

- Adult: 1 g 3 times daily (max. 1 g 4 times daily) during bleeding

## **Duration**

- 3 to 5 days

# Contra-indications, adverse effects, precautions

- Do not administer in patients with (or with history of) venous or arterial thromboembolic disease.
- Administer with caution in the event of haematuria of renal origin (risk of anuria).
- May cause: gastrointestinal disturbances; rarely, allergic reactions, seizures.
- <u>Pregnancy</u>: this drug is not indicated in the event of bleeding during pregnancy.
- Breast-feeding: no contra-indication

#### Remarks

- The treatment may given at each bleeding episode. In situations of repeated bleeding, it may be helpful to combine tranexamic acid with a non-steroidal anti-inflammatory drug (oral ibuprofen, 400 to 800 mg maximum 3 times daily for 3 to 5 days) and/or a long-term treatment with oral estroprogestogens or injectable progestogens.
- Storage: below 25 °C

# TRICLABENDAZOLE oral

Prescription under medical supervision

# Therapeutic action

- Anthelminthic

## **Indications**

- Fascioliasis (Fasciola hepatica and Fasciola gigantica infections)
- Paragonimiasis

## Forms and strengths

- 250 mg tablet

# **Dosage and duration**

- Fascioliasis

Child and adult: 10 mg/kg single dose

- Paragonimiasis

Child and adult: 10 mg/kg 2 times daily

# Contra-indications, adverse effects, precautions

- Do not administer to patients with hypersensitivity to triclabendazole or other benzimidazoles (albendazole, flubendazole, mebendazole, tiabendazole).
- May cause: abdominal pain, mild fever, headache, dizziness.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### **Remarks**

- Take tablets after meals.
- Due to its efficacy, good tolerance, and ease of administration, triclabendazole is the drug of choice for fascioliasis.
- Bithionol may be used as an alternative to triclabendazole in the treatment of fascioliasis: 30 mg/kg daily for 5 days.
- Unlike infections with other flukes, fascioliasis does not respond to praziquantel.
- Storage: below 25 °C V

# TRIHEXYPHENIDYL oral

Prescription under medical supervision

# Therapeutic action

- Anticholinergic antiparkinson drug

## **Indications**

- Second-line treatment of extrapyramidal reactions induced by antipsychotics

# Forms and strengths

- 2 mg tablet

## **Dosage**

- Adult: 2 mg once daily, then increase if necessary up to 2 mg 2 or 3 times daily (max. 12 mg daily)
- Administer the lowest effective dose in elderly patients and do not exceed 10 mg daily.

#### **Duration**

– As long as antipsychotic treatment lasts.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with closed-angle glaucoma, prostate disorders, gastrointestinal obstruction or atony.
- Administer with caution and carefully monitor use in elderly patients (risk of mental confusion, hallucinations).
- May cause: anticholinergic effects (dry mouth, constipation, blurred vision, tachycardia, disorders of micturition), confusion, hallucinations, memory loss.
- Avoid or monitor combination with other anticholinergic drugs (atropine, amitriptyline, chlorpromazine, promethazine, etc.).
- <u>Pregnancy</u>: re-evaluate whether the antipsychotic treatment is still necessary; if treatment is continued, administer trihexyphenidyl at the lowest effective dose; observe the neonate if the mother was under treatment in the 3<sup>rd</sup> trimester (risk of anticholinergic effects, e.g. tremors, abdominal distension).
- <u>Breast-feeding</u>: if treatment is necessary, administer at the lowest effective dose and observe the child (risk of anticholinergic effects, e.g. tachycardia, constipation, thickening of bronchial secretions).

## **Remarks**

- Take with meals.
- Also comes in 2 mg extended-release capsule, administered once daily.
- Trihexyphenidyl is also used in treatment of Parkinson's disease.
- Storage: below 25 °C V T

# TRINITRIN oral

See GLYCERYL TRINITRATE oral(see page 83)

# **ULIPRISTAL** oral

## Therapeutic action

- Hormonal contraceptive, progesterone receptor modulator with agonist/antagonist effects

## **Indications**

- Emergency contraception after unprotected or inadequately protected intercourse (e.g. forgotten pill or condom breaking)

# Forms and strengths

- 30 mg tablet

# **Dosage and duration**

– One 30 mg tablet, whatever the day of the cycle, as soon as possible after unprotected or inadequately protected intercourse and preferably within the first 120 hours (5 days)

# Contra-indications, adverse effects, precautions

- May cause: headache, nausea, vomiting, abdominal pain, dysmenorrhea, disturbance of next menstrual cycle.
- Re-administer treatment immediately if vomiting occurs within 3 hours of taking treatment.
- Avoid combination with:
- omeprazole and antacids containing aluminium or magnesium hydroxide (decreased effectiveness of the contraceptive);
- enzyme-inducing drugs: rifampicin, rifabutine, efavirenz, nevirapine, lopinavir, ritonavir, phenobarbital, phenytoin, carbamazepine, griseofulvin, etc. (decreased effectiveness of the contraceptive). In both cases, use levonorgestrel (doble the dose with enzyme-inducing drugs) or a copper intrauterine device as emergency contraception.
- Avoid combination with hormonal contraceptives: decreased effectiveness of ulipristal and of the hormonal contraceptive if taken immediately after the administration of ulipristal.
- <u>Pregnancy</u>: in the event of treatment failure (i.e. pregnancy develops) or if used during an undiagnosed pregnancy, there is no known harm for the foetus.
- Breast-feeding: no contra-indication

## Remarks

- Emergency contraception is intended to prevent pregnancy; it cannot terminate an ongoing pregnancy.
- If an oral contraceptive pill is missed, use preferably levonorgestrel or a copper intrauterine device as emergency contraception (fewer drug interactions).
- Start or resume hormonal contraception the 6<sup>th</sup> day after the administration of ulipristal. Use condoms for:
- the first 7 days of taking an oral oestroprogestogen pill or an injection of medroxyprogesterone or the insertion of an implant;
- the first 2 days of taking an oral progestogen only pill.
- There is a risk of treatment failure; carry out a pregnancy test if signs or symptoms of pregnancy (no menstruation, etc.) appear one month after taking ulipristal.
- Storage: below 25°C 🌽

# VALPROIC acid = SODIUM VALPROATE oral

Prescription under medical supervision



Valproic acid should not be used during pregnancy and in women of childbearing age. The risk of foetal malformations is higher than with other antiepileptics.

# Therapeutic action

- Antiepileptic

## **Indications**

- Epilepsy (generalised and partial seizures)
- Prevention of recurrence of bipolar disorder

## Forms and strengths

- 200 mg and 500 mg enteric coated tablets
- 200 mg/5 ml oral solution

# **Dosage**

- Epilepsy (generalised and partial seizures)
- Child under 20 kg: 10 mg/kg 2 times daily
- Child over 20 kg: start with 200 mg (irrespective of weight) 2 times daily, then increase gradually until the optimal dose for the individual patient is reached, usually 10 to 15 mg/kg 2 times daily
- Adult: start with 300 mg 2 times daily, then increase by 200 mg every 3 days until the optimal dose for the individual patient is reached, usually 500 to 1000 mg 2 times daily
- Prevention of recurrence of bipolar disorder

Adult: start with 200 mg 2 times daily. Increase if necessary until the optimal dose for the individual patient is reached, usually around 500 mg 2 times daily (max. 1000 mg 2 times daily).

## **Duration**

- Lifetime treatment

# Contra-indications, adverse effects, precautions

- Do not administer:
- to women of childbearing age. If the treatment is absolutely necessary and if there is no alternative, an effective contraception is required (intrauterine device);
- to patients with pancreatitis, hepatic disease or history of hepatic disease.
- May cause:
- increase in the frequency of seizures at the beginning of therapy, drowsiness, weight gain, amenorrhoea, gastrointestinal disturbances, extrapyramidal symptoms, behavioural disturbances, confusion, thrombocytopenia;
- rarely: pancreatitis, hepatic disorders, severe allergic reactions (Lyell's and Stevens-Johnson syndromes), prolongation of bleeding time. In these cases, stop treatment.
- Monitor, if possible, liver transaminases and prothrombin time during first 3-6 months of therapy (risk of hepatitis).
- Reduce dosage in patients with renal impairment.
- Do not combine with mefloquine (increased risk of seizures).
- Monitor combination with: tricyclic antidepressants, other antiepileptics.
- If other antiepileptics have been prescribed, increase the dose of valproic acid gradually over 2 weeks and reduce the dose of other antiepileptics.

- <u>Pregnancy</u>: do not start treatment during pregnancy (risk of neural tube defects; urogenital, limb and face malformations; psychomotor developmental disorders). If treatment was started before pregnancy: replace valproic acid with a safer antiepileptic.
- Breast-feeding: no contra-indication

#### Remarks

- Take with meals.
- Also comes in 100 mg crushable tablets.
- Storage: below 25 °C 7 7

# **VITAMIN A oral**

See RETINOL(see page 146) oral(see page 146)

# **VITAMIN B1 oral**

See THIAMINE oral(see page 161)

# VITAMIN B3 oral

See NICOTINAMIDE oral(see page 122)

# VITAMIN B6 oral

See PYRIDOXINE oral(see page 142)

# **VITAMIN B9 oral**

See FOLIC acid oral (see page 78)

# **VITAMIN C oral**

See ASCORBIC acid oral(see page 26)

# VITAMIN D2 oral

See ERGOCALCIFEROL oral(see page 69)

# **VITAMIN D3 oral**

See COLECALCIFEROL(see page 52) oral(see page 52)

# **VITAMIN PP oral**

See NICOTINAMIDE oral(see page 122)

# ZIDOVUDINE = AZT = ZDV oral

Prescription under medical supervision

# Therapeutic action

- Antiretroviral, HIV-1 and HIV-2 nucleoside reverse transcriptase inhibitor

## **Indications**

- HIV-1 or HIV-2 infection, in combination with other antiretroviral drugs

# Forms and strengths

- 300 mg tablet
- 50 mg/5 ml oral solution

# Dosage

- Preterm infant: 1.5 mg/kg 2 times daily for the first 2 weeks after birth then 4 mg/kg 2 times daily
- Child under 1 month: 4 mg/kg 2 times daily
- Child 1 month to 13 years: 180 to 240 mg/m<sup>2</sup> 2 times daily
- Adult: 300 mg 2 times daily

Weight	10 mg/ml oral sol.	300 mg tablet
5 to 6 kg	6 ml x 2	-
7 to 9 kg	8 ml x 2	-
10 to 14 kg	12 ml x 2	-
15 to 19 kg	17 ml x 2	-
20 to 24 kg	20 ml x 2	-
25 to 29 kg	25 ml x 2	1 tab x 2

30 to 39 kg	28 ml x 2	1 tab x 2
≥ 40 kg	-	1 tab x 2

#### **Duration**

– The duration of treatment depends on the efficacy and tolerance of zidovudine.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with severe haematological disorders (leukopenia, anaemia), to neonates with hyperbilirubinaemia or raised transaminases.
- May cause: haematological disorders (monitor complete blood count), gastrointestinal disturbances (nausea, diarrhoea, etc.), headache, myopathy, hepatic disorders, lactic acidosis. Stop taking zidovudine in the event of severe haematological disorders or hepatic disorders (hepatomegaly, raised transaminases).
- Reduce dosage in patients with severe renal or hepatic impairment.
- Pregnancy: no contra-indication

## Remarks

- For prophylactic treatment to reduce mother-to-child transmission, check national recommendations.
- Many fixed-dose combinations containing zidovudine are available.
- <u>Storage</u>: below 25 °C Ţ

# **ZINC SULFATE oral**

# Therapeutic action

- Micronutrient

## **Indications**

Adjunct to oral rehydration therapy in the event of acute and/or persistent diarrhoea in children under
 5 years

# Forms and strengths

- 20 mg scored and dispersible tablet, packed in a blister

# **Dosage and duration**

- Child under 6 months: 10 mg (½ tablet) once daily for 10 days
- Child from 6 months to 5 years: 20 mg (1 tablet) once daily for 10 days

Place the half-tablet or full tablet in a teaspoon, add a bit of water to dissolve it, and give the entire spoonful to the child.

# Contra-indications, adverse effects, precautions

- No contra-indication.
- If the child vomits within 30 minutes after swallowing the tablet, re-administer the dose.
- Do not give simultaneously with ferrous salts, administer at least 2 hours apart.

## Remarks

- Zinc sulfate is given as an adjunct to oral rehydration therapy in order to reduce the duration and severity of diarrhoea, as well as to prevent further occurrences in the 2 to 3 months after treatment. Zinc sulfate must never replace oral rehydration therapy which is essential (nor can it replace antibiotic therapy that may, in specific cases, be necessary).
- <u>Storage</u>: below 25 °C **7 ₹**

Tablets are packed in a blister. Leave tablets in blister until use. Once a tablet is removed from the blister, it must be dissolved and administered immediately.

# Injectable drugs

- ACETAMINOPHEN injectable(see page 174)
- ADRENALINE injectable (see page 174)
- ALBUTEROL injectable(see page 174)
- AMOXICILLIN/CLAVULANIC ACID = CO-AMOXICLAV injectable(see page 175)
- AMPHOTERICIN B conventional injectable(see page 176)
- AMPHOTERICIN B liposomal injectable(see page 177)
- AMPICILLIN injectable(see page 180)
- ! Artemether injectable(see page 181)
- ARTESUNATE injectable(see page 181)
- ATROPINE injectable(see page 183)
- BENZATHINE BENZYLPENICILLIN injectable(see page 184)
- BENZYLPENICILLIN = PENICILLIN G injectable(see page 186)
- BENZYLPENICILLIN PROCAINE = PENICILLIN G PROCAINE injectable(see page 187)
- BUTYLSCOPOLAMINE injectable(see page 188)
- CALCIUM GLUCONATE injectable(see page 188)
- CEFOTAXIME injectable(see page 190)
- CEFTRIAXONE injectable(see page 191)
- CHLORAMPHENICOL injectable(see page 192)
- ! Long-acting oily chloramphenicol injectable(see page 194)
- CHLORPROMAZINE injectable(see page 194)
- CLINDAMYCIN injectable(see page 195)
- CLOXACILLIN injectable(see page 196)
- CO-AMOXICLAV injectable(see page 197)
- DEXAMETHASONE injectable(see page 198)
- DEXTROSE 50% injectable(see page 199)
- DIAZEPAM emulsion(see page 199)
- DIAZEPAM solution(see page 200)
- DICLOFENAC injectable(see page 202)
- DIGOXIN injectable(see page 203)
- ! Dipyrone injectable(see page 204)
- EFLORNITHINE injectable(see page 204)
- EPINEPHRINE = EPN = ADRENALINE injectable(see page 205)
- ETONOGESTREL subdermal implant(see page 206)
- FLUCONAZOLE injectable(see page 207)
- FUROSEMIDE injectable(see page 208)
- GENTAMICIN injectable(see page 209)
- GLUCOSE 50% = DEXTROSE 50% injectable(see page 211)
- HALOPERIDOL injectable(see page 211)
- HALOPERIDOL decanoate injectable(see page 212)
- HEPARIN injectable(see page 214)
- HYDRALAZINE injectable(see page 215)
- HYDROCORTISONE injectable(see page 217)
- HYOSCINE BUTYLBROMIDE = BUTYLSCOPOLAMINE injectable(see page 217)
- INSULIN injectable(see page 218)
- INSULIN, INTERMEDIATE-ACTING injectable(see page 220)
- INSULIN, LONG-ACTING injectable(see page 221)
- INSULIN, SHORT-ACTING injectable(see page 221)
- INSULIN, BIPHASIC injectable(see page 222)
- KETAMINE injectable(see page 223)

- LABETALOL injectable(see page 224)
- LEVONORGESTREL subdermal implant(see page 225)
- LIDOCAINE = LIGNOCAINE injectable(see page 226)
- MAGNESIUM SULFATE = MgSO4 injectable(see page 227)
- MEDROXYPROGESTERONE injectable(see page 228)
- MELARSOPROL injectable(see page 229)
- ! Metamizole injectable(see page 230)
- METHYLERGOMETRINE injectable(see page 231)
- METOCLOPRAMIDE injectable(see page 232)
- METRONIDAZOLE injectable(see page 233)
- MORPHINE injectable(see page 233)
- NALOXONE injectable(see page 235)
- ! Noramidopyrine injectable(see page 236)
- OMEPRAZOLE injectable(see page 236)
- ONDANSETRON injectable(see page 237)
- OXYTOCIN injectable(see page 238)
- PARACETAMOL = ACETAMINOPHEN injectable(see page 239)
- PENICILLIN G injectable(see page 240)
- PENTAMIDINE injectable(see page 240)
- PHENOBARBITAL injectable(see page 241)
- PHENYTOIN injectable(see page 243)
- PHYTOMENADIONE = VITAMIN K1 injectable(see page 244)
- POTASSIUM CHLORIDE 10% = KCl 10% injectable(see page 245)
- ! Promethazine injectable(see page 246)
- PROTAMINE injectable(see page 246)
- !Quinine injectable(see page 247)
- SALBUTAMOL = ALBUTEROL injectable(see page 248)
- SODIUM BICARBONATE 8.4% injectable(see page 249)
- SPECTINOMYCIN injectable(see page 249)
- STREPTOMYCIN injectable(see page 250)
- SURAMIN injectable(see page 251)
- THIAMINE = VITAMIN B1 injectable (see page 252)
- TRAMADOL injectable(see page 253)
- TRANEXAMIC acid injectable(see page 254)
- VITAMIN B1 injectable(see page 255)
- VITAMIN K1 injectable(see page 255)

# **ACETAMINOPHEN** injectable

See PARACETAMOL injectable(see page 239)

# ADRENALINE injectable

See EPINEPHRINE = EPN injectable(see page 205)

# **ALBUTEROL** injectable

# AMOXICILLIN/CLAVULANIC ACID = CO-AMOXICLAV injectable

Prescription under medical supervision

## Therapeutic action

– Penicillin antibacterial, combined with a beta-lactamase inhibitor. The addition of clavulanic acid to amoxicillin extends its spectrum of activity to cover beta-lactamase producing Gram-positive and Gramnegative organisms, including some Gram-negative anaerobes.

## **Indications**

- Erysipelas and cellulitis
- Necrotizing infections of the skin and soft tissues (necrotizing fasciitis, gas gangrene, etc.), in combination with clindamycin
- Severe postpartum upper genital tract infection, in combination with gentamicin

# Forms and strengths, route of administration

– Powder for injection, in vials containing 1 g amoxicillin/100 mg clavulanic acid and 1 g amoxicillin/200 mg clavulanic acid, to be dissolved in 20 ml water for injection or 0.9% sodium chloride, for slow IV injection (3 minutes) or IV infusion (30 minutes). DO NOT DILUTE IN GLUCOSE.

# **Dosage**

Doses expressed in amoxicillin:

- Erysipelas, cellulitis

Child under 3 months: 30 mg/kg every 12 hours

Child 3 months and over: 20 to 30 mg/kg every 8 hours (max. 3 g daily)

Adult: 1 g every 8 hours

- Necrotizing infections

Child under 3 months: 50 mg/kg every 12 hours

Child 3 months and over and < 40 kg: 50 mg/kg every 8 hours (max. 6 g daily)

Child 40 kg and over and adult: 2 g every 8 hours

- Upper genital tract infection

Adult: 1 g every 8 hours

For administration by IV infusion, dilute each dose of amoxicillin/clavulanic acid in 5 ml/kg of 0.9% sodium chloride in children less than 20 kg and in a bag of 100 ml of 0.9% sodium chloride in children 20 kg and over and in adults.

#### **Duration**

- Erysipelas, cellulitis: 7 to 10 days; necrotizing infections: 14 days; upper genital tract infection: depending on clinical response. Change to oral treatment as soon as possible.

# Contra-indications, adverse effects, precautions

- Do not administer to penicillin-allergic patients, patients with history of hepatic disorders during a previous treatment with co-amoxiclav, patients with infectious mononucleosis.
- Administer with caution to patients allergic to cephalosporins (cross-sensitivity may occur), patients with hepatic impairment or severe renal impairment (reduce dosage and give every 12 to 24 hours).
- May cause: diarrhoea; hepatic disorders (avoid treatments longer than 14 days); allergic reactions sometimes severe.
- Do not combine with methotrexate (increased methotrexate toxicity).
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

## Remarks

- Preferably use 1 g amoxicillin/100 mg clavulanic acid, especially in children.
- Do not mix with other drugs in the same syringe or infusion bag.
- Storage: below 25 °C

Once reconstituted, the solution must be used immediately; discard any unused open vial.

# **AMPHOTERICIN B conventional injectable**

Prescription under medical supervision



# Therapeutic action

- Antifungal

## **Indications**

- Cryptococcal meningitis (induction phase), in combination with flucytosine or fluconazole
- Severe histoplasmosis or penicilliosis

## Forms and strengths, route of administration

– Powder for injection, in 50 mg vial, to be dissolved in 10 ml of water for injection, to obtain a concentrated solution containing 5 mg/ml. The concentrated solution must be diluted in 500 ml of 5% glucose to obtain a solution containing 0.1 mg/ml, for slow IV infusion.

## **Dosage**

- Child and adult: 0.7 to 1 mg/kg once daily over 4 to 6 hours depending on tolerance

## **Duration**

- *Cryptococcal meningitis*: one week if in combination with flucytosine; 2 weeks if in combination with fluconazole
- Histoplasmosis: 1 to 2 weeks; penicilliosis: 2 weeks

# Contra-indications, adverse effects, precautions

- Administer with caution to patients with renal impairment.
- May cause:
- intolerance reactions during administration: fever, chills, headache, nausea, vomiting, hypotension; local reaction: pain and thrombophlebitis at injection site; allergic reactions;
- muscle or joint pain, cardiovascular disorders (arrhythmias, heart failure, hypertension, cardiac arrest), neurologic (seizures, blurred vision, dizziness), haematological or hepatic disorders;
- disturbances in renal function (reduced glomerular filtration, hypokalaemia, hypo magnesiemia).
- Avoid combination with: drugs causing hypokalaemia (furosemide, corticosteroids), nephrotoxic drugs (amikacin, ciclosporine); digoxin, zidovudine, tenofovir.
- To prevent renal toxicity, administer 500 ml to 1 litre of 0.9% sodium chloride or Ringer lactate prior to each amphotericin B infusion.
- In adults, as soon as the patient can swallow, give supplements of potassium (2 tab of 8 mmol 2 times daily) and magnesium (500 mg 2 times daily) until the end of amphotericin treatment.
- In the event of intolerance, stop infusion, give paracetamol or an antihistamine then, resume administration reducing infusion rate by half.
- Monitor serum creatinine levels, and if possible, serum potassium levels (1 to 2 times weekly) throughout treatment.
- If serum creatinine levels rise by over 50%, increase preventive hydration (1 litre every 8 hours) or stop treatment. Then, after improvement, resume amphotericin at the lowest effective dose or on alternate days.
- Use liposomal amphotericin B if serum creatinine levels increase again or if clearance is < 30 ml/minute or in patients with pre-existing severe renal failure.
- <u>Pregnancy</u>: check for renal dysfunction in the newborn if administered during the last month of pregnancy.
- Breast-feeding: avoid, except if vital

#### Remarks

- Only use 5% glucose for administration (incompatible with other infusion fluids). Do not use the preparation if there is visible precipitation (the glucose solution is too acid).
- Do not add other drugs in the infusion bottle or bag.
- Protect infusion bottle from light during administration (wrap in dark paper).
- Storage: 🖊
- Vial of powder: must be kept refrigerated (between 2 °C and 8 °C); in the absence of a refrigerator, 7 days maximum, below 25 °C.
- Concentrated solution (5 mg/1 ml): may be kept refrigerated 24 hours (between 2 °C and 8 °C).
- Solution for infusion (0.1 mg/ml): must be used immediately.

# **AMPHOTERICIN B liposomal injectable**

Prescription under medical supervision



# Therapeutic action

- Antifungal

## **Indications**

- Cryptococcal meningitis, when conventional amphotericin B is contra-indicated (severe pre-existing renal impairment or amphotericin B induced renal impairment)
- Cutaneomucous or visceral leishmaniasis
- Severe histoplasmosis

# Forms and strengths, route of administration

- Powder for injection, in 50 mg vial, to be dissolved in 12 ml of water for injection, to obtain a concentrated suspension containing 4 mg/ml
- With a syringe, withdraw the required dose of concentrated suspension. Attach the filter provided with the vial to the syringe; inject the contents of the syringe, through the filter, into the volume of 5% glucose (50 ml, 250 ml, 500 ml) needed to obtain a solution containing between 0.2 to 2 mg/ml, for IV perfusion.

# **Dosage and duration**

Cryptococcal meningitis, severe histoplasmosis
 Child over 1 month and adult: 3 mg/kg once daily over 30 to 60 minutes for 2 weeks

	Liposomal amphotericin B, 50 mg-vial in 12 ml			<b>G5</b> %
Weight	Daily dose in mg/kg	Nb of vials	Volume of suspension (4 mg/ml) to be withdrawn	Volume required for administration
4 kg	12		3 ml	
5 kg	15		4 ml	
6 kg	18	1	4,5 ml	
7 kg	21		5 ml	50 ml
8 kg	24		6 ml	
9 kg	27		7 ml	
10 kg	30		7,5 ml	
15 kg	45		11 ml	
20 kg	60	2	15 ml	
25 kg	75		19 ml	250 ml
30 kg	90		23 ml	

35 kg	105		26 ml	
40 kg	120	3	30 ml	
45 kg	135		34 ml	
50 kg	150		38 ml	500 ml
55 kg	165		41 ml	
60 kg	180	4	45 ml	
65 kg	195		50 ml	
70 kg	210	5	53 ml	

<sup>-</sup> Cutaneomucous or visceral leishmaniasis

Follow the recommended protocol, which varies from one region to another (exact dose, administration schedule, etc.). For information, the total dose in children over 1 month and adults is 15 to 30 mg/kg.

# Contra-indications, adverse effects, precautions

- May cause:
- intolerance reactions during administration: fever, chills, headache, nausea, vomiting, hypotension; local reaction: pain and thrombophlebitis at injection site; allergic reactions;
- gastrointestinal disturbances, disturbances in renal function (raised creatinine or urea levels, renal impairment), hypokalaemia, hypomagnesiemia, elevated liver enzymes; rarely, haematological disorders (thrombocytopenia, anaemia).
- Avoid combination with: drugs causing hypokalaemia (furosemide, corticosteroids), nephrotoxic drugs (amikacin, ciclosporine); digoxin, zidovudine.
- The infusion may be administered over 2 hours if necessary to prevent or minimize adverse effects.
- Monitor serum creatinine levels, and if possible, serum potassium levels (once to twice weekly)
   throughout treatment; adapt adjunctive therapy (potassium and magnesium supplementation)
   according to the results.
- If renal function deteriorates, reduce the dose by half for a few days.
- <u>Pregnancy</u>: check for renal dysfunction in the newborn if administered during the last month of pregnancy.
- Breast-feeding: avoid, except if vital

- Liposomal amphotericin B is better tolerated and less nephrotoxic than conventional amphotericin B.
- Do not add other drugs in the infusion bottle or bag; do not use the preparation if there is visible precipitation.
- Before each infusion, rinse the IV catheter with 5% glucose.
- Storage:
- Vial of powder: must be kept refrigerated (between 2 °C and 8 °C) or below 25 °C.
- Solutions (reconstituted and for infusion): be kept refrigerated 24 hours (between 2 °C and 8 °C).

# **AMPICILLIN** injectable

Prescription under medical supervision

# Therapeutic action

- Penicillin antibacterial

## **Indications**

- Severe bacterial infections: meningitis, pneumonia, pyelonephritis, postpartum upper genital tract infection, etc., in combination with other antibacterials
- Severe typhoid fever if the strain is susceptible (recent drug susceptibility test)

## Forms and strengths, route of administration

- Powder for injection, in 500 mg and 1 g vials, to be dissolved in 5 ml of water for injection
- Prefer adminstration by slow IV injection (3 to 5 minutes) or IV infusion (30 minutes) in 0.9% sodium chloride or 5% glucose; use IM route only if correct IV administration is not possible .
- In neonates, administer only by slow IV injection or IV infusion.

## **Dosage**

- Meningitis in young children, in combination with cefotaxime or gentamicin
- Neonate:

0 to 7 days (< 2 kg): 100 mg/kg every 12 hours 0 to 7 days (≥ 2 kg): 100 mg/kg every 8 hours 8 days to < 1 month: 100 mg/kg every 8 hours • Child 1 to 3 months: 100 mg/kg every 8 hours

- Pneumonia and pyelonephritis, in combination with gentamicin
- Neonate

0 to 7 days (< 2 kg): 50 mg/kg every 12 hours 0 to 7 days (≥ 2 kg): 50 mg/kg every 8 hours 8 days to < 1 month: 50 mg/kg every 8 hours

- Child 1 month and over: 50 mg/kg every 6 to 8 hours
- Adult: 1 g every 6 or 8 hours (2 g every 6 hours in pyelonephritis)
- Postpartum upper genital tract infection, in combination with metronidazole and gentamicin
   Adult: 2 g every 8 hours
- Severe typhoid fever

Child: 50 mg/kg every 6 to 8 hours

Adult: 1 g every 6 to 8 hours

For administration by IV infusion, dilute each dose of ampicillin in 5 ml/kg of 0.9% sodium chloride or 5% glucose in children less than 20 kg and in a bag of 100 ml of 0.9% sodium chloride or 5% glucose in children 20 kg and over and in adults.

#### **Duration**

- According to indication and clinical response. Change to oral treatment as soon as possible with amoxicillin or a combination of antibacterials, depending on the indication.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with infectious mononucleosis (risk of skin eruption) or to penicillin allergic patients.
- Administer with caution to patients allergic to cephalosporins (cross-sensitivity may occur) or patients with severe renal impairment (reduce dosage).
- May cause: skin eruption, gastrointestinal disturbances, allergic reactions sometimes severe.
- Do not combine with methotrexate (increased methotrexate toxicity).
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Do not mix with another drug in the same syringe or infusion.
- Injectable amoxicillin is used for the same indications.
- <u>Storage</u>: below 25 °C 🌽

Once reconstituted, the solution must be used immediately.

# ! Artemether injectable

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see ARTEMETHER injectable(see page 319)

# ARTESUNATE injectable

Prescription under medical supervision

## Therapeutic action

- Antimalarial

#### **Indications**

- Treatment of severe malaria
- Initial treatment of uncomplicated malaria, when persistent vomiting precludes oral therapy

#### Forms and strengths, route of administration

- Powder for injection, in 60 mg-vial, with one 1 ml-ampoule of 5% sodium bicarbonate and one 5 mlampoule of 0.9% sodium chloride, for slow IV injection (3 to 5 minutes) or slow IM injection. NEVER ADMINISTER BY IV INFUSION.
- Dissolve the powder in the entire volume of 5% sodium bicarbonate and shake the vial until the solution becomes clear. Then, add the 0.9% sodium chloride into the vial:
- 5 ml of 0.9% sodium chloride to obtain 6 ml of artesunate solution containing 10 mg/ml, for IV injection
- 2 ml of 0.9% sodium chloride to obtain 3 ml of artesunate solution containing 20 mg/ml, for IM injection

# **Dosage and duration**

- Child under 20 kg: 3 mg/kg/dose
- Child 20 kg and over and adult: 2.4 mg/kg/dose
- One dose on admission (H0) then 12 hours after admission (H12) then 24 hours after admission (H24) then, once daily.

Administer parenterally at least 24 hours (3 doses), then, if the patient can tolerate the oral route, change to a complete 3-day course of an artemisinin-based combination. If not, continue parenteral treatment once daily until the patient can change to oral route (without exceeding 7 days of parenteral treatment).

Weight	IV injection artesunate solution 10 mg/ml	IM injection artesunate solution 20 mg/ml
< 3 kg	1 ml	0.5 ml*
3 to < 4 kg	1.2 ml	0.6 ml*
4 to < 5 kg	1.5 ml	0.8 ml*
5 to < 6 kg	2 ml	1 ml
6 to < 8 kg	2.5 ml	1.2 ml
8 to < 10 kg	3 ml	1.5 ml
10 to < 13 kg	4 ml	2 ml
13 to < 15 kg	4.5 ml	2.5 ml
15 to < 17 kg	5 ml	2.5 ml
17 to < 20 kg	6 ml	3 ml
20 to < 25 kg	6 ml	3 ml
25 to < 29 kg**	7 ml	3.5 ml
29 to < 33 kg	8 ml	4 ml
33 to < 37 kg	9 ml	5 ml

Weight	IV injection artesunate solution 10 mg/ml	IM injection artesunate solution 20 mg/ml
37 to < 41 kg	10 ml	5 ml
41 to < 45 kg	11 ml	6 ml
45 to < 50 kg	12 ml	6 ml
50 to < 55 kg**	13 ml	7 ml
55 to < 62 kg	15 ml	8 ml
62 to < 67 kg	16 ml	8 ml
67 to < 71 kg	17 ml	9 ml
71 to < 76 kg	18 ml	9 ml
76 to 81 kg**	20 ml	10 ml

<sup>\*</sup> Use a 1 ml syringe graduated in 0.01 ml when the dose required is less than 1 ml.

# Contra-indications, adverse effects, precautions

- May cause: gastrointestinal disturbances, dizziness, headache, fever, muscle and joint pain, pruritus; rarely rash, delayed haemolytic anaemia (appearing 2 to 3 weeks after treatment, especially in case of hyperparasitaemia and in young children).
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- The solution should be clear, do not use if the solution is cloudy or if a precipitate is present.
- Do not use water for injection for:
- reconstitution (only use sodium bicarbonate);
- dilution (only use sodium chloride).
- Storage: below 30 °C ✓ 🗍

Once reconstituted, the solution must be used immediately.

# **ATROPINE** injectable

Prescription under medical supervision



# Therapeutic action

- Parasympatholytic, antispasmodic

<sup>\*\*</sup> For patients over 25 kg, a 2<sup>nd</sup> vial must be prepared to obtain the volume needed, a 3<sup>rd</sup> vial for patients over 50 kg and a 4<sup>th</sup> vial for patients over 76 kg.

#### **Indications**

- Premedication in anaesthesia
- Spasms of the gastrointestinal tract
- Organophosphorus pesticide poisoning

# Forms and strengths, route of administration

-1 mg atropine sulfate in 1 ml ampoule (1 mg/ml) for SC, IM, IV injection Also comes in 0.25 mg/ml and 0.5 mg/ml ampoules.

#### Dosage

- Premedication in anaesthesia

Child: 0.01 to 0.02 mg/kg by SC or IV injection

Adult: 1 mg by SC or IV injection

- Spasms of the gastrointestinal tract

Child from 2 to 6 years: 0.25 mg by SC injection, single dose

Child over 6 years: 0.5 mg by SC injection, single dose

Adult: 0.25 to 1 mg by SC injection, every 6 hours if necessary (max. 2 mg daily)

- Organophosphorus pesticide poisoning

Child: 0.02 to 0.05 mg/kg by IM or slow IV injection

Adult: 2 mg by IM or slow IV injection

Repeat every 5 to 10 minutes until signs of atropinisation appear (reduced secretions, tachycardia, dilatation of the pupils).

# Contra-indications, adverse effects, precautions

- Do not administer to patients with urethro-prostatic disorders, cardiac disorders, glaucoma.
- Do not administer to children with high fever.
- May cause: urinary retention, dryness of the mouth, constipation, dizziness, headache, dilatation of the pupils, tachycardia.
- Administer with caution and under close supervision to patients taking other anti cholinergic drugs (antidepressants, neuroleptics, H1 antihistamines, antiparkinsonians, etc.).
- <u>Pregnancy</u>: no contra-indication; NO PROLONGED TREATMENT
- Breast-feeding: avoid; NO PROLONGED TREATMENT

#### Remarks

- Atropine IV is also used to prevent bradycardic effects of neostigmine when used to reverse the effects of competitive muscle relaxants: 0.02 mg/kg in children; 1 mg in adults.
- Do not mix with other drugs in the same syringe.
- Storage: below 25 °C V

# **BENZATHINE BENZYLPENICILLIN injectable**

Prescription under medical supervision

# Therapeutic action

- Long-acting penicillin antibacterial

#### **Indications**

- Early syphilis (primary, secondary, or early latent infection of less than 12 months duration)
- Late latent syphilis (infection of more than 12 months duration or of unknown duration)
- Congenital syphilis (absence of clinical signs in the neonate and adequate treatment in the mother)
- Endemic treponematoses (yaws, bejel, pinta)
- Streptococcal tonsillitis
- Prophylaxis of diphtheria in the event of direct contact
- Primary and secondary prophylaxis of rheumatic fever

# Forms and strengths, route of administration

- Powder for injection in vials of:
- 1.2 MIU (900 mg), to be dissolved in 4 ml of water for injection, for IM injection
- 2.4 MIU (1.8 g), to be dissolved in 8 ml of water for injection, for IM injection NEVER FOR IV INJECTION NOR INFUSION

#### **Dosage**

- Syphilis

Child: 50 000 IU (37.5 mg)/kg per injection (max. 2.4 MIU or 1.8 g per injection) Adult: 2.4 MIU (1.8 g) per injection

- Yaws, bejel, pinta

Child under 10 years: 1.2 MIU (900 mg) per injection

Child 10 years and over and adult: 2.4 MIU (1.8 g) per injection

Streptococcal tonsillitis, prophylaxis of diphtheria, prophylaxis of rheumatic fever
 Child under 30 kg: 600 000 IU (450 mg) per injection
 Child 30 kg and over and adult: 1.2 IU (900 mg) per injection

#### **Duration**

– Early syphilis, congenital syphilis, tonsillitis, yaws, bejel, pinta, prophylaxis of diphtheria, primary prophylaxis of rheumatic fever. single dose; late latent syphilis: one injection/week for 3 weeks; secondary prophylaxis of rheumatic fever. one injection every 4 weeks for several years

# Contra-indications, adverse effects, precautions

- Do not administer to penicillin-allergic patients.
- Administer with caution to patients allergic to cephalosporins (cross-sensitivity may occur) and renal impairment (reduce dosage).
- May cause:
- gastroinstestinal disturbances, pain at injection site, allergic reactions sometimes severe;
- Jarisch-Herxheimer reaction (fever, chills, myalgia, tachycardia) in patients with syphilis;
- convulsions in the event of high dosages or renal impairment;
- symptoms of shock with neuropsychiatric disorders in case of accidental IV injection.
- Ensure that the IM injection does not enter a blood vessel.
- Do not combine with methotrexate.
- Pregnancy and breast-feeding: no contra-indication

- For a 2.4 MIU (1.8 g) dose, administer 1.2 MIU (900 mg) in each buttock.
- Do not confuse long-acting benzathine benzylpenicillin, for IM injection, with rapidly acting benzylpenicillin (or penicillin G), administered by Iv route.
- Do not mix with other drugs in the same syringe.
- <u>Storage</u>: below 25 °C 🖊 Ť

Once reconstituted, suspension must be used immediately.

# **BENZYLPENICILLIN = PENICILLIN G injectable**

Prescription under medical supervision

This penicillin should be administered in a hospital setting (injections every 4 to 6 hours).

# Therapeutic action

- Short-acting penicillin antibacterial

#### **Indications**

- Diphtheria, neurosyphilis
- Congenital syphilis (presence of clinical signs in the neonate and lack of adequate treatment in the mother)

# Forms and strengths, route of administration

- Powder for injection in vials of:
- 1 MIU (600 mg), to be dissolved in 2 ml of water for injection or 0.9% sodium chloride
- 5 MIU (3 g), to be dissolved in 5 ml of water for injection or 0.9% sodium chloride For IM injection or slow IV injection through an infusion tube (3 to 5 minutes) or infusion (60 minutes) in 0.9% sodium chloride or 5% glucose.

# Dosage

- Diphtheria

Child: 50 000 IU (30 mg)/kg every 6 hours (max. 4 MIU or 2.4 g daily) Adult: 1 MIU (600 mg) every 6 hours

- Neurosyphilis

Adult: 2 to 4 MIU (1.2 to 2.4 g) by IV injection every 4 hours

- Congenital syphilis
- 50 000 IU (30 mg)/kg by IV injection every 12 hours from D1 to D7, then
- 50 000 IU (30 mg)/kg by IV injection every 8 hours from D8 to D10

#### **Duration**

- Diphtheria, neurosyphilis: 14 days; congenital syphilis: 10 days
- For diphtheria, change to oral route as soon as possible.

# Contra-indications, adverse effects, precautions

- Do not administer to penicillin-allergic patients.
- Administer with caution to patients allergic to cephalosporins (cross-sensitivity may occur) and renal impairment (reduce dosage in patients with neurosyphilis).
- May cause:
- gastroinstestinal disturbances, pain at injection site, anaemia, allergic reactions sometimes severe;
- Jarisch-Herxheimer reaction (fever, chills, myalgia, tachycardia) in patients with syphilis;
- convulsions in the event of rapid IV injection, high dosages or renal impairment.
- Do not combine with methotrexate.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Do not confuse short-acting benzylpenicillin, administered several times a day by IV route, with long-acting penicillins (benzathine benzylpenicillin and procaine benzylpenicillin) administered by IM route only.
- Do not mix with other drugs in the same syringe or infusion.
- <u>Storage</u>: below 25 °C **¼ †**

Once reconstituted, suspension must be used immediately.

# **BENZYLPENICILLIN PROCAINE = PENICILLIN G PROCAINE injectable**

Last updated: January 2021

Prescription under medical supervision

# Therapeutic action

- Long-acting penicillin antibacterial (12 to 24 hours)

#### **Indications**

- Diphtheria, when oral treatment is not possible
- Congenital syphilis, if the neonate has clinical signs of syphilis or the mother did not receive adequate treatment for syphilis during pregnancy

# Forms and strengths, route of administration

- Powder for injection in:
- 0.6 MIU vial, to be dissolved with the diluent supplied by the manufacturer (4 ml-ampoule of water for injection)
- 1.2 MIU vial, to be dissolved with the diluent supplied by the manufacturer (5 ml-ampoule of water for injection)
- For IM injection only. **NEVER ADMINISTER BY IV INJECTION OR INFUSION**.

#### **Dosage**

- Diphtheria

Child: 50 000 IU/kg (= 50 mg/kg) once daily (max. 1.2 MIU = 1.2 g daily)

Adult: 1.2 MIU (= 1.2 g) once daily

- Congenital syphilis

Neonate: 50 000 IU/kg (= 50 mg/kg) once daily

#### **Duration**

- *Diphtheria:* change to an oral treatment as soon as the patient can swallow, to complete 14 days of treatment; *congenital syphilis*: 10 days

# Contra-indications, adverse effects, precautions

- Do not administer to patients allergic to penicillin and/or procaine.
- Administer with caution to patients allergic to cephalosporins (cross-sensitivity may occur) or with renal impairment.
- May cause:
- gastrointestinal disturbances;
- allergic reactions sometimes severe. In the event of allergic reactions, stop treatment immediately.
- Ensure that the needle does not accidentally enter a vessel (risk of serious neurovascular damage).
- Pregnancy and breast-feeding: no contra-indication

#### Remarks

- Also comes in 1 MIU and 3 MIU vials of powder for injection.
- Do not confuse procaine benzylpenicillin with short-acting benzylpenicillin (penicillin G), administered several times per day by IV route.
- Do not mix with other drugs in the same syringe.
- Storage: below 25 °C ✓

Once reconstituted, suspension must be used immediately.

# **BUTYLSCOPOLAMINE** injectable

See HYOSCINE BUTYLBROMIDE injectable(see page 217)

# **CALCIUM GLUCONATE injectable**

Prescription under medical supervision

# Therapeutic action

- Calcium therapy
- Antidote to magnesium sulfate

#### **Indications**

- Severe hypocalcaemia (hypocalcaemic tetany, neonatal hypocalcaemia, etc.)
- Symptomatic hypermagnesaemia due to excessive doses of magnesium sulfate

# Forms and strengths, route of administration

– 1 g ampoule (100 mg/ml, 10 ml; 10% solution) for slow IV injection or infusion in 5% glucose or 0.9% sodium chloride or Ringer lactate

Also comes in 5 g ampoule (100 mg/ml, 50 ml), 10 g vial (100 mg/ml, 100 ml), 20 g vial (100 mg/ml, 200 ml).

#### **Dosage**

- Severe hypocalcaemia

Neonate: 2 ml/kg of a 10% solution by IV infusion over 30 minutes followed by 4 ml/kg of a 10% solution administered by continuous infusion over 24 hours

Adult: 10 ml by slow IV injection (over at least 5 minutes), either repeated as required, or followed by continuous infusion of 40 ml of a 10% solution over 24 hours Change to oral route as soon as possible.

- Magnesium sulfate intoxication

Adult: 10 ml of a 10% solution by slow IV injection (over at least 5 minutes), to be repeated once if necessary

#### **Duration**

- According to clinical response and plasma-calcium levels

# Contra-indications, adverse effects, precautions

- Do not administer to patients with severe renal disease or patients receiving cardiac glycosides.
- Do not administer by IM or SC route (pain and risk of tissue necrosis or abscess formation at injection site, especially in infants and children).
- May cause:
- tingling sensations, warm flushes, dizziness;
- tissue necrosis in the event of extravasation;
- hypercalcaemia in the event of too rapid IV injection or overtreatment. First signs of hypercalcaemia include nausea, vomiting, thirst and polyuria. In severe cases, hypo tension, bradycardia, arrhythmia, syncope and cardiac arrest may develop.
- Hypercalcaemia can be confirmed by monitoring of serum-calcium levels and ECG changes. Do not use in prolonged treatment if plasma-calcium levels cannot be monitored.
- The patient should be placed in the horizontal position prior to injection and should remain lying down for 30 to 60 minutes.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Calcium gluconate is also administered as adjunctive therapy in insect bites or stings (black widow spider, scorpions) for the management of muscle pain and spasms. Several doses at 4-h intervals may be necessary.
- 1 g of calcium gluconate (2.2 mmol or 4.5 mEq) is equivalent to 89 mg of calcium.
- Calcium gluconate is incompatible with many drugs: do not mix with other drugs in the same syringe or

#### infusion fluid.

- Do not use if the solution appears cloudy or particles are visible (calcium gluconate precipitate).
- Storage: below 25 °C 🖊

# **CEFOTAXIME** injectable

Prescription under medical supervision

# Therapeutic action

- Third-generation cephalosporin antibacterial

#### **Indications**

In neonates:

- Bacterial meningitis, in combination with another antibacterial
- Urinary infection
- Pneumonia (ampicillin + gentamicin is preferred for this indication)
- Gonococcal conjunctivitis (if ceftriaxone is not available or contraindicated)

# Forms and strengths, route of administration

– Powder for injection, in 250 mg and 500 mg vials, to be dissolved in 2 ml water for injection, for IM or slow IV injection (3 to 5 minutes) or IV infusion (20 to 60 minutes) in 0.9% sodium chloride or 5% glucose.

#### Dosage

Meningitis, urinary infection, pneumonia
0 to 7 days (< 2 kg): 50 mg/kg every 12 hours</li>
0 to 7 days (≥ 2 kg): 50 mg/kg every 8 hours
8 days to < 1 month: 50 mg/kg every 8 hours</li>

Gonococcal conjunctivitis
 100 mg/kg IM single dose

For IV administration, cefotaxime powder can only be dissolved in water for injection. For infusions, each dose of cefotaxime must be dissolved in 5 ml/kg of 0.9% sodium chloride or 5% glucose.

#### **Duration**

- Depending on indication and clinical response

#### Contra-indications, adverse effects, precautions

- Do not administer to patients allergic to cephalosporins or penicillins (risk of cross-sensitivity).
- Administer with caution and reduce dosage in patients with renal impairment.
- Avoid or monitor combination with other nephrotoxic drugs: amphotericin B, aminoglycosides, pentamidine, etc.
- May cause: gastrointestinal disturbances (diarrhoea, nausea), haematological disorders (neutropenia, leucopenia), heart rhythm disorders if IV injection is too fast, allergic reactions and cutaneous reactions (Stevens-Johnson and Lyell syndromes), sometimes severe.

- Do not mix with other drugs in the same syringe or bottle.
- <u>Storage</u>: below 25 °C **∅** <del>†</del>

Once reconstituted, the solution must be used immediately.

# **CEFTRIAXONE** injectable

Prescription under medical supervision

# Therapeutic action

- Third-generation cephalosporin antibacterial

#### **Indications**

- Severe bacterial infections: meningitis, pneumonia, typhoid fever, shigellosis, leptospirosis, pyelonephritis, neurosyphilis, etc.
- Cervicitis, urethritis and conjunctivitis due to *Neisseria gonorrhoeae* (in combination with a treatment for chlamydia, except in neonates), chancroid

# Forms and strengths, route of administration

- Powder for injection, in 250 mg or 1 g vials, to be dissolved:
- with the solvent containing lidocaine for IM injection only. DO NOT ADMINISTER BY IV INJECTION OR INFUSION the solution reconstituted with this solvent.
- with water for injection for slow IV injection (3 minutes) or infusion (30 minutes) in 0,9% sodium chloride or 5% glucose

# **Dosage and duration**

- Severe bacterial infections

Child 1 month and over: 50 to 100 mg/kg once daily (max. 2 g daily and 4 g daily for typhoid fever and meningitis)

Adult: 1 to 2 g once daily (up to 2 g once daily or 2 times daily for typhoid fever and meningitis) Duration varies according to indication and clinical response.

- Gonococcal cervicitis and urethritis, chancroid

Child under 45 kg: 125 mg IM single dose

Child 45 kg and over and adult: 250 mg IM single dose

- Gonococcal conjunctivitis

Neonate: 50 mg/kg IM single dose (max. 125 mg)

Adult: 1 g IM single dose

For administration by IV route, ceftriaxone powder is to be reconstituted in water for injection only. for administration by IV infusion, dilute each dose of ceftriaxone in 5 ml/kg of 0.9% sodium chloride or 5% glucose in children less than 20 kg and in a bag of 100 ml of 0.9% sodium chloride or 5% glucose in children 20 kg and over and in adults.

#### Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to cephalosporins or penicillins (cross-sensitivity may occur) and to neonates with jaundice (risk of bilirubin encephalopathy).
- Administer with caution in patients with hepatic or renal impairment. reduce dosage in patients with severe renal impairment (max. 50 mg/kg daily or 2 g daily in IV).
- May cause: gastrointestinal disturbances, hepatic dysfunction, blood disorders (anaemia, leucopenia, neutropenia), renal dysfunction; allergic reactions sometimes severe (Stevens-johnson syndrome).
- Do not mix ceftriaxone with calcium-containing solutions such as ringer lactate (risk of particulate formation).
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Doses greater than 1 g IM should be administered in 2 equally divided injections (one in each buttock). Doses greater than 2 g should be administered by IV infusion only.
- Do not mix with another drug in the same syringe or infusion.
- Storage: below 25°C 🌽

Once reconstituted, the solution must be used immediately.

# **CHLORAMPHENICOL** injectable

Prescription under medical supervision



The use of chloramphenicol should be restricted to severe infections when other less toxic antibacterials are not effective or contra-indicated.

# Therapeutic action

- Phenicol antibacterial

#### **Indications**

- First-line treatment of plague meningitis
- Alternative to first-line treatments of septicaemic plague
- Severe typhoid fever if the strain is susceptible (recent drug susceptibility test)

#### Forms and strengths, route of administration

– 1 g powder for injection, to be dissolved in 10 ml of water for injection, for IV injection over 1 to 2 minutes

#### **Dosage**

- Child from 1 year to < 13 years: 25 mg/kg every 8 hours
- Child ≥ 13 years and adult: 1 g every 8 hours

Age	Weight	1 g vial (to be dissolved in 10 ml)
1 to < 2 years	10 to < 13 kg	3 ml x 3
2 to < 3 years	13 to < 15 kg	3.5 ml x 3
3 to < 6 years	15 to < 20 kg	5 ml x 3
6 to < 8 years	20 to < 25 kg	6 ml x 3
8 to < 9 years	25 to < 30 kg	7 ml x 3
9 to < 11 years	30 to < 35 kg	8 ml x 3
11 to < 13 years	35 to < 45 kg	9 ml x 3
≥ 13 years and adult	≥ 45 kg	10 ml x 3

#### **Duration**

- Plague: 10 days; typhoid fever. 14 days. Change to oral route as soon as possible.

# Contra-indications, adverse effects, precautions

- Do not administer to children under 1 year.
- Do not administer to patients with:
- history of allergic reaction or bone marrow depression during a previous treatment with chloramphenicol;
- G6PD deficiency.
- May cause:
- dose-related haematological toxicity (bone marrow depression, anaemia, leucopenia, thrombocytopenia), allergic reactions. In these events, stop treatment immediately;
- gastrointestinal disturbances, peripheral and optic neuropathies.
- Reduce dosage in patients with hepatic or renal impairment.
- Avoid or monitor combination with potentially haematotoxic drugs (carbamazepine, co-trimoxazole, flucytocine, pyrimethamine, zidovudine, etc.).
- <u>Pregnancy</u>: **CONTRA-INDICATED**, except if vital, if there is no therapeutic alternative. If used during the 3<sup>rd</sup> trimester, risk of grey syndrome in the neonate (vomiting, hypothermia, blue-grey skin colour and cardiovascular depression).
- Breast-feeding: CONTRA-INDICATED

#### Remarks

- Oral treatment is more effective than parenteral treatment: blood and tissue concentrations are higher when chloramphenical is given orally.
- Storage: below 25 °C 🌽

# ! Long-acting oily chloramphenicol injectable

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see Long-acting oily CHLORAMPHENICOL injectable(see page 322)

# **CHLORPROMAZINE** injectable

Prescription under medical supervision



# Therapeutic action

- Sedative antipsychotic

#### **Indications**

- Agitation or aggressive behaviour in patients with acute or chronic psychosis

# Forms and strengths, route of administration

- 50 mg in 2 ml ampoule (25 mg/ml) for IM injection

#### **Dosage**

- Adult: one injection of 25 to 50 mg. Subsequent doses, if needed, should be given at 8 hour intervals (max. 150 mg in 24 hours).
- Administer one-quarter of the usual dose in elderly patients.

#### **Duration**

- Change to oral treatment with another antipsychotic as soon as possible

## Contra-indications, adverse effects, precautions

- Do not administer to patients with cardiac disorders (heart failure, recent myocardial infarction, conduction disorders, bradycardia, etc.), dementia (e.g. Alzheimer's disease), closed-angle glaucoma, prostate disorders, Parkinson's disease and history of neuroleptic malignant syndrome.
- Administer with caution and carefully monitor use in elderly patients; patients with hypokalaemia, hypotension, renal or hepatic impairment, history of seizures.
- May cause:
- drowsiness, dyskinesia, extrapyramidal syndrome, weight gain, orthostatic hypotension, hyperprolactinaemia, anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation, tachycardia), pain at injection site;
- hyperglycaemia, photosensitivity, impaired thermoregulation; agranulocytosis, neuroleptic malignant syndrome (unexplained hyperthermia with neuromuscular disorders), rare but requiring immediate

treatment discontinuation.

- Avoid combination with:
- central nervous system depressants (opioid analgesics, sedatives, H1 antihistamines, etc.); drugs with anticholinergic effects (amitriptyline, atropine, clomipramine, promethazine, etc.), antidiabetics, lithium;
- antihypertensive drugs (risk of hypotension); drugs that prolong the QT interval (amiodarone, chloroquine, erythromycin, fluconazole, mefloquine, pentamidine, quinine, etc.).
- Keep the patient in the supine position for 30 minutes after injection (risk of orthostatic hypotension).
- <u>Pregnancy</u>: avoid (risk of maternal hypotension)
- Breast-feeding: avoid

#### Remarks

- Avoid contact with skin (risk of contact dermatitis).
- Storage: below 25°C 🌽

# **CLINDAMYCIN** injectable

Prescription under medical supervision



# Therapeutic action

- Lincosamide antibacterial

#### **Indications**

- Second-line treatment of severe staphylococcal and/or streptococcal infections (e.g. cellulitis, erysipelas, pneumonia)
- Necrotizing skin and soft tissues infections (necrotizing fasciitis, gas gangrene, etc.), severe cutaneous anthrax, in combination with other antibacterials

# Forms and strengths, route of administration

– 300 mg ampoule (150 mg/ml, 2 ml), for IV infusion in 0.9% sodium chloride or 5% glucose, to be administered over 30 minutes. DO NOT ADMINISTER FOR IV WITHOUT SOLUTION.

#### Dosage

- Severe staphylococcal and/or streptococcal infections

Neonate 0 to 7 days (< 2 kg): 5 mg/kg every 12 hours

Neonate 0 to 7 days (≥ 2 kg): 5 mg/kg every 8 hours

Neonate 8 days to < 1 month (< 2 kg): 5 mg/kg every 8 hours

Neonate 8 days to < 1 month (≥ 2 kg): 10 mg/kg every 8 hours

Child 1 month and over: 10 mg/kg every 8 hours (max. 1800 mg daily)

Adult: 600 mg every 8 hours

- Necrotizing infections, severe cutaneous anthrax

Neonate: as above

Child 1 month and over: 10 to 13 mg/kg every 8 hours (max. 2700 mg daily)

Adult: 900 mg every 8 hours

Dilute each dose of clindamycin in 5 ml/kg of 0.9% sodium chloride or 5% glucose in children less than 20 kg and in a bag of 100 ml of 0.9% sodium chloride or 5% glucose in children 20 kg and over and in adults.

#### **Duration**

- Cellulitis, erysipelas: 7 to 10 days; pneumonia: 10 to 14 days; severe cutaneous anthrax: 14 days; necrotizing infections: according to clinical evolution. Change to oral route as soon as possible.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to lincosamides or history of pseudomembranous colitis.
- Reduce dosage in patients with hepatic impairment.
- May cause: pseudomembranous colitis, rash, jaundice, severe allergic reactions. In these cases, stop treatment.
- In the event of pseudomembranous colitis, treat for *Clostridium difficile* infection (oral metronidazole).
- <u>Pregnancy</u>: no contra-indication
- <u>Breast-feeding</u>: use only when there are no therapeutic alternative. Check child's stools (risk of pseudomembranous colitis).

#### Remarks

- Do not mix with other drugs in the same infusion bottle.
- Some presentations contain benzyl alcohol and should not be used in neonates.
- Storage: below 25 °C V

# **CLOXACILLIN** injectable

Prescription under medical supervision

# Therapeutic action

- Penicillin antibacterial

#### **Indications**

- Severe infections due to streptococci and/or staphylococci: meningitis, pneumonia, omphalitis, septicaemia of cutaneous origin, endocarditis, osteomyelitis, necrotizing skin and soft tissues infections, etc.
- Erysipelas, cellulitis

# Forms and strengths, route of administration

– Powder for injection, in 500 mg vial, to be dissolved in 4 ml of water for injection, for IV infusion in 0.9% sodium chloride or 5% glucose, to be administered in 60 minutes

# Dosage

- Severe infections
- Neonate:

0 to 7 days (< 2 kg): 50 mg/kg every 12 hours 0 to 7 days ( $\geq 2 \text{ kg}$ ): 50 mg/kg every 8 hours

- 8 days to < 1 month (< 2 kg): 50 mg/kg every 8 hours
- 8 days to  $< 1 \text{ month } (\ge 2 \text{ kg})$ : 50 mg/kg every 6 hours
- Child 1 month and over: 25 to 50 mg/kg every 6 hours (max. 8 g daily)
- Adult: 2 g every 6 hours (12 g daily for septicaemia, endocarditis, osteomyelitis or if resistance is suspected and in patients ≥ 85 kg)

Age	Weight	<b>500 mg vial</b> (diluted in 4 ml, 125 mg/ml)	
1 to < 3 months	4 to < 6 kg	1 ml x 4	
3 months to < 1 year	6 to < 10 kg	2 ml x 4	
1 to < 5 years	10 to < 20 kg	4 ml x 4	(1 vial x 4)
5 to < 8 years	20 to < 28 kg	8 ml x 4	(2 vials x 4)
8 to < 12 years	28 to < 38 kg	12 ml x 4	(3 vials x 4)
≥ 12 years and adult	≥38 kg	16 ml x 4	(4 vials x 4)

Dilute each dose of cloxacillin in 5 ml/kg of 0.9% sodium chloride or 5% glucose in children less than 20 kg and in a bag of 100 ml of 0.9% sodium chloride or 5% glucose in children 20 kg and over and in adults.

- Erysipelas, cellulitis

Neonate, child and adult: half of above dose

#### **Duration**

– Change to oral route as soon as possible with amoxicillin/clavulanic acid or cefalexin depending on the indication. Do not use oral cloxacillin for completion treatment following parenteral therapy.

# Contra-indications, adverse effects, precautions

- Do not administer to penicillin-allergic patients.
- Administer with caution to patients with allergy to cephalosporins (cross-sensitivity may occur) or with renal impairment (reduce the dose).
- May cause: gastrointestinal disturbances (particularly diarrhoea), allergic reactions sometimes severe; rarely, haematological disorders.
- Do not combine with methotrexate (increased methotrexate toxicity).
- Pregnancy and breast-feeding: no contra-indication

#### Remarks

- Dicloxacillin, flucloxacillin and oxacillin are used for the same indications.
- Do not mix with other drugs in the same infusion.
- Storage: below 25 °C ₹

Reconstituted solution must be used immediately.

# **CO-AMOXICLAV** injectable

# **DEXAMETHASONE** injectable

Prescription under medical supervision

# Therapeutic action

- Corticosteroid

#### **Indications**

- Inflammatory syndrome in severe infections: severe typhoid fever, acute subglottic laryngitis, etc.
- Foetal lung maturation, in the event of threatened premature delivery before 34 weeks of gestation

# Forms and strengths, route of administration

- 4 mg dexamethasone phosphate in 1 ml ampoule (4 mg/ml) for IM or IV injection or infusion

# **Dosage and duration**

Inflammatory syndrome in severe infections
 Dosage and duration vary according to severity and clinical response:
 Child: 0.2 to 0.4 mg/kg daily
 Adult: initial dose of 0.5 to 24 mg daily

– Foetal lung maturation

Administer to the mother: 6 mg by IM injection every 12 hours for 2 days (total dose: 24 mg)

# Contra-indications, adverse effects, precautions

- For systemic infections, only administer if patient is under antibiotic treatment.
- In the event of treatment longer than 10 days, decrease doses gradually to avoid adrenal gland failure.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Foetal lung maturation:
- after 34 weeks of gestation, corticosteroid treatment is not indicated;
- dexamethasone may be replaced by betamethasone: 2 doses of 12 mg by IM injection at 24-hour interval (total dose: 24 mg).
- For allergic reactions (Quinke's oedema, anaphylactic shock) and status asthmaticus, use hydrocortisone.
- Dexamethasone acetate, insoluble in water, is a suspension used only for local treatment: intraarticular or peri-articular injection, epidural injection (sciatica).
- Storage: below 25 °C W

The solution precipitates at 0 °C, it must not be exposed to cold temperatures.

# **DEXTROSE 50% injectable**

See GLUCOSE 50% injectable(see page 211)

# **DIAZEPAM** emulsion

Prescription under medical supervision



For administration, equipment for ventilation must be available and ready for use.

# Therapeutic action

- Anxiolytic, sedative, anticonvulsant, muscle relaxant

#### **Indications**

- Muscle spasms due to tetanus in neonates

# Forms and strengths, route of administration

– 10 mg ampoule (5 mg/ml, 2 ml) emulsion for slow IV injection (3 to 5 minutes) or infusion in 10% glucose (if not available, 5%). DO NOT ADMINISTER BY IM OR RECTAL ROUTE.

# **Dosage and duration**

- The dosage range is variable, depending on the severity of symptoms and clinical response. For information:
- $\bullet$  0.1 to 0.3 mg/kg by slow IV injection every 1 to 4 hours or
- 0.1 to 0.5 mg/kg/hour by continuous perfusion, preferably via an electric syringe Dilute one ampoule of diazepam emulsion (10 mg) in a syringe of 50 ml of 10% glucose to obtain a solution containing 0.2 mg of diazepam per ml.

Every 6 hours, discharge the content remaining in the electric syringe and prepare a new syringe for 6 hours.

Weight	Dose	Diluted solution 0.2 mg/ml
	0.1 mg/kg/hour	1.3 ml/hour
2.5 kg	0.3 mg/kg/hour	3.8 ml/hour
	0.5 mg/kg/hour	6.2 ml/hour
	0.1 mg/kg/hour	1.5 ml/hour
3 kg	0.3 mg/kg/hour	4.5 ml/hour

	0.5 mg/kg/hour	7.5 ml/hour
3.5 kg	0.1 mg/kg/hour	1.8 ml/hour
	0.3 mg/kg/hour	5.2 ml/hour
	0.5 mg/kg/hour	8.8 ml/hour

#### Contra-indications, adverse effects, precautions

- Do not administer to patients with severe respiratory insufficiency or severe hepatic impairment.
- Reduce the dose by one half in patients with renal or hepatic impairment.
- May cause:
- hypotension, respiratory depression, if injected too rapidly by IV route and if large doses are administered;
- drowsiness, muscle weakness;
- in the event of overdose: hypotonia, lethargy, respiratory distress, coma.
- Avoid and monitor in combination with:
- drugs containing alcohol, opioid analgesics, other anticonvulsants, etc. (increased sedation);
- enzyme inducers such as nevirapine, ritonavir, phenobarbital, phenytoin, etc. (efficacy of diazepam reduced);
- omeprazole, macrolides, ritonavir, fluconazole, etc. (effects of diazepam increased);
- phenytoin (phenytoin plasmatic concentrations modified).

#### Remarks

- Diazepam is subject to international controls: follow national regulations.
- Do not mix with other drugs in the same syringe or infusion.
- Storage: below 25 °C 🖊

Emulsion diluted in glucose can be kept 6 hours maximum.

# **DIAZEPAM** solution

Prescription under medical supervision



- Do not use this solution in neonates, use diazepam *emulsion* only.
- For IV administration, equipment for ventilation must be available and ready for use.

# Therapeutic action

- Anxiolytic, sedative, anticonvulsant, muscle relaxant

#### **Indications**

- Seizures
- Muscle spasms due to tetanus in children over 1 month and adults
- Severe agitation in adults

# Forms and strengths, route of administration

- 10 mg ampoule (5 mg/ml, 2 ml) for IM or slow IV injection (3 to 5 minutes) or infusion in 0.9% sodium chloride or 5% glucose
- The injectable solution may be used rectally.

# **Dosage and duration**

- Seizures

Child:

• Rectal route: 0.5 mg/kg/dose (= 0.1 ml/kg/dose); max. 10 mg/dose

Age	Weight	10 mg/2 ml solution*
6 to < 12 months	7 to < 10 kg	1 ml
1 to < 3 years	10 to < 14 kg	1.25 ml
3 to < 5 years	14 to < 19 kg	1.5 ml
≥ 5 years and adult	≥ 19 kg	2 ml

<sup>\*</sup> Use a 1 ml syringe without needle and insert it 2 to 3 cm into the rectum, or attach a nasogastric tube n°8 cut to a length of 2 to 3 cm to the tip of a 2 ml syringe. Hold the buttocks together for a few minutes.

• Slow IV injection: 0.3 mg/kg/dose (= 0.06 ml/kg/dose); max. 10 mg/dose

#### Adult:

Slow IV injection or rectal route: 10 mg/dose (= 2 ml/dose)

In children and adults, if seizures do not stop within 10 minutes after the first dose, repeat the same dose once, whatever the route of administration.

- Muscle spasms due to tetanus

The dosage range is variable, depending on the severity of symptoms and clinical response. For information:

Child and adult:

- 0.1 to 0.3 mg/kg by slow IV injection every 1 to 4 hours or
- 0.1 to 0.5 mg/kg/hour by continuous perfusion over 24 hours
- Severe agitation

Adult: 10 mg by IM injection, to be repeated once after 30 to 60 minutes if necessary

# Contra-indications, adverse effects, precautions

- Do not administer to neonates (contains benzyl alcohol) and to patients with severe respiratory insufficiency or severe hepatic impairment.
- Reduce the dose by one half in elderly patients and patients with renal or hepatic impairment.
- May cause:
- pain at injection site, drowsiness, muscle weakness;
- hypotension, respiratory depression, if injected too rapidly by IV route and if large doses are administered (tetanus):
- in the event of overdose: hypotonia, lethargy, respiratory distress, coma.
- Avoid and monitor in combination with:

- drugs containing alcohol, opioid analgesics, antipsychotics, antihistamines, antidepressants, other anticonvulsants, etc. (increased sedation);
- enzyme inducers such as rifampicin, rifabutin, nevirapine, ritonavir, phenobarbital, phenytoin, carbamazepine, griseofulvin, etc. (efficacy of diazepam reduced);
- omeprazole, macrolides, ritonavir, isoniazid, fluconazole, itraconazole, etc. (effects of diazepam increased);
- phenytoin (phenytoin plasmatic concentrations modified).
- <u>Pregnancy and breast-feeding</u>: avoid if possible, except if vital (passage through the placenta and breast milk)

- Diazepam is subject to international controls: follow national regulations.
- For administration by infusion, the concentration of diazepam in the solution should not exceed 0.25 mg/ml (e.g. 1 mg in at least 4 ml).
- Do not mix with other drugs in the same syringe or infusion.
- Storage: below 25 °C ₩

# **DICLOFENAC** injectable

Prescription under medical supervision



# Therapeutic action

- Non-steroidal anti-inflammatory drug (NSAID), analgesic

#### **Indications**

- Moderate pain due to inflammation (acute sciatic neuralgia, renal colic, postoperative pain, etc.)

# Forms and strengths, route of administration

- 75 mg in 3 ml ampoule (25 mg/ml) for deep IM injection or IV infusion

#### Dosage

- Adult: 75 mg by deep IM injection, to be repeated after 6 hours if necessary
- For postoperative pain, may be administered by infusion: 75 mg over 30 to 120 minutes, to be repeated after 4 to 6 hours if necessary.
- Do not exceed 150 mg in 24 hours.

#### **Duration**

– Maximum 2 days; change to oral treatment with an analgesic, e.g. ibuprofen or paracetamol, as soon as possible.

# Contra-indications, adverse effects, precautions

– Do not administer to patients with allergy to NSAID (aspirin, ibuprofen, etc.), peptic ulcer, coagulation defects, haemorrhage, surgery with risk of major blood loss, severe renal, hepatic or cardiac impairment, severe malnutrition, uncorrected dehydration or hypovolaemia, asthma, severe infection.

- May cause: local reactions at the injection site, renal impairment, gastrointestinal disturbances, allergic reactions (skin rash, bronchospasm).
- Administer with caution and carefully monitor use in older patients or patients with cardiovascular disorders (hypertension, diabetes, etc.).
- Do not combine with other NSAID (aspirin, ibuprofen, etc.), diuretics, anticoagulants.
- <u>Pregnancy</u>: **CONTRA-INDICATED**
- Breast-feeding: CONTRA-INDICATED

- For infusion, use a solution of 5% glucose or 0.9% sodium chloride and add 0.5 ml of 8.4% sodium bicarbonate per 500 ml.
- Diclofenac is not included in the WHO list of essential medicines.
- Storage: below 25°C 🌽

# **DIGOXIN** injectable

Prescription under medical supervision



# Therapeutic action

- Cardiotonic

#### **Indications**

- Supraventricular arrhythmias (fibrillation, flutter, paroxysmal tachycardia)
- Heart failure

# Forms and strengths, route of administration

– 500 micrograms ampoule (250 micrograms/ml, 2 ml) for slow IV injection or infusion in 5% glucose or 0.9% sodium chloride

# Dosage

- Adult:
- Loading dose: 500 to 1000 micrograms

The loading dose can be administered either by intravenous infusion as a single dose given over 2 hours minimum or in divided doses, by slow IV injections over 5 minutes minimum.

- Maintenance dose: change to oral treatment
- Reduce the dose by one half in elderly patients and in patients with renal impairment.

#### Contra-indications, adverse effects, precautions

- Do not administer to patients with bradycardia, ill defined arrhythmia, coronary artery disease.
- It is essential to monitor heart rate in the initial stage of treatment.
- Narrow margin between therapeutic and toxic dose.
- May cause in the event of overdose: gastrointestinal disturbances (nausea, vomiting, diarrhoea), blurred vision, headache, confusion, conduction and rhythm disorders. If so, reduce dose or stop treatment.

- Do not combine with calcium, particularly by IV injection (serious arrhythmias).
- Monitor combination with:
- amiodarone, macrolides, itraconazole, quinine, chloroquine (increased digoxin concentration);
- potassium-depleting drugs: diuretics, corticoids, amphotericin B (increased risk of digoxin toxicity).
- Monitor if possible serum potassium level in patients taking potassium-depleting drugs and serum creatinine level in patients with renal impairment.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

- A loading dose may be administered in arrhythmias if a rapid digitalisation is required. It is usually not required for heart failure.
- Storage: below 25 °C 🖊

# ! Dipyrone injectable

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see METAMIZOLE = DIPYRONE = NORAMIDOPYRINE injectable(see page 326)

# **EFLORNITHINE** injectable

Prescription under medical supervision



# Therapeutic action

- Trypanocide

#### **Indications**

– Meningoencephalitic stage of African trypanosomiasis due to *T.b. gambiense*, in combination with nifurtimox (first choice treatment) or in monotherapy if nifurtimox is not available or is contra-indicated

# Forms and strengths, route of administration

– 20 g in 100 ml ampoule (200 mg/ml) to be diluted in 250 ml of sterile distilled water (or, if not available, 0.9% sodium chloride), for IV infusion administered over 2 hours

#### **Dosage and duration**

In combination with nifurtimox
 Child and adult: 200 mg/kg every 12 hours for 7 days

- In monotherapy

Child under 12 years: 150 mg/kg every 6 hours for 14 days

Child 12 years and over and adult: 100 mg/kg every 6 hours for 14 days

# Contra-indications, adverse effects, precautions

- May cause: haematological disorders (anaemia, leucopenia, thrombocytopenia), gastrointestinal disturbances (diarrhoea, abdominal pain, vomiting), seizures, tremor, fever, deep tissue infection, headache, alopecia, dizziness.
- The catheter must be handled with great attention to avoid local or general bacterial superinfections: thoroughly disinfect the insertion site, protect the site with a sterile dressing, ensure secure catheter fixation and change the catheter every 48 hours or earlier in the event of phlebitis.
- <u>Pregnancy</u>: **CONTRA-INDICATED** unless, due to the mother's general condition, treatment cannot be delayed until after delivery.

#### Remarks

- When administering nifurtimox-eflornithine combined therapy, the dosage of nifurtimox in children and adults is 5 mg/kg every 8 hours for 10 days.
- Eflornithine is also called difluoromethylornithine or DFMO.
- <u>Storage</u>: below 25 °C 🌽

Diluted solution must be kept refrigerated (2 °C to 8 °C) and used within 24 hours.

# **EPINEPHRINE = EPN = ADRENALINE** injectable

Prescription under medical supervision



# Therapeutic action

- Sympathomimetic

#### **Indications**

- Severe anaphylactic reaction
- Cardiopulmonary arrest

# Forms and strengths, route of administration

- 1 mg in 1 ml ampoule (1 mg/ml) for IM injection only
- -1 mg in 1 ml ampoule (1 mg/ml) for **IV injection only** after dilution in 0.9% sodium chloride to obtain a solution containing 0.1 mg/ml

Before administration, check concentration and route of administration indicated on the ampoule.

# Dosage

- Severe anaphylactic reaction

IM epinephrine is the first line treatment (anterolateral part of the thigh), however use IV epinephrine in

patients with circulatory collapse or those who deteriorate despite receiving two IM injections of epinephrine.

• IM treatment

Use *undiluted* solution (1 mg/ml = 1:1000) and a 1 ml syringe graduated in 0.01 ml:

Child under 6 years: 0.15 ml Child from 6 to 12 years: 0.3 ml

Child over 12 years and adult: 0.5 ml

In children, if 1 ml syringe is not available, use a *diluted* solution, i.e. add 1 mg EPN to 9 ml of 0.9% sodium chloride to obtain a 0.1 mg/ml solution (1:10 000):

Child under 6 years: 1.5 ml Child from 6 to 12 years: 3 ml

Repeat after 5 minutes if there is no clinical improvement.

IV treatment

Use a *diluted* solution, i.e. add 1 mg EPN to 9 ml of 0.9% sodium chloride to obtain a 0.1 mg/ml solution (1:10 000):

Child: 0.1 ml/kg (0.01 mg/kg) administered over several minutes

Adult: 1 to 2 ml (0.1 to 0.2 mg), to be repeated every 1 to 2 minutes, until improvement occurs

- Cardiopulmonary arrest

Use a *diluted* solution by IV route, i.e. add 1 mg EPN to 9 ml of 0.9% sodium chloride to obtain a 0.1 mg/ml solution (1:10 000):

Child: 0.1 ml/kg (0.01 mg/kg), to be repeated every 3 to 5 minutes, until improvement occurs Adult: 10 ml (1 mg), to be repeated every 3 to 5 minutes, until improvement occurs

#### Contra-indications, adverse effects, precautions

- Administer with caution to patients with hypertension, angina, ischaemic heart disease, hyperthyroidism and to elderly patients.
- Do not exceed indicated dose: risk of arrhythmia.
- <u>Pregnancy and breast-feeding</u>: no contra-indication

#### Remarks

- Epinephrine is colourless: discard any ampoules with a pink or brownish colour.
- Also comes in 0.1 mg/ml (1:10 000 solution) ampoules.
- Storage: V

# **ETONOGESTREL** subdermal implant

Prescription under medical supervision

# Therapeutic action

- Hormonal contraceptive, progestogen

#### **Indications**

- Long-acting contraception

# Forms and strengths, route of administration

– Flexible rod containing 68 mg of etonogestrel, in a sterile disposable applicator, to be inserted subdermally into the inner side of the non-dominant arm, 6 to 8 cm above the elbow crease, under local anaesthesia and aseptic conditions

#### **Dosage**

– The implant may be inserted at any moment of the cycle if it is reasonably certain the woman is not pregnant, including when switching from another form of contraception.

Use condoms for 7 days after insertion of the implant if it is inserted:

- more than 7 days after the start of menstruation;
- more than 28 days postpartum if not breastfeeding;
- more than 7 days after an abortion.

#### **Duration**

– As long as this method of contraception is desired and it is well tolerated, for max. 3 years after which it no longer provides contraception and must be changed.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with breast cancer, severe or recent liver disease, unexplained vaginal bleeding, active thromboembolic disorders.
- May cause: menstrual irregularities, amenorrhoea, menometrorrhagia, breast tenderness, headache, weight gain, itching, acne, mood changes, abdominal pain, gastrointestinal disturbances, allergic reactions.
- Enzyme-inducing drugs (rifampicin, rifabutin, efavirenz, nevirapine, lopinavir, ritonavir, phenobarbital, phenytoin, carbamazepine, griseofulvin, etc.) reduce the effectiveness of the contraceptive.
- Pregnancy: CONTRA-INDICATED
- Breast-feeding: no contra-indication

#### Remarks

- Fertility returns rapidly after removal of the implant.
- For the conditions for insertion or removal the implant, follow manufacturer's instructions.
- Storage: below 25 °C W

# **FLUCONAZOLE** injectable

Prescription under medical supervision

# Therapeutic action

- Antifungal

#### **Indications**

- Severe fungal infections, when oral administration is not possible:
- Cryptococcal meningitis, in combination with amphotericin B
- Severe oesophageal candidiasis

# Forms and strengths, route of administration

- 200 mg in 100 ml bag (2 mg/ml), for infusion

#### **Dosage**

- Cryptococcal meningitis, in combination with amphotericin B

Child over 1 week: 12 mg/kg once daily (max. 800 mg daily) administered over 20 minutes minimum (max. 5 ml/minute)

Adult: 800 mg once daily, administered over 10 minutes minimum (max. 10 ml/minute)

- Severe oesophageal candidiasis

Child over 1 week: 3 to 6 mg/kg once daily

Adult: 200 mg once daily

These doses may be increased up to 400 mg daily if necessary.

#### **Duration**

- Change to oral treatment as soon as possible.

# Contra-indications, adverse effects, precautions

- Administer with caution to patients with hepatic or renal impairment, cardiac disorders (bradycardia, heart rhythm disorders, etc.).
- Reduce the dose by half in patients with renal impairment.
- May cause: gastrointestinal disturbances, headache, skin reactions sometimes severe, anaphylactic reactions; severe hepatic disorders, haematological (leukopenia, thrombo cytopenia) and cardiac disorders (QT-prolongation). Stop treatment in the event of anaphylactic reaction, hepatic disorders or severe skin reaction.
- Avoid or monitor combination with:
- drugs that prolong the QT interval (amiodarone, chloroquine, erythromycin, haloperidol, mefloquine, pentamidine, quinine);
- warfarin, carbamazepine, phenytoin, rifabutin, benzodiazepines, calcium-channel blockers, certain antiretrovirals (e.g. nevirapine, saquinavir, zidovudine): increased blood concentration of these drugs.

#### Remarks

- For cryptococcocal meningitis, when amphotericin B is not available or not tolerated, fluconazole may be administered alone during the induction phase (same doses as the oral route).
- Do not add any drug in the infusion bag.
- Storage: below 25 °C. Do not store in a refrigerator.

# **FUROSEMIDE** injectable

Prescription under medical supervision

# Therapeutic action

- Diuretic

#### **Indications**

- Emergency treatment of:
- Oedema caused by renal, hepatic or congestive heart failure
- Hypertensive crisis (except that of pregnancy)
- Pulmonary oedema

# Forms and strengths, route of administration

- 20 mg in 2 ml ampoule (10 mg/ml) for IM or slow IV injection

#### **Dosage**

- Child: 0.5 to 1 mg/kg/injection
- Adult: 20 to 40 mg/injection

Repeat after 2 hours if necessary.

– For *pulmonary oedema*: if an initial IV injection of 40 mg does not produce a satisfactory response within one hour, the dose may be increased to 80 mg by slow IV injection.

#### **Duration**

- According to clinical response;
- If prolonged use is required, change to oral treatment 3 hours after the last injection.

# Contra-indications, adverse effects, precautions

- Do not administer in other types of oedema, especially those due to kwashiorkor.
- Do not administer in case of hepatic encephalopathy.
- May cause: hypokalaemia, especially in cases of cirrhosis, denutrition, congestive heart failure.
- Closely monitor combination with digoxin (furosemide enhances toxicity of digoxin).
- <u>Pregnancy</u>: **CONTRA-INDICATED** to treat hypertension in pregnancy
- Breast-feeding: avoid (excreted in milk and may reduce milk production)

#### Remarks

- If doses greater than 50 mg are required, it is recommended that they be given by IV infusion.
- Storage: below 25 °C 7

# **GENTAMICIN** injectable

Prescription under medical supervision



# Therapeutic action

- Aminoglycoside antibacterial

#### **Indications**

– Severe bacterial infections: meningitis, pneumonia, pyelonephritis, postpartum upper genital tract infections, brucellosis, etc., in combination with other antibacterials

# Forms and strengths, route of administration

– 80 mg ampoule (40 mg/ml, 2 ml) and 20 mg vial (10 mg/ml, 2 ml), for IM or slow IV injection (3 minutes) or IV infusion (30 minutes) in 0.9% sodium chloride or 5% glucose

#### **Dosage**

- Meningitis in young children, in combination with ampicillin or cloxacillin
- Neonate:

0 to 7 days (< 2 kg): 3 mg/kg once daily by IV injection or infusion 0 to 7 days (≥ 2 kg): 5 mg/kg once daily by IV injection or infusion

8 days to < 1 month: 5 mg/kg once daily by IV injection or infusion

- Child 1 to 3 months: 2.5 mg/kg every 8 hours by IV injection or infusion
- Other severe infections
- Neonate: as above
- Child 1 month and over and adult: 5 to 6 mg/kg once daily

For administration by IV infusion, dilute each dose of gentamicin in 5 ml/kg of 0.9% sodium chloride or 5% glucose in children less than 20 kg and in a bag of 100 ml of 0.9% sodium chloride or 5% glucose in children 20 kg and over and in adults.

#### **Duration**

– According to indication and clinical response. Given the risk of renal and auditory toxicity, do not prolong treatment unnecessarily.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to aminoglycosides or auditory and vestibular damage.
- Administer with caution and reduce dosage (1 mg/kg daily) in patients with renal impairment.
- May cause: renal impairment, irreversible auditory and vestibular damage, blockage of neuromuscular transmission, allergic reactions.
- Do not combine with another aminoglycoside.
- Monitor combination with: furosemide, amphotericin B, vancomycin (enhanced renal and/or auditory toxicity); neuromuscular blockers, general anaesthetics (potentialization of their effects).
- <u>Pregnancy</u>: administer only if clearly needed (risk of fetal ototoxicity).
- Breast-feeding: no contra-indication

#### Remarks

- Do not mix with other drugs in the same syringe or infusion.
- Gentamicin is also used in the treatment of plague in pregnant and breast-feeding women at a dose of 5 mg/kg once daily for 10 days.
- Storage: below 25 °C 🖊

# **GLUCOSE 50% = DEXTROSE 50% injectable**

Prescription under medical supervision

#### **Indications**

- Treatment of severe hypoglycaemia

# Forms and strengths, route of administration

– 50% hypertonic glucose solution in 50 ml vial (500 mg/ml), for slow IV injection (3 to 5 minutes). NEVER BY IM OR SC INJECTION.

# **Dosage and duration**

- Adult: 1 ml/kg by slow IV injection
- Check blood glucose level 15 minutes after injection. If blood glucose level is still < 3.3 mmol/litre or < 60 mg/dl, administer a second dose or give oral glucose, according to the patient's clinical condition.

# Contra-indications, adverse effects, precautions

- May cause:
- vein irritation;
- severe tissue damage (necrosis) in the event of extravasation.
- The solution is viscous: use a large vein and a large calibre needle.

#### **Remarks**

- 50% glucose solution is too viscous, concentrated and irritant to be used in children.
- In children use 10% glucose solution. If ready-made 10% glucose solution is not available: add 10 ml of 50% glucose per 100 ml of 5% glucose to obtain a 10% glucose solution. The dose of 10% glucose to be administered is 2 ml/kg by slow IV injection.
- Storage: below 25 ℃

# **HALOPERIDOL** injectable

Prescription under medical supervision



# Therapeutic action

- Antipsychotic

#### **Indications**

- Agitation or aggressive behaviour in patients with acute or chronic psychosis

#### Forms and strengths, route of administration

- 5 mg in 1 ml ampoule (5 mg/ml) for IM injection

#### **Dosage**

- Adult: one injection of 2.5 mg. Subsequent doses, if needed, should be given at 1 to 8 hour intervals (max. 15 mg in 24 hours).
- Reduce the dose by half in elderly patients (max. 5 mg in 24 hours).

#### **Duration**

- Change to oral treatment as soon as possible.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with cardiac disorders (cardiac failure, recent myocardial infarction, conduction disorders, bradycardia, etc.), dementia (e.g. Alzheimer's disease), Parkinson's disease and history of neuroleptic malignant syndrome.
- Administer with caution and carefully monitor use in elderly patients and patients with hypokalaemia, hypotension, hyperthyroidism, renal or hepatic impairment, history of seizures.
- May cause: drowsiness, extrapyramidal syndrome, dyskinesia, anticholinergic effects (constipation, dry mouth), sexual dysfunction, QT-prolongation, ventricular arrhythmia, orthostatic hypotension; neuroleptic malignant syndrome (unexplained hyperthermia with neuromuscular disorders), rare but requiring immediate treatment discontinuation.
- Avoid combination with:
- central nervous system depressants (opioid analgesics, sedatives, H1 antihistamines, etc.);
- fluoxetine, paroxetine, sertraline, promethazine, ritonavir (increased plasma concentrations of haloperidol):
- carbamazepine, rifampicin, phenobarbital, phenytoin (decreased plasma concentrations of haloperidol);
- antihypertensive drugs (risk of hypotension); drugs that prolong the QT interval (amiodarone, chloroquine, erythromycin, fluconazole, mefloquine, pentamidine, quinine, etc.).
- Keep the patient in the supine position for 30 minutes after injection (risk of orthostatic hypotension):
- <u>Pregnancy</u>: re-evaluate whether the treatment is still necessary; if it is continued, administer at the lowest effective dose and monitor the neonate for reversible extrapyramidal effects (tremors) if the mother was treated in the 3<sup>rd</sup> trimester.
- Breast-feeding: if absolutely necessary, do not exceed 10 mg in 24 hours.

#### Remarks

- Haloperidol decanoate is a long-acting form used as maintenance therapy of chronic psychotic disorders after stablisation with oral treatment.
- Storage: below 25 °C 🌽

# **HALOPERIDOL** decanoate injectable

Prescription under medical supervision



# Therapeutic action

- Long-acting antipsychotic

#### **Indications**

- Chronic psychosis, maintenance therapy after stabilisation with oral haloperidol

# Forms and strengths, route of administration

- 50 mg in 1 ml ampoule (50 mg/ml) for IM injection. DO NOT ADMINISTER BY IV INJECTION.

# **Dosage and duration**

- Adult: one injection every 3 to 4 weeks

The initial dose of haloperidol decanoate corresponds to approximately 10 times the daily dose of oral haloperidol.

Daily dose oral haloperidol	Monthly dose haloperidol decanoate IM	50 mg solution haloperidol decanoate IM
2.5 mg	25 mg	½ amp
5 mg	50 mg	1 amp
10 mg	100 mg	2 amp
15 mg	150 mg	3 amp

# Contra-indications, adverse effects, precautions

- Do not administer to patients with cardiac disorders (cardiac failure, recent myocardial infarction, conduction disorders, bradycardia, etc.), dementia (e.g. Alzheimer's disease), Parkinson's disease and history of neuroleptic malignant syndrome.
- Administer with caution and carefully monitor use in elderly patients and patients with hypokalaemia, hypotension, hyperthyroidism, renal or hepatic impairment, history of seizures.
- May cause: drowsiness, extrapyramidal syndrome, early or tardive dyskinesia, constipation, dry mouth, sexual dysfunction, QT-prolongation, ventricular arrhythmia, orthostatic hypotension.
- In the event of extrapyramidal symptoms, combine with biperiden or trihexyphenidyl.
- Avoid or monitor combination with:
- fluoxetine, paroxetine, sertraline, promethazine, ritonavir (increased plasma concentrations of haloperidol);
- carbamazepine, rifampicin, phenobarbital, phenytoin (decreased plasma concentrations of haloperidol);
- drugs that prolong the QT interval (amiodarone, chloroquine, erythromycin, fluconazole, mefloquine, pentamidine, quinine, etc.).
- Avoid alcohol during treatment.
- Avoid in women of childbearing age or offer effective contraception.
- Pregnancy and breastfeeding: avoid

- Change buttock for each injection.
- Storage: below 25 °C V

# **HEPARIN** injectable

Prescription under medical supervision



# Therapeutic action

- Anticoagulant

By IV injection: acts immediately for about 2 to 4 hours SC injection: acts within 1 hour for about 8 to 12 hours

#### **Indications**

- Venous and arterial thrombosis: pulmonary embolism, myocardial infarction, thrombophlebitis
- Prevention of venous and arterial thrombosis, especially in pre-operative and postoperative period and in patients on bedrest

Prescription of heparin requires systematic monitoring of coagulation parameters.

#### Forms and strengths, route of administration

- 1000 IU in 1 ml ampoule (1000 IU/ml) and 5000 IU in 1 ml ampoule (5000 IU/ml) for IV injection or infusion, diluted in an isotonic solution of glucose or sodium chloride
- 25 000 IU in 1 ml ampoule (25 000 IU/ml) for SC injection

Also comes in various concentrations (500 IU, 12 500 IU, 20 000 IU/ml) and volumes (0.5 ml, 2 ml, 5 ml). Check label before use.

#### Dosage

- Curative treatment
- By IV route

Child and adult: initial dose of 50 to 100 IU/kg followed by 400 to 600 IU/kg daily, by continuous infusion over 24 hours or by IV injection every 2 to 4 hours. Adjust dosage according to coagulation tests.

• By SC route

Child and adult: 1 SC injection every 12 hours. Start with an initial dose of 250 IU/kg and adjust dosage according to coagulation tests.

- Preventive treatment

Usually: 5000 IU by SC injection 2 hours before surgery, repeated every 8 to 12 hours. Dosage depends on patient's weight and risk of thrombo-embolic complications: 75 IU/kg 2 times daily or 50 UI/kg 3 times daily.

#### **Duration**

- About 7 to 10 days or more according to clinical response.
- In postoperative period, administer until fully ambulatory.

– For long-term therapy, administer heparin simultaneously with oral anticoagulants for 2 to 3 days before stopping heparin.

# Contra-indications, adverse effects, precautions

- Do not administer if:
- haemorrhage or risk of haemorrhage: haemophilia, active peptic ulcer, acute bacterial endocarditis, severe hypertension; in postoperative period after neurosurgery or ophtalmic surgery;
- thrombocytopenia or history of heparin-induced thrombocytopenia.
- Do not administer by IM route. SC injections must be made deep into abdominal fat, between umbilicus and iliac crest.
- Intramuscular or intra-arterial injections and infiltrations are contra-indicated during heparin therapy.
- May cause:
- severe thrombocytopenia, usually after 5 days of heparin, with thrombo-embolic complications requiring discontinuation of treatment;
- localised reactions at the injection site, rarely, necrosis;
- allergic reactions, osteoporosis after prolonged use, alopecia;
- haemorrhage in case of overdosage, pre-existing lesions, trauma.
- Use with caution and reduce dosage in elderly patients and in hepatic or renal failure.
- Overdosage: neutralise heparin by slow IV injection of protamine. 1 mg protamine neutralises 100 IU of heparin.

Reduce doses of protamine if more than 15 minutes has elapsed since heparin administration.

- Laboratory tests: monitor coagulation parameters in order to adjust dose. Partial thromboplastin time should be maintained at 1.5 to 2 times the control value (Howell's test at 2 to 3 times the control value). Monitor platelet count prior to initiation of treatment and then 2 times per week.
- Avoid combination with aspirin, non-steroidal anti-inflammatory drugs: increased risk of haemorrhage.
- Closely monitor clinical and biological parameters in case of combination with corticosteroids, dextran, and transition to an oral anticoagulant.
- <u>Pregnancy</u>: **CONTRA-INDICATED** at the end of pregnancy (risk of haemorrhage during delivery)
- Breast-feeding: no contra-indication

#### Remarks

- Preparations containing calcium salt of heparin are available. Heparin sodium is usually used by IV route. Both sodium and calcium heparin are used by SC route. There is a little difference in the action of these 2 medications.
  - Do not mix with other drugs in the same syringe.
  - Storage: below 25 °C 7

# **HYDRALAZINE** injectable

Prescription under medical supervision



# Therapeutic action

- Antihypertensive vasodilatator

#### **Indications**

- Hypertension in pregnancy, in case of severe symptoms or when oral treatment is not possible

#### Forms and strengths, route of administration

– Powder for injection, in 20 mg vial, to be dissolved in 1 ml of water for injection, for IV infusion or slow diluted IV injection

#### **Dosage**

Dosage should be adjusted according to blood pressure (BP). The goal is to reduce the blood pressure to 140/90 mmHg. Diastolic BP must not fall below 90 mmHg.

- By IV infusion
- Dilute 100 mg (5 vials of reconstituted hydralazine solution) in 500 ml of 0.9% sodium chloride or Ringer lactate, to obtain a solution containing 200 micrograms/ml.
- Initial dose: 200 to 300 micrograms/minute
- Maintenance dose: 50 to 150 micrograms/minute
- Administer by increasing the rate up to 20 drops/minute (max. 30 drops/minute), check BP every 5 minutes.
- As soon as hypertension is controlled, decrease progressively the rate (15 drops/minute, then 10, then 5) until stopping infusion. An abrupt discontinuation may provoke a hypertensive crisis.
- By slow diluted IV injection
- Dilute 20 mg (1 vial of reconstituted hydralazine solution in 1 ml of water for injection) in 9 ml of 0.9% sodium chloride, to obtain 10 ml of solution containing 2 mg/ml.
- Administer 5 mg (2.5 ml of the diluted solution) over 2 to 4 minutes. Check BP for 20 minutes. If BP remains uncontrolled, repeat injection. Continue repeating if necessary, waiting 20 minutes between each injection (max. 20 mg total dose).

#### **Duration**

– According to clinical response. Change to oral treatment as soon possible with labetalol or methyldopa.

# Contra-indications, adverse effects, precautions

- Administer with caution to patients with heart failure, coronary insufficiency, recent myocardial infarction, severe tachycardia, history of stroke.
- May cause:
- hypotension, tachycardia, headache, gastrointestinal disturbances;
- abrupt fall in maternal blood pressure with placental hypoperfusion and foetal death when administered too rapidly by IV injection or in case of overdose.
- Reduce doses in patients with renal or hepatic impairment.
- Do not exceed recommended dosage and administration rate. During administration, monitor maternal BP and heart rate, as well as foetal heart rate.
- In the event of hypotension, administer Ringer lactate to maintain diastolic BP ≥ 90 mmHg.
- Breast-feeding: no contra-indication

#### Remarks

- For administration, only use sodium chloride 0.9% or Ringer lactate (incompatibility with glucose and other solutions).
- Do not mix with other drugs in the same syringe or infusion bottle.
- Storage: below 25 °C W

Reconstituted solution must be used immediately.

# **HYDROCORTISONE** injectable

Prescription under medical supervision

# Therapeutic action

- Steroidal anti-inflammatory drug (corticosteroid)

### **Indications**

- Symptomatic treatment of severe allergic and inflammatory reactions, e.g.: severe acute asthma (in addition to inhaled salbutamol), allergic angioedema, anaphylactic shock (as an adjunct to epinephrine)

### Forms and strengths, route of administration

– Powder for injection, 100 mg hydrocortisone (hemisuccinate, succinate or phosphate) in vial, to be dissolved in 2 ml water for injection, for IM or slow IV injection or infusion

### **Dosage and duration**

- Child under 1 year: 25 mg/injection
- Child from 1 to 5 years: 50 mg/injection
- Child from 6 to 12 years: 100 mg/injection
- Adult: 100 to 500 mg/injection

Doses may be repeated 3 or 4 times daily according to the severity of the symptoms and the patient's response.

# Contra-indications, adverse effects, precautions

- Avoid prolonged administration in patients with peptic ulcer, diabetes mellitus or cirrhosis.
- Administer with caution to patients receiving digitalis glycosides: increases digitalis toxicity associated with hypokalaemia.
- <u>Pregnancy</u>: use only if clearly needed, for a short period.
- Breast-feeding: no contra-indication

### Remarks

- Hydrocortisone acetate is a suspension insoluble in water, used as a local treatment only: intra- or periarticular injection, epidural (sciatic neuralgia).
- Storage: below 25 °C W

# **HYOSCINE BUTYLBROMIDE = BUTYLSCOPOLAMINE injectable**

Prescription under medical supervision



### Therapeutic action

- Antispasmodic, anticholinergic drug

### **Indications**

- Spasms of the gastrointestinal tract and genitourinary tract

# Forms and strengths, route of administration

- 20 mg in 1 ml ampoule (20 mg/ml) for IM, SC or slow IV injection

### **Dosage**

- Adult: 20 to 40 mg to be repeated if necessary (max. 100 mg daily)

### **Duration**

- According to clinical response; no prolonged treatment.

### Contra-indications, adverse effects, precautions

- Do not administer to patients with benign prostatic hyperplasia, urinary retention, closed-angle glaucoma, tachycardia.
- May cause: urinary retention, dryness of the mouth, constipation, blurred vision, tachycardia (anticholinergic effects).
- Administer with caution and under close supervision:
- in the event of heart failure, coronary insufficiency, cardiac rhythm disorders, hypertension;
- to patients taking other anticholinergic drugs (antidepressants, antipsychotics, H-1 antihistamines, antiparkinsonians, etc.).
- Administer with caution to patients with fever (may affect thermoregulation).
- <u>Pregnancy</u>: no contra-indication; NO PROLONGED TREATMENT
- <u>Breast-feeding</u>: no contra-indication; NO PROLONGED TREATMENT

### Remarks

– <u>Storage</u>: below 25 °C - 🖊

# **INSULIN** injectable

Prescription under medical supervision

# General information on use of insulin by SC route

### Therapeutic action

- Pancreatic hormone, antidiabetic

### Types of insulin

SC administration	Short-acting* human insulin (Actrapid®)	Intermediate- acting human insulin (Insulatard®)	Biphasic insulin		
			human	analogue	
Onset	30 minutes to 1 hour	1 to 2 hours	30 minutes	10 to 20 minutes	
Peak time	2 to 4 hours	4 to 12 hours	2 to 8 hours	2 to 8 hours	
Duration	7 to 8 hours	around 24 hours	around 24 hours	around 24 hours	
Dosage form	solution	suspension	suspension	suspension	
Aspect	clear	cloudy	cloudy	cloudy	

<sup>\*</sup> Short-acting insulin is also known as regular insulin.

- For each preparation, onset and duration of activity are indicated by the manufacturer. Nevertheless, for the same preparation, onset and duration vary from one patient to another.
- In one same patient, duration of activity varies depending on the dose, site of injection, blood flow, body temperature and exercise.
- The type of insulin used depends of several factors: type of diabetes, patient's age, patient's response (blood glucose levels).
- Analogue insulins have a different chemical structure to human insulin that modifies their onset and duration of activity after SC injection.

#### **Indications**

- Type 1 and type 2 diabetes
- Diabetes during pregnancy
- Transient therapy of type 2 diabetes during periods of severe infection, trauma, surgery

#### Dosage

– Dosage must be individualised. Frequency of administration depends on the type of insulin and the patient's response.

#### **Duration**

- *Type 1 diabetes*: life-time treatment
- Other indications: according to clinical response and laboratory tests

- Do not administer in patients with allergy to insulin (rare).
- May cause:
- hypoglycaemia due to overdosage or inadequate diet;
- weight gain;
- local reactions: pain, erythema at the injection site, lipodystrophy. Rotate injection sites systematically and use all available sites (abdomen, thigh, buttock or arm).
- Monitor combination with:
- drugs enhancing hypoglycaemic effect of insulin: acetylsalicylic acid, angiotensin-converting enzyme

inhibitors, beta-blockers (which in addition, may mask symptoms of hypoglycaemia);

- drugs increasing blood glucose levels: corticosteroids, hydrochlorothiazide, salbutamol, chlorpromazine.
- Avoid alcohol (enhances and prolongs hypoglycaemic effect of insulin).
- In the event of renal or hepatic impairment and during the first trimester of pregnancy, reduce insulin doses.
- In the event of infection, emotional stress, accident or surgical intervention and during the last 2 trimesters of pregnancy, increase insulin doses.
- Use sterile technique.
- Pregnancy and breast-feeding: no contra-indication

#### Remarks

- Insulin cannot be administered by mouth since it is inactivated in the gastrointestinal tract.
- After SC injection, insulin absorption is rapid in the abdomen, slower in thighs, buttocks and arms.
- When using an insulin pen, hold the needle in the skin at least six seconds to ensure the entire dose is injected

# INSULIN, INTERMEDIATE-ACTING injectable

Prescription under medical supervision

## Therapeutic action

– Intermediate-acting pancreatic antidiabetic hormone mixed with protamine, in order to prolong the duration of activity

### **Indications**

– Diabetes

### Forms and strengths, route of administration

– 1000 IU of insulin suspension in 10 ml vial (100 IU/ml) for deep SC injection (abdomen, thigh, buttock or arm), administered with a syringe calibrated in insulin units for U-100 insulin (100 IU/ml). NEVER ADMINISTER BY IV INJECTION.

### **Dosage**

– Child and adult: one to 2 injections daily in combination with short-acting insulin or metformine Dosage must be individualised according to need. Adapt dose in the event of physical activity, change in diet or infection.

- See "insulin: general information(see page 218)".
- Do not administer if known allergy to protamine.
- In the event of combination with short-acting insulin, always prepare the mix in the syringe immediately before administration and in the following order: first draw the short-acting insulin then the intermediate-acting insulin.

- After removing vial from the refigerator, leave to reach room temperature.
- Shake the vial gently before use.
- Storage: do not freeze 🖊
- Unopened vial: to be kept refrigerated (2 °C to 8 °C)
- Opened vial: max. 4 weeks at below 25 °C and protected from light.

# INSULIN, LONG-ACTING injectable

See INSULIN, INTERMEDIATE-ACTING injectable (see page 220)

# INSULIN, SHORT-ACTING injectable

Prescription under medical supervision

### Therapeutic action

- Rapid-acting pancreatic antidiabetic hormone

### **Indications**

- Diabetes
- Emergency treatment of hyperglycaemia (diabetic ketoacidosis and hyperosmolar hyperglycaemic state)

### Forms and strengths, route of administration

1000 IU of insulin in 10 ml vial (100 IU/ml) for deep SC injection (abdomen, thigh, buttock or arm) or IV injection, administered with a syringe calibrated in insulin units for U-100 insulin (100 UI/ml) or IV infusion

### **Dosage**

- Diabetes

Child and adult: one SC injection 15 to 30 minutes before a meal, in combination with intermediate-acting insulin

Dosage must be individualised according to need. Adapt dose in the event of physical activity, change in diet or infection.

- Emergency treatment of hyperglycaemia

Adult: initial dose of 0.1 IU/kg by IV injection then 0.1 IU/kg/hour by continuous IV infusion. Adapt the protocol to blood glucose levels.

- See "Insulin: general information(see page 218)".
- In the event of combination with intermediate-acting insulin, always prepare the mix in the syringe

immediately before administration and in the following order: first draw the short-acting insulin then the intermediate-acting insulin.

#### Remarks

- By IV route, insulin has a very short half-life of around 5 minutes and the effect disappears within 30 minutes of injection.
- Storage: do not freeze 🌽
- Unopened vial: to be kept refrigerated (2 °C to 8 °C)
- Opened vial: max. 4 weeks at below 25 °C and protected from light.

# INSULIN, BIPHASIC injectable

Prescription under medical supervision

### Therapeutic action

- Pancreatic antidiabetic hormone: combination of short-acting + intermediate acting insulin

### **Indications**

- Diabetes

### Forms and strengths, route of administration

– 1000 IU vial containing a combination of 30% short-acting insulin + 70% intermediate-acting insulin in suspension (100 IU/ml with a ratio of 30:70, 10 ml), for deep SC injection (abdomen, thigh, buttock or arm), administered with a syringe calibrated in insulin units for U-100 insulin (100 IU/ml). NEVER ADMINISTER BY IV INJECTION.

### Dosage

- Child and adult: one to 2 injections daily

Dosage must be individualised according to need. Adapt dose in the event of physical activity, change in diet or infection.

### Contra-indications, adverse effects, precautions

- See "Insulin: general information(see page 218)".
- Do not administer if known allergy to protamine.

#### Remarks

- After removing vial from the refrigerator, leave to reach room temperature.
- Shake the vial gently before use.
- Also comes in biphasic human insulin 30/70 pens and biphasic analogue insulin 30/70 (aspart) and 25/75 (lispro) pens.
- Storage: do not freeze 🌽
- Unopened vial: to be kept refrigerated (2 °C to 8 °C)
- Opened vial: max. 4 weeks at below 25 °C and protected from light. Follow manufacturer's instructions.

# **KETAMINE** injectable

Prescription under medical supervision



# Therapeutic action

- General anaesthetic

### **Indications**

- Induction and maintenance of general anaesthesia

# Forms and strengths, route of administration

- 250 mg in 5 ml ampoule (50 mg/ml) for IM, IV injection or infusion

### **Dosage**

Child and adult:

- Induction
- IV: 2 mg/kg to be injected slowly. Anaesthesia is produced within one minute and lasts 10 to 15 minutes.
- IM: 8 to 10 mg/kg. Anaesthesia is produced within 5 minutes and lasts 15 to 30 minutes.
- Maintenance
- IV: 0.5 to 1 mg/kg depending on recovery signs (approximately every 15 minutes)
- IM: 5 mg/kg approximately every 20 to 30 minutes

#### **Duration**

- Depending on duration of the operation

- Do not administer to patients with intraocular hypertension, pre-eclampsia.
- Administer with caution to patients with arterial or intracranial hypertension, coronary insufficiency, psychiatric disorders.
- May cause: hypertension, hypersalivation, hallucinations during recovery (less frequent in children or when injected IM), apnoea following rapid IV injection.
- Premedication to prevent hypersalivation and hallucinations:
- $\bullet$  atropine IV: 0.01 to 0.015 mg/kg + diazepam slow IV: 0.1 mg/kg, during induction or
- atropine IM: 0.01 to 0.015 mg/kg + diazepam IM: 0.1 mg/kg, 30 minutes before induction
- Technical equipment for intubation and ventilation must be available and ready for use.
- <u>Pregnancy</u>: no contra-indication, except in pre-eclampsia. For ceaserean sections, do not exceed 1 mg/kg by IV injection (risk of neonatal respiratory depression at higher doses).
- Breast-feeding: no contra-indication

- Ketamine has no muscle relaxant properties.
- In some countries, ketamine is on the list of narcotics: follow national regulations.
- Also comes in 10 ml ampoule containing 500 mg (50 mg/ml).
- Storage: below 25 °C //

# LABETALOL injectable

Prescription under medical supervision



### Therapeutic action

- Non cardioselective beta-blocker

### **Indications**

- Hypertension in pregnancy, in case of severe symptoms or when oral treatment is not possible

### Forms and strengths, route of administration

- 100 mg ampoule (5 mg/ml, 20 ml) for IV injection

### **Dosage**

Dosage should be adjusted according to blood pressure (BP). The goal is to reduce the blood pressure to 140/90 mmHg. Diastolic BP must not fall below 90 mmHg.

– One dose of 20 mg (4 ml) over at least one minute. If hypertension remains uncontrolled 5 and 10 minutes after injection, administer another dose of 20 mg (4 ml). Administer additional doses of 40 mg (8 ml) then 80 mg (16 ml) at 10 minute intervals as long as hypertension is not controlled (max. 300 mg total dose).

### **Duration**

– According to clinical response. Change to oral treatment as soon as possible.

- Do not administer to patients with asthma, chronic obstructive bronchopneumonia, heart failure, severe hypotension, bradycardia < 50/minute, atrio-ventricular heart blocks, Raynaud's syndrome, hepatic impairment.
- May cause:
- bradycardia, orthostatic hypotension, heart failure, bronchospasm, hypoglycaemia, gastrointestinal disturbances, dizziness, headache, weakness, urinary retention;
- abrupt fall in maternal blood pressure with placental hypoperfusion and foetal death when administered too rapidly by IV injection or in case of overdose.
- Administer with caution to patients with diabetes (risk of hypoglycaemia).
- Reduce dosage in patients with renal impairment.
- In the event of anaphylactic shock, risk of resistance to epinephrine.
- Avoid or monitor combination with: mefloquine, digoxin, amiodarone, diltiazem, verapamil (risk of

bradycardia); tricyclic antidepressants, neuroleptics, other anti- hypertensive drugs (risk of hypotension).

- Monitor the newborn: risk of hypoglycaemia, bradycardia, respiratory distress occurring most often during the first 24 hours and until 72 hours after the birth.
- In the event of hypotension, administer Ringer lactate to maintain diastolic BP ≥ 90 mmHg.
- Breast-feeding: no contra-indication

#### Remarks

- Labetalol IV is also used in the treatment of hypertensive crises with serious end-organ damage.
- Storage: below 25°C 🌽

# **LEVONORGESTREL** subdermal implant

Prescription under medical supervision

### Therapeutic action

- Hormonal contraceptive, progestogen

### **Indications**

- Long-acting contraception

# Forms and strengths, route of administration

– Set of two flexible rods containing 75 mg of levonorgestrel, with a sterile applicator, to be inserted subdermally into the inner side of the non-dominant arm, 6 to 8 cm above the elbow crease, under local anaesthesia and aseptic conditions

### Dosage

– The implant may be inserted at any moment of the cycle if it is reasonably certain the woman is not pregnant, including when switching from another form of contraception.

Use condoms for 7 days following the insertion of the implant if it is inserted:

- more than 7 days after the start of menstruation;
- more than 28 days postpartum if not breastfeeding;
- more than 7 days after an abortion.

#### **Duration**

– As long as this method of contraception is desired and it is well tolerated, for max. 5 years (4 years in obese women) after which it no longer provides contraception and must be changed.

- Do not administer to patients with breast cancer, severe or recent liver disease, unexplained vaginal bleeding, active thromboembolic disorders.
- May cause: menstrual irregularities, amenorrhoea, menometrorrhagia, breast tenderness, headache, weight gain, itching, acne, mood changes, abdominal pain, gastrointestinal disturbances, allergic reactions.

- Enzyme-inducing drugs (rifampicin, rifabutin, efavirenz, nevirapine, lopinavir, ritonavir, phenobarbital, phenytoin, carbamazepine, griseofulvin, etc.) reduce the effectiveness of the contraceptive.
- <u>Pregnancy</u>: **CONTRA-INDICATED**
- Breast-feeding: no contra-indication

- Fertility returns rapidly after removal of the implant.
- The duration of action of the levonorgestrel implant (5 years) is longer than that of the etonogestrel implant (3 years). However, the etonogestrel implant (one rod) is easier to insert and remove than the levonorgestrel implant (2 rods).
- For the conditions for insertion or removal the implant, follow manufacturer's instructions.
- Storage: below 25 °C 7

# LIDOCAINE = LIGNOCAINE injectable

Prescription under medical supervision

# Therapeutic action

- Local anaesthetic

### **Indications**

- Local anaesthesia:
- minor operations: 1% lidocaine
- dental surgery: 2% lidocaine (plain or with epinephrine)

# Forms and strengths, route of administration

- 1% solution in 20 and 50 ml vials (10 mg/ml), for SC infiltration
- 2% solution in 20 and 50 ml vials (20 mg/ml), for SC infiltration

# **Dosage**

- The volume to be injected depends on the surface area to be anesthetised.
- Do not exceed:

Child: 5 mg/kg/injection

Adult: 200 mg = 20 ml of lidocaine 1% or 10 ml of lidocaine 2%

AGE (	o mor	2 nths ye	1 ear ye	-	5 ars
WEIGHT	4 k	1 8			35 8
1% solution, 10 mg/ml		2 to 3 ml	4 to 8 ml	9 to 15 ml	15 to 20 ml
2% solution, 20 mg/ml		1 to 1½ ml	2 to 4 ml	4 to 7 ml	7 to 10 ml

### **Duration**

- One injection, repeated if necessary.

# Contra-indications, adverse effects, precautions

- Do not administer if known allergy to lidocaine, impaired cardiac conduction.
- When anaesthetising the extremities, inject distally (at the base), in circle, without tourniquet and without epinephrine (adrenaline).
- Do not use lidocaine for the incision of abscesses: risk of spreading the infection.
- Lidocaine with epinephrine (adrenaline):
- in dental surgery, epinephrine added to lidocaine prolongs anaesthesia;
- never use solutions with epinephrine for the anaesthesia of extremities (fingers, penile nerve block): risk of ischemia and necrosis.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Anaesthesia is produced within 2 to 5 minutes and lasts 1 to 1.5 hours.
- Do not confuse with lidocaine 5% hyperbaric which is reserved for spinal anaesthesia.
- The more concentrated the lidocaine, the more localised the anaesthetic effect.
- To simplify protocols, use lidocaine 2% with epinephrine for dental anaesthesia and lidocaine 1% without epinephrine for cutaneous anaesthesia.
- <u>Storage</u>: below 25 °C 🌽

# **MAGNESIUM SULFATE = MgSO4 injectable**

Prescription under medical supervision



### Therapeutic action

- Anticonvulsant

### **Indications**

- Severe pre-eclampsia: prevention of eclamptic seizures
- Eclampsia: treatment of eclamptic seizures and prevention of recurrence

# Forms and strengths, route of administration

- 5 g ampoule (0,5 g/ml, 10 ml) for IM injection or IV infusion

# **Dosage and duration**

- IV/IM protocol

4 g by IV infusion in 100 ml of 0.9% sodium chloride over 15 to 20 minutes then, 10 g by IM route (5 g in each buttock) then, 5 g by IM route every 4 hours (changing buttock for each injection)

- IV protocol
- 4 g by IV infusion in 100 ml of 0.9% sodium chloride over 15 to 20 minutes then 1 g per hour by continuous IV infusion

Regardless of the protocol chosen:

- Continue the treatment for 24 hours after the delivery or the last seizure.
- If seizures persist or recur, administer a further 2 g (patients less than 70 kg) to 4 g by IV infusion, without exceeding 8 g total dose during the first hour.

### Contra-indications, adverse effects, precautions

- Reduce the dose in patients with renal impairment; do not administer to patients with severe renal impairment.
- May cause:
- pain at the injection site, warm flushes; decreased fetal heart rate;
- in case of overdosage (hypermagnesaemia):
- For the mother: diminished then absent patellar reflex (early sign), hypotension, drowsiness, confusion, difficulty in speaking, bradycardia, respiratory depression (respiratory rate < 12/minute).
  - For the neonate: hypotonia, neurobehavioural impairment, apnoea, respiratory depression.
- Do not combine with nifedipine.
- Check urine output every hour. In the event of decreased urine output (< 30 ml/hour or 100 ml/4 hour), stop magnesium sulfate and perform delivery as soon as possible. If delivery cannot be performed immediately in a woman with eclampsia, stop magnesium sulfate for one hour then resume magnesium sulfate perfusion until delivery.
- Check patellar reflex, blood pressure, heart and respiratory rate every 15 minutes during the first hour of treatment. If no signs of overdosage are observed, continue this surveillance every hour. If signs of overdosage are observed: stop magnesium sulfate and give 1 g calcium gluconate by slow IV route as an antidote (in this event, seizures may recur).
- Breast-feeding: no contra-indication

#### Remarks

- Also comes in ampoules containing 1 g (0.5 mg/ml, 2 ml) and many other dosages. Check the strength of the ampoule carefully before use.
- 1 g magnesium sulfate contains approximately 4 mmol (8 mEg) of magnesium.
- Do not mix with other drugs in the same syringe or infusion fluid.
- Storage: below 25 °C V

# MEDROXYPROGESTERONE injectable

Prescription under medical supervision

## Therapeutic action

- Hormonal contraceptive, progestogen

### **Indications**

Long-acting contraception

### Forms and strengths, route of administration

- 150 mg in 1 ml vial or prefilled syringe (150 mg/ml) for IM injection

### **Dosage**

- 150 mg every 3 months (13 weeks). Subsequent injections may be administered up to 2 weeks before or 4 weeks after the scheduled date.
- The injection may be administered at any moment of the cycle if it is reasonably certain the woman is not pregnant, including when switching from another form of contraception.

  Use condoms for 7 days after the injection if it is administered:
- more than 7 days after the start of menstruation;
- more than 28 days postpartum if not breastfeeding;
- more than 7 days after an abortion.

#### **Duration**

- As long as this method of contraception is desired.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with breast cancer, severe hypertension (≥ 160/100), active thromboembolic disorders, uncontrolled or complicated diabetes, severe or recent liver disease, unexplained vaginal bleeding.
- May cause: menstrual irregularities, amenorrhoea, menometrorrhagia, breast tenderness, headache, weight gain, acne, mood change, abdominal pain, gastrointestinal disturbances.
- The contraceptive efficacy of medroxyprogesterone does not seem to be reduced in women taking enzyme-inducing drugs.
- Pregnancy: CONTRA-INDICATED
- Breast-feeding: no contra-indication

### Remarks

- Shake the vial vigorously before use to homogenise the suspension.
- Return to fertility is delayed for 3 to 12 months after stopping injections.
- Also comes in prefilled single-use injection system (104 mg/0.65 ml) for SC self-administration in the abdomen or anterior thigh.
- Storage: below 25 °C W

# **MELARSOPROL** injectable

Prescription under medical supervision



# Therapeutic action

- Trypanocide (arsenical derivative)

### **Indications**

– Meningoencephalitic stage of African trypanosomiasis due to *T. b. gambiense* and *T. b. rhodesiense* 

### Forms and strengths, route of administration

– 180 mg in 5 ml ampoule (36 mg/ml), 3.6 % solution in propylene glycol, for slow IV injection. NEVER BY IM OR SC INJECTION.

### **Dosage and duration**

- Patients must be treated in hospital, under close medical supervision.
- Child and adult: 2.2 mg/kg (max. 5 ml) once daily for 10 days

# Contra-indications, adverse effects, precautions

- May cause:
- reactive encephalopathy (5-10% of cases): repeated or prolonged seizures, coma, psychical disorders, usually between the 5<sup>th</sup> and the 8<sup>th</sup> day of the ten-day treatment (but sometimes later, even after the patient has been discharged) or just before/during the 2<sup>nd</sup> course of the intermittent treatment;
- arsenical reactions: headache, fever, tachycardia, hypertension, jaw pain, neurological disorders (hyperreflexia);
- gastrointestinal disturbances, skin reactions (exfoliative dermatitis, urticaria), peripheral neuropathy, haematological disorders (haemolytic anaemia in patients with G6PD deficiency, agranulocytosis), hepatic or renal impairment, myocardial damage;
- swelling, pain, phlebitis, venous sclerosis, necrosis at injection site in the event of extravasation during IV administration.
- Use a completely dry syringe: the solution precipitates in presence of water. As propylene glycol can dissolve plastic, the drug should preferably be administered using a glass syringe (only if sterilisation is reliable), otherwise inject immediately (but slowly) using a plastic syringe.
- Pregnancy: CONTRA-INDICATED

### Remarks

- Oral prednisolone is frequently associated during the course of treatment.
- For the meningoencephalitic stage of gambiense trypanosomiasis, the treatment of choice is nifurtimox + eflornithine (NECT).
- Storage: below 25 °C 🖊

# ! Metamizole injectable

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see METAMIZOLE = DIPYRONE = NORAMIDOPYRINE injectable(see page 326)

# **METHYLERGOMETRINE** injectable

Prescription under medical supervision



# Therapeutic action

- Uterotonic, oxytocic

### **Indications**

- Postpartum haemorrhage due to uterine atony (preferably use oxytocin for this indication)

### Forms and strengths, route of administration

- 0,2 mg in 1 ml ampoule (0,2 mg/ml), for IM injection

### **Dosage**

- Adult: 0,2 mg every 2 to 4 hours if necessary (max. 1 g)

### Contra-indications, adverse effects, precautions

- Do not administer during delivery or labour.
- Do not administer in case of allergy to ergot alkaloids (cabergoline, bromocriptine, ergotamine, etc.), severe hypertension, pre-eclampsia, eclampsia, and septicaemia.
- Do not combine with another ergot alkaloid.
- Administer with caution to patients with hepatic or renal impairment, ischemic disorders.
- Do not administer simultaneously with prostaglandins or oxytocin (addition of uterotonic activity).
- May cause: gastrointestinal disturbances, headache, paraesthesia, confusion, dizziness, tinnitus, hypertension, peripheral vasoconstriction, chest pain.
- Monitor combination with: metronidazole, azole antifungals, macrolides, protease inhibitors, efavirenz, fluoxetine (risk of ergotism).
- Pregnancy: CONTRA-INDICATED
- Breast-feeding: avoid

#### Remarks

- Do not confuse with dihydroergotamine, another ergot alkaloid used for totally different indications.
- Methylergometrine is also called methylergonovine or methylergobasine.
- Ergometrine is another uterotonic used for the same indications.
- <u>Storage</u>: to be kept refrigerated (2 °C to 8 °C). Do not freeze 🌠
- Expiry date indicated on the label is only valid if stored under refrigeration and protected from light. Exposure to heat and especially light causes the deterioration of the active ingredient and thus loss of efficacy.
- The solution must be colourless. Discolouration indicated a deterioration of the active ingredient. Never use a coloured solution.
- If refrigeration is not available, vials can be kept for one month on condition that they are protected from light and the temperature remains under 25 °C.

# **METOCLOPRAMIDE** injectable

Prescription under medical supervision

# Therapeutic action

- Antiemetic (dopamine antagonist)

### **Indications**

- Prevention or symptomatic treatment of nausea and vomiting in adults

# Forms and strengths, route of administration

- 10 mg in 2 ml ampoule (5 mg/ml) for IM or slow IV injection (3 to 5 minutes)

### **Dosage**

- Adult: 10 mg every 8 hours if necessary

### **Duration**

- According to clinical evolution, as short as possible

## Contra-indications, adverse effects, precautions

- Do not administer to children < 18 years and to patients with gastrointestinal haemorrhage, obstruction or perforation.
- Reduce the dose by half in patients with severe renal impairment.
- Administer with caution and monitor use in patients > 60 years and patients with epilepsy or Parkinson's disease.
- May cause: drowsiness, dizziness, confusion, extrapyramidal symptoms, seizures (especially in epileptics), allergic reactions, cardiac disorders (hypotension, bradycardia, cardiac arrest); neuroleptic malignant syndrome (unexplained hyperthermia with neuromuscular disorders), rare but requiring immediate treatment discontinuation.
- Do not combine with levodopa (antagonism).
- Avoid combination with CNS depressants (opioid analgesics, antipsychotics, sedatives, antidepressants, antihistamines, etc.) and antihypertensive drugs (increased risk of hypotension).
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

### Remarks

- For postoperative nausea and vomiting in adults, efficacy of metoclopramide is limited: ondansetron is preferred.
- Metoclopramide is also used as a gastrointestinal prokinetic agent in patients receiving enteral feeding by a nasogastric tube in intensive care units.
- Storage: below 25 °C 🖊

# **METRONIDAZOLE** injectable

Prescription under medical supervision

# Therapeutic action

- Antiprotozoal, antibacterial

#### **Indications**

- Severe infections due to anaerobic bacteria (Bacteroides sp., Clostridium sp., etc.)

### Forms and strengths, route of administration

- 500 mg in 100 ml vial or bag (5 mg/ml), for infusion, to be administered over 30 minutes

### **Dosage**

- Child 1 month and over: 10 mg/kg every 8 hours (max. 1500 mg daily)
- Adult: 500 mg every 8 hours

### **Duration**

- According to indication. Change to oral treatment as soon as possible.

### Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to metronidazole or another nitroimidazole (tinidazole, secnidazole, etc.).
- Do not drink alcohol during treatment (antabuse reaction).
- May cause: gastrointestinal disturbances, brownish urine, allergic reactions, headache, dizziness.
- Monitor combination with anticoagulants (increased risk of haemorrhage), lithium, phenytoin and ergometrine (increased plasma concentrations of these drugs).
- Administer with caution, reduce total daily dose to ⅓ and give once daily to patients with severe hepatic impairment.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: avoid (significantly excreted in milk)

### Remarks

- Metronidazole is as effective by oral route as by parenteral route.
- Do not add any drug in the infusion vial.
- Storage: below 25 °C 🖊

# **MORPHINE** injectable

Prescription under medical supervision



### Therapeutic action

- Centrally acting opioid analgesic

### **Indications**

- Severe pain, especially in surgery, trauma and neoplastic disease

# Forms and strengths, route of administration

- 10 mg ampoule (10 mg/ml, 1 ml) for SC, IM or IV injection

### **Dosage**

- SC and IM route

Child over 6 months and adult: 0.1 to 0.2 mg/kg every 4 hours if necessary

- IV route

Child over 6 months and adult: 0.1 mg/kg administered in fractionated doses (0.05 mg/kg every 10 minutes) every 4 hours if necessary

### **Duration**

- Change to oral treatment as soon as possible.

- Do not administer to patients with severe respiratory impairment or decompensated hepatic impairment.
- May cause:
- dose-related sedation and respiratory depression, nausea, vomiting, constipation, urinary retention, confusion, raised intracranial pressure, pruritus;
- in the event of overdose: excessive sedation, respiratory depression, coma.
- Management of respiratory depression includes assisted ventilation and/or administration of naloxone. Monitor patient closely for several hours.
- Administer with caution to patients with respiratory impairment, head injury, raised intracranial pressure, uncontrolled epilepsy or urethroprostatic disorders.
- In elderly patients and in patients with severe renal or hepatic impairment: reduce doses by half and administer less frequently, according to clinical response (risk of accumulation).
- Do not combine with opioid analgesics with mixed agonist-antagonist activity such as buprenorphine, nalbuphine, pentazocine (competitive action).
- Increased risk of sedation and respiratory depression, when combined with alcohol and drugs acting on the central nervous system: benzodiazepines (diazepam, etc.), antipsychotics (chlorpromazine, haloperidol, etc.), antihistamines (chlorphenamine, promethazine), phenobarbital, etc.
- <u>Pregnancy and breast-feeding</u>: no contra-indication. The child may develop withdrawal symptoms, respiratory depression and drowsiness when the mother receives morphine at the end of the 3<sup>rd</sup> trimester and during breast-feeding. In these situations, administer with caution, for a short period, at the lowest effective dose, and monitor the child.

- Administer an appropriate laxative (e.g. lactulose) if analgesic treatment continues more than 48 hours.
- Morphine is on the list of narcotics: follow national regulations.
- Storage: W

# **NALOXONE** injectable

Prescription under medical supervision



### Therapeutic action

- Specific opioid antagonist

### **Indications**

- Respiratory depression induced by opioids (analgesia, anaesthesia, intoxication)

### Forms and strengths, route of administration

- 0.4 mg in 1 ml ampoule (0.4 mg/ml) for IV, IM injection or infusion in sodium chloride 0.9% or glucose 5%

### Dosage

IV route is preferred, use IM route if IV route is not feasible:

- Child: 5 to 10 micrograms/kg by IV injection, repeated if necessary after 2 to 3 minutes, until adequate spontaneous ventilation is restored, followed by a continuous infusion of 1 to 5 micrograms/kg/hour, or by 5 to 10 micrograms/kg by IM injection every 90 minutes
- Adult: 1 to 3 micrograms/kg by IV injection, repeated if necessary after 2 to 3 minutes, until adequate spontaneous ventilation is restored, followed by a continuous infusion of 1 to 5 micrograms/kg/hour, or by 5 to 10 micrograms/kg by IM injection every 90 minutes

#### **Duration**

– The duration of action of naloxone (20 to 30 minutes by IV route) is shorter than that of opioids: administration must be maintained several hours even if breathing improves.

- May cause:
- tachycardia, fibrillation, hypertension, pulmonary oedema when given postoperatively, due to a sudden reversal of analgesia;
- nausea, vomiting;
- acute withdrawal syndrome in opioid-dependent patients.
- Administer with caution and reduce dosage in case of heart failure or coronary artery disease.
- Naloxone is used in addition to assisted ventilation and must be administered under close medical supervision.
- <u>Pregnancy</u>: risks linked to respiratory depression appear greater than risks linked to naloxone.
- Breast-feeding: no contra-indication

- Naloxone is a specific opioid antidote. It cannot be used to antagonise the effects of other drugs producing CNS or respiratory depression.
- Efficacy in antagonising opioid effects depends not only on the dose of naloxone but also on the dose and potency of the specific opioid involved.
- Storage: below 25°C 🌽

# ! Noramidopyrine injectable

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see METAMIZOLE = DIPYRONE = NORAMIDOPYRINE injectable(see page 326)

# **OMEPRAZOLE** injectable

Prescription under medical supervision

# Therapeutic action

- Antiulcer drug (proton pump inhibitor)

### **Indications**

- Peptic ulcer perforation

# Forms and strengths, route of administration

– Powder for injection, 40 mg vial, to be dissolved in 100 ml of 0.9% sodium chloride or 5% glucose, for IV infusion

### Dosage

- Adult: 40 mg once daily to be administered over 20 to 30 minutes

### **Duration**

- Change to oral treatment as soon as the patient can eat.

- May cause: headache, diarrhoea, skin rash, nausea, abdominal pain, dizziness.
- Avoid combination with itraconazole and ketoconazole (decreases efficacy of these drugs).
- Monitor combination with warfarin, digoxin, phenytoin.

- Do not exceed 20 mg daily in patients with severe hepatic impairment.
- Pregnancy: no contra-indication
- Breast-feeding: avoid, administer only if clearly need

- Only use 0.9% sodium chloride or 5% glucose for dilution.
- Injectable omeprazole is not included in the WHO list of essential medicines.
- Storage: below 25 °C W

# **ONDANSETRON** injectable

Prescription under medical supervision

### Therapeutic action

- Antiemetic (serotonin 5-HT3 receptor antagonist)

### **Indications**

- Prevention of post-operative nausea and vomiting in children
- Treatment of post-operative nausea and vomiting

# Forms and strengths, route of administration

- 4 mg ampoule (2 mg/ml, 2 ml) for slow IV injection (3 to 5 minutes)

### **Dosage and duration**

- Prevention of post-operative nausea and vomiting
   Child over 1 month: 0.1 mg/kg at the end of surgery (max. 4 mg per injection)
- Treatment of nausea and vomiting
- Child over 1 month:
  - no prophylactic dose of ondansetron received: 0.1 mg/kg every 8 hours if necessary
  - prophylactic dose of ondansetron received and late postoperative vomiting (≥ 6 hours after surgery):
- 0.1 mg/kg every 6 hours if necessary
  - Do not exceed 4 mg per injection and 3 injections per 24 hours.
- Adult: 4 mg every 8 hours if necessary (max. 3 injections per 24 hours)

- Do not administer to children less than 1 month of age.
- Administer with caution and monitor use in patients with congenital long QT syndrome, cardiac insufficiency and bradycardia.
- Reduce the dose in patients with hepatic failure (max. 8 mg daily).
- May cause: headache, sensation of flushing or warmth, hiccups, constipation, heart rhythm disorders, QT interval prolongation, extrapyramidal reactions, seizures, cutaneous allergic reactions (Lyell's and Stevens-johnson syndromes).
- Avoid or monitor combination with:
- drugs that prolong the QT interval: amiodarone, bedaquilline, chloroquine, co-artemether,

erythromycin, fluconazole, haloperidol, moxifloxacin, mefloquine, pentamidine, quinine, etc.;

- serotonergics: fluoxetine, paroxetine, tricyclic antidepressants, etc.;
- enzyme inducers: rifampicin, rifabutin, nevirapine, ritonavir, phenobarbital, phenytoin, carbamazepine, griseofulvin, etc. (efficacy of ondansetron reduced);
- tramadol (antalgic effect reduced).
- <u>Pregnancy</u>: avoid during the first trimester; not recommended for nausea and vomiting of pregnancy
- Breast-feeding: not recommended

#### **Remarks**

- Storage: below 25 °C - 🖊

# **OXYTOCIN** injectable

Prescription under medical supervision



### Therapeutic action

- Synthetic oxytocic

### **Indications**

- Induction and augmentation of labour in the event of dynamic dystocia
- Postpartum haemorrhage due to uterine atony
- Prevention of postpartum haemorrhage, after vaginal delivery or caesarean section

# Forms and strengths, route of administration

- 10 IU in 1 ml ampoule (10 IU/ml) for IM or slow IV injection or infusion

### **Dosage**

- Induction and augmentation of labour

Dilute 5 IU in 500 ml or 10 IU in 1 litre of Ringer lactate or 0.9% sodium chloride to obtain a solution of 10 milliunits per ml. Start an infusion of 5 drops/minute, then increase by 5 drops/minute every 30 minutes (max. 60 drops/minute) until efficient contractions are obtained (3 to 4 contractions lasting 40 seconds over 10 minutes).

- Treatment of postpartum haemorrhage due to uterine atony
   IU in 1 litre of Ringer lactate or 0.9% sodium chloride, administered over 2 hours (160 drops/minute).
   Simultaneously, 5 to 10 IU by slow IV injection, to be repeated if necessary until the uterus is retracted (max. total dose 60 IU).
- Prevention of postpartum haemorrhage (vaginal delivery)
   to 10 IU by slow IV or IM injection before or after the delivery of placenta
- Prevention of postpartum haemorrhage (caesarean section)
   10 IU by slow IV injection after cord clamping, then 20 UI in 1 litre of Ringer lactate or 0.9% sodium chloride, administered over 2 hours (160 drops/minute).

### **Duration**

- According to clinical response

# Contra-indications, adverse effects, precautions

- Do not administer by rapid IV injection (risk of hypotension with flushing and reflex tachycardia, uterine hypertonia and/or rupture, foetal distress).
- During labour:
- Do not administer to patients with history of two caesarean sections or more.
- Administer with caution and do not exceed 30 drops/minute in patients with history of single caesarean section and in grand multipara (risk of uterine rupture).
- Respect the dosage and rate of administration, monitor uterine contractility and foetal heart rate.
- May cause: nausea, vomiting, heart rhythm disorders.
- Do not administer simultaneously with prostaglandins. Only administer oxytocin 6 hours after the last administration of prostaglandins.

### Remarks

- Storage: to be kept refrigerated (2 °C to 8 °C). Do not freeze V
- Expiry date indicated on the label is only valid if stored under refrigeration and protected from light. Exposure to light and heat causes the deterioration of the active ingredient and thus loss of efficacy.
- If refrigeration is not available, ampoules kept below 25 °C and protected from light may be s tored for a maximum of one month.

# PARACETAMOL = ACETAMINOPHEN injectable

Prescription under medical supervision

# Therapeutic action

- Analgesic, antipyretic

### **Indications**

- Very high fever, only when oral administration is not possible
- Mild pain, only when oral administration is not possible

# Forms and strengths, route of administration

– 500 mg (10 mg/ml, 50 ml) and 1 g (10 mg/ml, 100 ml) vials, for infusion

### Dosage

- Neonate: 7.5 mg/kg (0.75 ml/kg) every 6 hours, to be administered over 15 minutes (max. 30 mg/kg daily)
- Child ≥ 1 month and < 10 kg: 10 mg/kg (1 ml/kg) every 6 hours, to be administered over 15 minutes

(max. 30 mg/kg daily)

- Patient ≥ 10 kg and < 50 kg: 15 mg/kg (1.5 ml/kg) every 6 hours, to be administered over 15 minutes (max. 60 mg/kg daily)</li>
- Patient ≥ 50 kg: 1 g (100 ml) every 6 hours, to be administered over 15 minutes (max. 4 g daily)

#### **Duration**

- According to clinical response. Change to oral route as soon as possible.

### Contra-indications, adverse effects, precautions

- Do not administer to patients with severe hepatic impairment.
- Administer with caution to patients with moderate hepatic impairment, severe renal impairment, chronic alcoholism, malnutrition, dehydration.
- May cause (very rarely): malaise, hypotension and rash.
- Do not exceed indicated doses, especially in children and elderly patients. Paracetamol intoxications are severe (hepatic cytolysis).
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- As the efficacy of IV paracetamol is not superior to the efficacy of oral paracetamol, the IV route is restricted to situations where oral administration is not possible.
- For mild pain, IV paracetamol is used alone or in combination with an NSAID administered parenterally.
- For moderate pain, IV paracetamol is used in combination with an NSAID and tramadol administered parenterally.
- For severe pain, IV paracetamol is used in combination with an NSAID and morphine administered parenterally.
- Paracetamol has no anti-inflammatory properties.
- Do not mix with other drugs in the same infusion bottle.
- <u>Storage</u>: below 25 °C 🌽

# **PENICILLIN G injectable**

See BENZYLPENICILLIN injectable(see page 186)

# **PENTAMIDINE** injectable

Prescription under medical supervision



### Therapeutic action

- Antiprotozoal active against *Pneumocystis jiroveci* (carinii)

### **Indications**

– Second-line treatment of pneumocystosis, in the event of contra-indication, intolerance or unresponsiveness to co-trimoxazole

### Forms and strengths, route of administration

– Powder for injection, 200 mg and 300 mg vials, to be dissolved in 10 ml water for injection, for IM injection or infusion in 250 ml of 5% glucose

# Dosage and duration

- Child and adult: 4 mg/kg once daily by IM injection or infusion (60 minutes minimum) for 14 to 21 days

### Contra-indications, adverse effects, precautions

- Do not administer to patients with severe renal impairment.
- Reduce dosage in patients with renal impairment.
- May cause:
- aseptic abscess by IM route; venous thrombosis by IV route;
- malaise, hypotension, particularly if administered too rapidly by IV route;
- gastrointestinal disturbances; renal, hepatic and haematologic disorders; pancreatitis, arrhythmia, *torsades de pointes*, hypoglycaemia followed by hyperglycaemia.
- Do not combine with drugs inducing *torsades de pointes*: anti-arrhythmics, neuroleptics, tricyclic antidepressants, IV erythromycin, halofantrine, etc.
- Avoid combination with: mefloquine, cardiac glycosides, azole antifungals, drugs inducing hypokalaemia (diuretics, glucocorticoids, injectable amphotericin B, etc.).
- Administer on a empty stomach, keep the patient supine during injection and 30 minutes after.
- Monitor blood pressure, blood glucose level, serum creatinine level, blood counts.
- <u>Pregnancy and breast-feeding</u>: **CONTRA-INDICATED**, except if vital and there is no therapeutic alternative.

### Remarks

- For the prophylaxis of pneumocystosis, pentamidine may be used by inhalation of nebulised solution using suitable equipment.
- Pentamidine is also used in the treatment of African trypanosomiasis and leishmaniasis.
- Storage: below 25 °C V

Once reconstituted, solution keeps for 24 hours maximum, between 2 °C to 8 °C.

# PHENOBARBITAL injectable

Prescription under medical supervision



# Therapeutic action

- Anticonvulsant, sedative and hypnotic

### **Indications**

- Emergency treatment of convulsive status epilepticus

### Forms and strengths, route of administration

– 200 mg in 1 ml ampoule (200 mg/ml) for infusion in 0.9% sodium chloride. DO NOT ADMINISTER BY DIRECT RAPID IV.

### **Dosage and duration**

- Child 1 month to < 12 years: one dose of 15 to 20 mg/kg (max. 1 g). If necessary, a second dose of 10 mg/kg may be administered 15 to 30 minutes after the first dose.
- Child 12 years and over and adult: one dose of 10 mg/kg (max. 1 g). If necessary, a second dose of 5 to 10 mg/kg may be administered 15 to 30 minutes after the first dose.
- Each dose must be administered over at least 20 minutes. Do not exceed 1 mg/kg/minute. For example:

Child weighing 8 kg: 120 mg (15 mg x 8 kg), i.e. 0.6 ml of phenobarbital in 20 ml of 0.9% sodium chloride over 20 minutes

Adult weighing 50 kg: 500 mg (10 mg x 50 kg), i.e. 2.5 ml of phenobarbital in a bag of 100 ml of 0.9% sodium chloride over 20 minutes

- For doses less than 1 ml, use a 1 ml syringe graduated 0.01 ml to draw phenobarbital.

### Contra-indications, adverse effects, precautions

- Do not administer in patients with severe respiratory depression.
- Do not administer by SC route (risk of necrosis).
- Administer with caution in children, the elderly and patients with respiratory insufficiency.
- May cause:
- dose dependant respiratory depression (enhanced by diazepam), drowsiness; cutaneous and allergic reactions, sometimes severe;
- hypotension, apnoea, laryngospasm, shock, especially if administered too rapidly by IV route.
- Monitor closely respiration and blood pressure during and after administration. Ensure that respiratory support (Ambu bag via face mask or intubation) and IV solutions for fluid replacement are ready at hand.
- Avoid combination with central nervous system depressants (opioid analgesics, sedatives, H1 antihistamines, etc.).
- For women taking estroprogestogen, use condoms until next menstruation (decreases the efficacy of the contraceptive).
- <u>Pregnancy and breast-feeding</u>: risks linked to status epilepticus appear greater than risks linked to phenobarbital.

### Remarks

- Do not mix with other drugs in the same infusion.
- Phenobarbital is subject to international controls: follow national regulations.
- Storage: below 25 °C 🌽

# **PHENYTOIN** injectable

Prescription under medical supervision



# Therapeutic action

Anticonvulsant

### **Indications**

- Emergency treatment of convulsive status epilepticus

### Presentation and route of administration

– 250 mg in 5 ml ampoule (50 mg/ml) for infusion in 0.9% sodium chloride. DO NOT DILUTE IN GLUCOSE. DO NOT ADMINISTER BY IM INJECTION.

### **Dosage and duration**

- Child 1 month and over and adult: one dose of 15 to 20 mg/kg to be administered over 20 minutes minimum and 60 minutes maximum
- The concentration of the diluted solution should be between 5 and 10 mg/ml. The infusion rate should not exceed 1 mg/kg/minute or 50 mg/minute (25 mg/minute in elderly patients or patients with cardiac disorders).

For example:

Child weighing 8 kg: 160 mg (20 mg x 8 kg), i.e. 3.2 ml of phenytoin in 17 ml of 0.9% sodium chloride over 30 minutes

Adult weighing 50 kg: 1 g (20 mg x 50 kg), i.e. 20 ml of phenytoin in a bag of 100 ml of 0.9% sodium chloride over 30 minutes

- Do not administer in patients with bradycardia, atrioventricular block.
- Administer with caution in patients with hepatic impairment (reduce dosage), heart failure, cardiac rhythm disorders, hypotension.
- Administer with caution in patients taking:
- sulfonamides, chloramphenicol, fluconazole, isoniazid, fluoxetine (effects of phenytoin increased);
- rifampicin, ciprofloxacin, ritonavir, folic acid (effects of phenytoin decreased).
- May cause:
- hypotension, bradycardia, conduction disorders, depression of the central nervous system when administered too quickly;
- irritation or swelling at injection site; necrosis in the event of extravasation;
- decreased coordination, confusion, dizziness, headache, nausea, vomiting;
- hepatotoxicity; haematologic disorders; allergic and cutaneous reactions, sometimes severe.
- Use a large catheter.
- Monitor closely heart rate, blood pressure and respiratory rate during and after administration. Reduce the infusion rate in the event of a drop in blood pressure or bradycardia.
- For women taking estroprogestogen, use condoms until next menstruation (decreases the efficacy of the contraceptive).

- <u>Pregnancy and breast-feeding</u>: risks related to status epilepticus are greater than risks related to phenytoin.

#### Remarks

- Never dilute phenytoin in glucose (risk of precipitation).
- After each infusion, rinse with 0.9% sodium chloride to limit local venous irritation due to alkaline pH of phenytoin.
- Do not mix with other drugs in the same infusion.
- Storage: below 25 °C V

If refrigerated a deposit may form in the solution that later dissolves at room temperature. Check the solution is completely clear before administration.

# PHYTOMENADIONE = VITAMIN K1 injectable

Prescription under medical supervision

### Therapeutic action

- Vitamin, anti-haemorrhagic

### **Indications**

- Prophylaxis and treatment of haemorrhagic disease of the newborn

# Forms and strengths, route of administration

- 2 mg ampoule (10 mg/ml, 0.2 ml), for oral administration, IM or slow IV injection

### Dosage

- Prophylaxis of haemorrhagic disease of the newborn
- By IM route, the day of birth:
- Neonate < 1.5 kg: 0.5 mg single dose
- Neonate ≥ 1.5 kg: 1 mg single dose
- Treatment of haemorrhagic disease of the newborn

By IM or slow IV route:

1 mg every 8 hours if necessary, depending on clinical evolution and coagulation tests results

### Contra-indications, adverse effects, precautions

- May cause: allergic reactions, especially by IV route; haematoma at IM injection site.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Also comes in 10 mg ampoules (10 mg/ml, 1 ml) for use in adults only (treatment of haemorrhage due to antivitamin K agents, etc.) .
- Vitamin K<sub>1</sub> is also used as prophylaxis for neonatal hypoprothrombinemia in mothers treated with

enzyme-inducing drugs (rifampicin, rifabutin, phenobarbital, phenytoin, carbamazepine) during pregnancy. Use 10 mg ampoules (10 mg/ml, 1 ml): administer 10 mg/day of vitamin  $K_1$  by oral route for 15 days before birth. This maternal prevention does not change the need for IM administration of vitamin  $K_1$  in neonates.

- Do not dilute or mix with other drugs in the same syringe.
- Storage: below 25 °C 🌽

# POTASSIUM CHLORIDE 10% = KCl 10% injectable

Prescription under medical supervision



### **Indications**

– Treatment of severe hypokalaemia (arrhythmia, marked muscular weakness, rhabdomyolysis or serum potassium level ≤ 2.5 mmol/litre)

### Forms and strengths, route of administration

- Ampoule containing 10% potassium chloride hypertonic solution (100 mg/ml, 10 ml), i.e. 1 g of potassium chloride (KCl) per 10 ml ampoule
- Ionic composition:
- potassium (K<sup>+</sup>): 13.4 mmol per 10 ml ampoule (*13.4 mEq*)
- chloride (Cl<sup>-</sup>): 13.4 mmol per 10 ml ampoule (13.4 mEq)
- *Check concentration before use*: potassium chloride also comes in ampoules containing 7.5%, 11.2%, 15% and 20% solutions.
- NEVER USE BY IV OR IM OR SC INJECTION. Potassium chloride must always be administered by slow IV infusion, diluted in 0.9% sodium chloride.
- For dilution:
- The potassium concentration in the infusion fluid should not exceed 40 mmol/litre.
- Mix thoroughly the potassium and the 0.9% sodium chloride solution by inverting at least 5 times the infusion bottle or bag.

### **Dosage and duration**

Dosage depends on the severity of hypokalaemia and the patient's underlying condition. For information:

Child over 1 month: 0.2 mmol/kg/hour for 3 hours
 Each mmol of potassium is diluted in 25 ml of 0.9% sodium chloride.
 Examples:

10 kg	0.2 (mmol) x 10 (kg) = 2 mmol/hour x 3 hours = 6 mmol 6 mmol (= 4.5 ml of 10% KCl solution) diluted in 150 ml of NaCl 0.9% and administered over 3 hours
15 kg	0.2 (mmol) x 15 (kg) = 3 mmol/hour x 3 hours = 9 mmol 9 mmol (= 6.5 ml of 10% KCl solution) diluted in 225 ml of NaCl 0.9% and administered over 3 hours

– Adult: 40 mmol (= 3 ampoules of 10 ml of 10% KCl) in one litre of 0.9% sodium chloride, to be administered over 4 hours. Do not exceed 10 mmol/hour.

The infusion may be repeated if severe symptoms persist or if the serum potassium level remains < 3 mmol/litre.

### Contra-indications, adverse effects, precautions

- Administer with caution to elderly patients.
- Administer with caution and reduce the dose in patients with renal impairment (increased risk of hyperkalaemia).
- May cause:
- in the event of rapid or excessive administration: hyperkalaemia, cardiac conduction and rhythm disorders, potentially fatal;
- in the event of extravasation: necrosis.
- Infusion must be constantly monitored.

### Remarks

- A 7.5% potassium solution contains 1 mmol of K<sup>+</sup>/ml; a 11.2% solution contains 1.5 mmol of K<sup>+</sup>/ml; a 15% solution contains 2 mmol of K<sup>+</sup>/ml; a 20% solution contains 2.68 mmol of K<sup>+</sup>/ml.
- Moderate hypokalaemia is defined as a potassium level < 3.5 mmol/litre; severe hypo kalaemia as a potassium level ≤ 2.5 mmol/litre.
- Storage: below 25 °C

# ! Promethazine injectable

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see PROMETHAZINE injectable(see page 327)

# **PROTAMINE** injectable

Prescription under medical supervision

# Therapeutic action

- Neutralisation of the anticoagulant action of unfractionated heparin
- Partial neutralisation of the anticoagulant action of low molecular weight heparin

### **Indications**

- Haemorrhagic syndromes resulting from accidental heparin overdosage

### Forms and strengths, route of administration

- 50 mg protamine sulfate in 5 ml ampoule (10 mg/ml) for slow IV injection Concentration may be expressed in antiheparin units (AHU): 1000 AHU = 10 mg.

### **Dosage**

Depends on the amount of heparin to be neutralised.

- Heparin overdosage

If administered between 0 and 30 minutes after the heparin injection, 1 mg of protamine sulfate (100 AHU) neutralises 100 units of heparin.

If more than 30 minutes have elapsed since the heparin injection, the dose of protamine to be given should be one half the dose of heparin injected.

Do not administer more than 50 mg for any one dose.

- Nadroparin overdosage

1 mg of protamine sulfate (100 AHU) neutralises 100 units of nadroparin. The dose of protamine to be given is equal to that of the nadroparin injected.

### **Duration**

– According to clinical response. Monitor coagulation parameters.

## Contra-indications, adverse effects, precautions

- May cause: hypotension, bradycardia and dyspnoea; allergic reactions, notably in diabetics treated by protamine-insulin.
- If excessive doses are used, haemorrhage may persist or reappear, as protamine sulfate itself has some anticoagulant activity.
- Administer by very slow IV (over 10 minutes) in order to reduce risks of hypotension and bradycardia.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

### Remarks

- In the case of nadroparin overdose, it is recommended to administer 1 or 2 units of fresh whole blood at the same time to counteract its activity against Factor Xa.
- Anticoagulant effect of protamine may vary according to the origin of the heparin: follow manufacturer's recommendations.
- Protamine sulfate may be used to neutralize the effect of heparin before surgery.
- Storage: to be kept refrigerated (2 °C to 8 °C) V

# !Quinine injectable

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see QUININE injectable(see page 328)

# SALBUTAMOL = ALBUTEROL injectable

Prescription under medical supervision

# Therapeutic action

- Uterine relaxant

#### **Indications**

- Threatened premature labour (preferably use nifedipine for this indication)

# Forms and strengths, route of administration

- 0.5 mg in 1 ml ampoule (0.5 mg/ml) for IV infusion

### **Dosage**

Dilute 5 mg (10 ampoules of 0.5 mg) in 500 ml of 5% glucose or 0.9% sodium chloride to obtain a solution of 10 micrograms/ml.

Start infusion at the rate of 15 to 20 micrograms/minute (30 to 40 drops/minute).

If contractions persist, increase the rate by 10 to 20 drops/minute every 30 minutes until uterine contractions cease. Do not exceed 45 micrograms/minute (90 drops/minute).

Continue for one hour after contractions have ceased, then reduce the rate by half every 6 hours.

### **Duration**

- 48 hours maximum

### Contra-indications, adverse effects, precautions

- Do not administer to patients with pre-eclampsia, eclampsia, uterine haemorrhage, intra- uterine infection, intra-uterine foetal death, placenta praevia, placental abruption, rupture of membranes, multiple pregnancy, severe cardiopathy.
- Administer with caution to patients with diabetes, hyperthyroidism.
- Do not combine with nifedipine.
- May cause: pulmonary oedema, myocardial ischemia, foetal and maternal tachycardia, hypotension, tremor, headache, hypokalaemia, hyperglycaemia.
- Monitor maternal pulse regularly. Reduce the infusion rate in the event of maternal tachycardia (> 120/minute).
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: avoid

#### Remarks

- Use salbutamol within 24 hours of mixing with infusion fluid.
- Do not mix with other drugs in the same infusion fluid.
- Also comes in 5 ml ampoule containing 0.25 mg (0.05 mg/ml).
- Storage: below 25 °C 🖊

# **SODIUM BICARBONATE 8.4% injectable**

Prescription under medical supervision

#### **Indications**

- Severe metabolic acidosis

### Forms and strengths

- 10 ml or 20 ml ampoule

### Composition

Sodium bicarbonate: 8.4 g per 100 ml

- Hypertonic solution
- Ionic composition:

sodium (Na<sup>+</sup>): 10 mmol (10 mEq) per 10 ml ampoule bicarbonate: 10 mmol (10 mEq) per 10 ml ampoule

### Contra-indications, adverse effects, precautions

- Do not use in case of alkalosis or respiratory acidosis.
- Do not administer hypertonic solutions by IM or SC route. Administer under close medical supervision, by slow direct IV injection diluted in 5% glucose or by continuous infusion in 5% glucose.
- Do not add: penicillins, chloramphenicol, aspirin, atropine, calcium, insulin, vitamins, etc. to sodium bicarbonate solution.

#### Remarks

- Contains a high concentration of bicarbonate and sodium ions. Its use is rarely justified in case of metabolic acidosis caused by dehydration. Inaccurate administration may induce hypernatraemia and hypokalaemia.
- Storage: below 25 °C

# SPECTINOMYCIN injectable

Prescription under medical supervision

Cephalosporins are the first choice treatment of gonococcal infections. Spectinomycin may be used as an alternative, when cephalosporins are not available or are contra-indicated.

### Therapeutic action

- Antibacterial (group of aminoglycosides)

### **Indications**

- Second choice treatment of gonococcal infections

### Forms and strengths, route of administration

- Powder for injection in 2 g vial, to be dissolved with the diluent supplied by the manufacturer (3.2 ml ampoule of water for injection with benzyl alcohol), for IM injection

### **Dosage and duration**

- Anogenital gonococcal infection and gonococcal conjunctivitis
   Adult: 2 g single dose (a dose of 4 g may be required, i.e. 2 g in each buttock)
- Disseminated gonococcal infection
   Adult: 2 g every 12 hours for 7 days

# Contra-indications, adverse effects, precautions

- May cause: nausea, dizziness, fever and chills, urticaria; pain at injection site.
- <u>Pregnancy</u>: **CONTRA-INDICATED** (safety is not established)
- Breast-feeding: no contra-indication for a single dose treatment

### Remarks

- Administer a concurrent anti-chlamydia treatment to patients with gonococcal infections (co-infections are frequent).
- Spectinomycin is poorly effective against pharyngeal gonococcal infections.
- For the treatment of neonatal gonococcal conjunctivitis, use cephalosporins.
- Shake well prior to withdrawal medication and use a 19G needle.
- Do not mix with other drugs in the same syringe.
- Storage: below 25 °C

# STREPTOMYCIN injectable

Prescription under medical supervision

### Therapeutic action

- Antibacterial (group of aminoglycosides)

### **Indications**

- Plague
- Brucellosis, in combination with doxycycline

# Forms and strengths, route of administration

– Powder for injection, vial containing 1 g of streptomycin base, to be dissolved in 4 ml of water for injection, for IM injection. DO NOT ADMINISTER BY IV INJECTION.

### **Dosage**

- Plague

Child: 15 mg/kg every 12 hours (max. 2 g daily)

Adult: 1 g every 12 hours

- Brucellosis

Adult: 1 g once daily

#### **Duration**

- Plague: 10 days; brucellosis: 2 weeks

# Contra-indications, adverse effects, precautions

- Do not administer in patients with allergy to aminoglycosides.
- Administer with caution to patients with history of renal, vestibular or auditory problems.
- Reduce the dose in patients with renal impairment.
- May cause: ototoxicity (vestibular and auditory damage), nephrotoxicity, neuropathy, neuromuscular blockade; rarely, allergic reactions.
- Stop treatment in the event of dizziness, paraesthesia, tinnitus or hearing defects (ototoxicity).
- Drink sufficient liquid to limit the risk of renal toxicity.
- Avoid or monitor combination with other ototoxic (e.g. quinine) or nephrotoxic drugs (e.g. other aminoglycosides, amphotericin B, pentamidine).
- Pregnancy: CONTRA-INDICATED
- Breast-feeding: no contra-indication

#### Remarks

- The volume of suspension obtained after reconstitution of 1 g of powder in 4 ml of water for injection is 4.83 ml and not 4 ml. The concentration of the suspension is 207 mg/ml and not 250 mg/ml.
- Storage: below 25 °C V

# **SURAMIN** injectable

Prescription under medical supervision



# Therapeutic action

- Trypanocide

### **Indications**

- Haemolymphatic stage of African trypanosomiasis due to T. b. rhodesiense

# Forms and strengths, route of administration

– Powder for injection in 1 g vial, to be dissolved in 10 ml of water for injection to obtain a 10% solution, for slow IV injection (or slow infusion in 500 ml of 0.9% NaCl). NEVER BY IM OR SC INJECTION.

### **Dosage and duration**

- Patients must be treated in hospital, under close medical supervision.
- Child and adult: 4 to 5 mg/kg by slow IV at D1 (test dose) then, in the absence of reaction after the test dose, 20 mg/kg by slow IV at D3, D10, D17, D24 and D31 (max. 1 g per injection)

### Contra-indications, adverse effects, precautions

- Do not administer in patients with severe renal or hepatic disease.
- May cause:
- anaphylactic reaction: administer a test dose before starting treatment. In the event of anaphylactic reaction, the patient should never receive suramin again;
- proteinuria (renal toxicity), diarrhoea, haematological disorders (haemolytic anaemia, agranulocytosis, etc.), eye disorders (photophobia, lachrymation), neurological disorders (paraesthesia, hyperaesthesia of the palms and soles, polyneuropathy), high fever, skin eruption, malaise, intense thirst, polyuria;
- local inflammation and necrosis when administered by IM or SC injection.
- Before each injection, check for proteinuria: moderate proteinuria is common at the start of treatment, heavy proteinuria calls for dose reduction and modification of treatment schedule; in the event of persisting heavy proteinuria, treatment should be discontinued.
- Ensure that the patient is well hydrated.
- <u>Pregnancy</u>: although suramin is toxic, it is recommended to treat pregnant women with rhodesiense trypanosomiasis at the haemolymphatic stage. Suramin is also used at the meningoencephalitic stage until the woman can be given melarsoprol after delivery, as melarsoprol is contra-indicated during pregnancy.

### Remarks

- Suramin is not administered at the meningoencephalitic stage (except in pregnant women) as it poorly penetrates into the cerebrospinal fluid.
- Due to its toxicity, suramin is no longer used for the treatment of onchocerciasis.
- Storage: below 25 °C //

# THIAMINE = VITAMIN B1 injectable

Prescription under medical supervision

# Therapeutic action

- Vitamin

### **Indications**

 Initial treatment of severe thiamine deficiency: severe acute forms of beriberi, neurological complications of chronic alcoholism (severe polyneuritis, Wernicke's encephalopathy, Korsakoff syndrome)

## Forms and strengths, route of administration

– 100 mg thiamine hydrochloride in 2 ml ampoule (50 mg/ml) for IM or very slow IV route (30 minutes)

## **Dosage and duration**

- Infantile beriberi

25 mg by IV route then, 25 mg by IM route once or 2 times daily then, change to oral route (10 mg once daily) as soon as symptoms have improved.

- Acute beriberi

50 mg by IM injection then change to oral route (50 mg 3 times daily until symptoms improve then, 10 mg once daily)

or, depending on severity, 50 mg by IM injection every 8 hours for a few days then change to oral route (10 mg once daily).

- Wernicke's encephalopathy, Korsakoff syndrome

250 mg once daily by IV route until the patient can take oral treatment. Higher initial doses may be required during the first 12 hours.

## Contra-indications, adverse effects, precautions

- May cause: hypotension; anaphylactic reaction, especially when injected IV (inject very slowly over 30 minutes).
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Thiamine is also called aneurine.
- Injectable thiamine is not included in the WHO list of essential medicines.
- Storage: below 25 °C V

# TRAMADOL injectable

Prescription under medical supervision



## Therapeutic action

- Opioid analgesic

#### **Indications**

- Moderate pain

## Forms and strengths, route of administration

- 100 mg ampoule (50 mg/ml, 2 ml) for IM, slow IV injection or infusion

#### Dosage

- Child over 12 years and adult: 50 to 100 mg every 4 to 6 hours (max. 600 mg daily)

#### **Duration**

- Change to oral route as soon as possible.

## Contra-indications, adverse effects, precautions

- Do not administer in the event of severe respiratory depression and to patients that risk seizures (e.g. epilepsy, head injury, meningitis).
- May cause:
- dizziness, nausea, vomiting, drowsiness, dry mouth, sweating;
- rarely: allergic reactions, seizures, confusion; withdrawal symptoms; respiratory depression in the event of overdosage.
- Do not combine with opioid analgesics, including codeine.
- Avoid combination with carbamazepine, fluoxetine, chlorpromazine, promethazine, clomipramine, haloperidol, digoxin.
- Reduce doses by half and administer every 12 hours in elderly patients and in patients with severe renal or hepatic impairment (risk of accumulation).
- Use tramadol by infusion over 20-30 minutes rather than by IV injection.
- <u>Pregnancy</u>: no contra-indication. The neonate may develop withdrawal symptoms, respiratory depression and drowsiness in the event of prolonged administration of large doses at the end of the 3<sup>rd</sup> trimester. In this event, closely monitor the neonate.
- <u>Breast-feeding</u>: use with caution, for a short period (2-3 days), at the lowest effective dose. Monitor the mother and the child: in the event of excessive drowsiness, stop treatment.

#### Remarks

- Tramadol is approximately 10 times less potent than morphine.
- In some countries, tramadol is on the list of narcotics: follow national regulations.
- Tramadol is not included in the WHO list of essential medicines.
- Storage: below 25 °C V

# TRANEXAMIC acid injectable

Prescription under medical supervision

## Therapeutic action

- Antifibrinolytic

#### **Indications**

- Postpartum haemorrhage

#### Presentation and route of administration

– 500 mg in 5 ml ampoule (100 mg/ml) for slow IV injection or infusion in 0.9% sodium chloride or 5% glucose

DO NOT ADMINISTER BY IM ROUTE.

#### **Dosage and duration**

- Adolescent under 15 years: 15 mg/kg (max. 1 g)
- Adult: 1 g (two 5 ml ampoules) in a bag of 100 ml of 0.9% sodium chloride to be administered over 15 minutes within 3 hours of delivery. Repeat after 30 minutes if bleeding continues or within 24 hours of the first dose if bleeding restarts (max. total dose 2 g).

## Contra-indications, adverse effects, precautions

- Do not administer to patients with (or with history of) venous or arterial thromboembolic disorders, severe renal impairment, history of seizures.
- May cause: gastrointestinal disturbances, hypotension and malaise if injected rapidly (rate > 1 ml/minute); rarely, seizures with high doses, blurred vision, allergic reactions.
- Reduce dosage in patients with mild to moderate renal impairment (risk of accumulation).
- Avoid combination with drugs that increase the risk of thromboembolism (e.g. oestrogenes).

#### **Remarks**

- Tranexamic acid is also used in the management of trauma patients with significant haemorrhage, at the same dosage, by slow IV injection or infusion, to be administered within the first hour after injury and a second dose 3 hours after the first dose. 3 hours after injury, tranexamic acid is no longer indicated as its administration increases the risk of death.
- Tranexamic acid is not indicated in the management of prepartum haemorrhage.
- Do not mix with benzylpenicillin (incompatibility).
- Storage: below 25 °C -



# **VITAMIN B1 injectable**

See THIAMINE injectable(see page 252)

# VITAMIN K1 injectable

See PHYTOMENADIONE injectable(see page 244)

## Infusion fluids

- Use of infusion fluids(see page 256)
- Volume expanders (see page 256)
- GLUCOSE 5% = DEXTROSE 5% (see page 257)
- GLUCOSE 10% = DEXTROSE 10%(see page 258)
- MODIFIED FLUID GELATIN (Plasmion<sup>®</sup>...)(see page 258)
- POLYGELINE (Haemaccel®...)(see page 259)
- RINGER LACTATE(see page 260)
- SODIUM CHLORIDE 0.9% = NaCl(see page 261)

## Use of infusion fluids

## Choice of infusion fluids according to indications

3 kinds of infusion fluids should be available:

- For IV rehydration: Ringer Lactate is the most suitable.
- For administration of IV drugs: 5% glucose solution and 0.9% sodium chloride solution are the most suitable.
- For volume expansion: see table next page.

#### Precautions for the use of infusion fluids

- Carefully read the labels on the infusion bottle to avoid mistakes.
- Indicate on the label any drugs added to the infusion as well as the patient's name and/or bed number.
- If drugs are added to the intravenous fluid, think of the risks of:
- physical and chemical incompatibilities,
- microbial contamination: aseptic technique.
- Examine each bottle against the light to check clearness. Discard any bottles that show particles in suspension or cloudiness.

# Volume expanders

	Duration*	Volume	Dosage	Indication s	Contra- indication s	Advantage s	Disadvant ages
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Cristalloid s Ringer Lactate NaCl 0.9%	1 to 2 hours	3 times the estimated fluid loss	According to patient's condition	<ul> <li>Hypovolae mia</li> <li>Prevention of hypotensio n induced by spinal anaesthesi a</li> </ul>	• None	• Free from adverse effects • Inexpensiv e	• Large amounts to be infused rapidly • Expansion of short duration
Colloids  Polygeline Modified fluid gelatin	2 to 3 hours	1 to 1.5 times the estimated fluid loss	According to patient's condition	• Hypovolae mia	• Allergy to gelatins	• Relatively good volume expansion	• Allergic reactions • Expansion of short duration • Expensive

<sup>\*</sup> Length of time during which the fluid remains in the intravascular compartment after infusion.

For more information, refer to relevant fact-sheet.

## **GLUCOSE 5% = DEXTROSE 5%**

#### **Indications**

- Vehicle for the administration of parenteral drugs

#### **Presentation**

- 500 ml and 1000 ml bottles or bags

#### Composition

- 5% isotonic glucose solution (50 mg of glucose/ml) for infusion

## Contra-indications, adverse effects, precautions

- Do not use glucose solution for the administration of hydralazine (incompatibility, rapid degradation of hydralazine): use only 0.9% sodium chloride or Ringer Lactate solution.
- Other drugs such as amoxicillin + clavulanic acid, aciclovir, phenytoin, bleomycin or chloroquine must also be administered in 0.9% sodium chloride solution.
- Amoxicillin diluted in 5% glucose must be administered in less than one hour. If infusion over more than one hour is required, use 0.9% sodium chloride.

## **Remarks**

– This solution does not contain electrolytes or lactate. Its use is not recommended for the IV treatment of dehydration. Use Ringer Lactate or 0.9% sodium chloride solutions.

- Low nutritional value: 200 kcal/litre.
- Storage: below 25 °C

## **GLUCOSE 10% = DEXTROSE 10%**

Prescription under medical supervision

#### **Indications**

- Treatment of hypoglycaemia

## Forms and strengths, route of administration

- 250 ml and 500 ml bottles or bags

#### Composition

- 10% hypertonic glucose solution (100 mg of glucose/ml) for slow IV injection or IV infusion

## **Dosage and duration**

- Conscious child: 10 ml/kg by oral route or nasogastric tube
- Child with impaired consciousness: 2 ml/kg by slow IV injection (2 to 3 minutes)
   Check blood glucose level 15 minutes after injection. If blood glucose level is still < 3.3 mmol/l or < 60 mg/dl, administer a second dose or give oral glucose, according to the patient's clinical condition.</li>

## Contra-indications, adverse effects, precautions

- Do not administer by IM or SC route.

#### Remarks

- If ready-made 10% glucose solution is not available: add 10 ml of 50% glucose solution per 100 ml of 5% glucose solution to obtain a 10% glucose solution.
- 10% glucose solution may be used as vehicle for administration of the loading dose of IV quinine in order to prevent hypoglycaemia. The following doses are administered in 5% glucose solution.
- Nutritional value: 400 kcal/litre.
- Storage: below 25 °C

# **MODIFIED FLUID GELATIN (Plasmion®...)**

Prescription under medical supervision

#### Therapeutic action

- Colloidal plasma substitute

#### **Indications**

- Fluid replacement in hypovolaemic shock (haemorrhagic shock, septic shock)

## Forms and strengths

- 500 ml plastic bottle or bag

## Composition

– Varies according to the manufacturer. Example:

	Plasmion®	Haemaccel®
Modified fluid gelatin	30 g/litre	-
Polygeline	-	35 g/litre
Sodium (Na+)	150 mmol ( <i>150 mEq</i> )	145 mmol ( <i>145 mEq</i> )
Potassium (K+)	5 mmol ( <i>5 mEq</i> )	5.10 mmol ( <i>5.10 mEq</i> )
Calcium (Ca++)	-	6.25 mmol ( <i>12.50 mEq</i> )
Chloride (Cl-)	100 mmol ( <i>100 mEq</i> )	145 mmol ( <i>145 mEq</i> )
Magnesium (Mg++)	1.5 mmol ( <i>3 mEq</i> )	-
Lactate	30 mmol ( <i>30 mEq</i> )	-

## **Dosage**

- Adjust dosage according to the patient's haemodynamic status.
- In the event of haemorrhage, replace the lost volume by the same volume of plasma substitute.

## Contra-indications, adverse effects, precautions

- May cause: allergic reactions, possibly severe (anaphylactic shock).
- <u>Pregnancy</u>: **CONTRA-INDICATED**: risk of maternal anaphylactic reaction with serious consequences for the foetus. Use Ringer lactate.

#### Remarks

- Do not add any drugs to the bottle.
- When plasma substitutes are not available, use Ringer lactate (giving 3 times the lost blood volume).
- Storage: below 25 ℃

# **POLYGELINE (Haemaccel®...)**

## RINGER LACTATE

#### **Indications**

- Severe dehydration
- Hypovolaemia (trauma, surgery, anaesthesia)

## Forms and strengths

- 500 ml and 1000 ml bottles or bags

## Composition

- Varies with manufacturer.
- Most frequent ionic composition per litre:

- Isotonic solution. Does not contain glucose.

## Contra-indications, adverse effects, precautions

- In cases of metabolic alkalosis, diabetes, severe hepatic failure, head injury: isotonic solution of NaCl 0.9% is preferred.
- Ringer Lactate provides appropriate amounts of sodium and calcium. It contains lactate which is converted to bicarbonate for correction of metabolic acidosis when it exists (if haemodynamic and liver function are normal).

Warning, some commercially available solutions do not contain lactate.

- It contains 4 mEq of potassium/litre, which is sufficient for short-term use. For prolonged use (after 2 to 3 days), addition of potassium chloride is necessary: 1 or 2 g per litre = one to two 10 ml ampoules of KCL 10%/litre.
- For moderate and mild dehydration, administer oral rehydration salts (ORS).

#### Remarks

- For correction of hypovolaemia due to haemorrhage; administer 3 times the lost volume only if:
- blood loss does not exceed 1500 ml in adults;
- cardiac and renal function are not impaired.
- May be used to prevent hypotension induced by spinal anaesthesia.
- Storage: below 25 °C

## **SODIUM CHLORIDE 0.9% = NaCl**

#### **Indications**

- Vehicle for the administration of parenteral drugs
- Fluid replacement

#### Forms and strengths

- 100 ml, 250 ml, 500 ml and 1000 ml bottles or bags

#### Composition

- Isotonic solution of sodium chloride (0.9 g per 100 ml) for infusion
- Ionic composition:

```
sodium (Na^+) 150 mmol (150 mEq) per litre chloride (Cl^-) 150 mmol (150 mEq) per litre
```

## Contra-indications, adverse effects, precautions

- Use with caution in patients with hypertension, heart failure, oedema, ascites due to cirrhosis, renal impairment and other conditions associated with sodium retention.
- May cause: pulmonary oedema in the event of too rapid infusion or infusion of excessive amounts.
- Do not use as vehicle for the administration of amphotericin B (incompatibility): use only 5% glucose solution.

#### Remarks

- For correction of hypovolaemia due to haemorrhage, administer 3 times the lost volume only if:
- blood loss does not exceed 1500 ml in adults;
- cardiac and renal function are not impaired.
- 0.9% sodium chloride solution may be used to prevent hypotension induced by spinal anaesthesia.
- This solution contains neither potassium nor lactate. In case of severe dehydration, use Ringer Lactate. If Ringer Lactate is not available, add KCl (2 g/l) + NaCl (4 g/l) to 5% glucose.
- For external use: sterile 0.9% sodium chloride solution is used for cleansing of non-infected wounds, wound irrigation, eye cleansing (conjunctivitis, eye irrigations), nasal lavage in the event of obstruction, etc.
- Storage: below 25 °C

# Vaccines, immunoglobulins and antisera

- ORAL CHOLERA VACCINE O1 and O139(see page 262)
- DIPHTERIA-TETANUS-PERTUSSIS VACCINE (DTP)(see page 263)
- DIPHTHERIA, TETANUS, PERTUSSIS, HEPATITIS B, Hib VACCINE(see page 264)
- HEPATITIS B VACCINE(see page 265)
- JAPANESE ENCEPHALITIS VACCINE(see page 266)
- MEASLES VACCINE(see page 267)
- MENINGOCOCCAL A CONJUGATE VACCINE(see page 268)
- MENINGOCOCCAL A+C VACCINE(see page 269)
- MENINGOCOCCAL A+C+W135 VACCINE(see page 270)
- HUMAN PAPILLOMAVIRUS VACCINE (HPV)(see page 271)
- PNEUMOCOCCAL CONJUGATE VACCINE (PCV)(see page 272)
- INACTIVATED POLIOMYELITIS VACCINE (IPV)(see page 273)
- ORAL POLIOMYELITIS VACCINE (OPV)(see page 274)
- HUMAN RABIES IMMUNOGLOBULIN (HRIG) (see page 275)
- RABIES VACCINE(see page 276)
- ORAL ROTAVIRUS VACCINE(see page 278)
- HUMAN TETANUS IMMUNOGLOBULIN (HTIG)(see page 279)
- TETANUS VACCINE (TT)(see page 279)
- TETANUS-DIPHTHERIA VACCINE (Td)(see page 280)
- ! Tetanus antitoxin (equine)(see page 281)
- TUBERCULOSIS VACCINE = BCG VACCINE(see page 281)
- TYPHOID CONJUGATE VACCINE (TCV)(see page 282)
- YELLOW FEVER VACCINE (see page 283)

## **ORAL CHOLERA VACCINE 01 and 0139**

#### **Indications**

- Prevention of cholera in epidemic, endemic or humanitarian emergency contexts

#### Composition, forms, route of administration

- Inactivated whole cell bivalent vaccine containing *Vibrio cholerae* O1 (serotypes Inaba and Ogawa, and biotypes classical and El Tor) and *Vibrio cholerae* O139
- Oral suspension, 1.5 ml in monodose plastic tube and vial. DO NOT ADMINISTER BY PARENTERAL ROUTE.

## Dosage and vaccination schedule

- Child 1 year and over and adult: 2 doses of 1.5 ml administered at least 14 days apart
- In certain contexts (e.g. outbreak and limited number of vaccines), a single dose of 1.5 ml is administered.
- Shake the vial, squirt the entire contents of the vial into the mouth.

For young children, the contents of the vial can be drawn up in a syringe and squirted into the mouth.

- Do not administer to children less than one year.
- Do not administer in the event of hypersensitivity to any component of the vaccine or history of an allergic reaction to a previous dose.
- Vaccination should be postponed in the event of severe acute febrile illness; minor infections are not contra-indications.
- May cause: nausea, vomiting, abdominal cramping, diarrhoea.
- Drinking water after swallowing the vaccine may reduce its unpleasant taste and prevent vomiting. If the patient vomits the dose of vaccine, wait for 10 minutes and re-administer the same dose and follow with a larger volume of water.
- <u>Pregnancy</u>: can be administered (the benefits outweigh the risks).
- Breast-feeding: no contra-indication

#### Remarks

- Immunity develops one week after administration and lasts up to 6 months after a single dose and at least 3 years after 2 doses.
- <u>Storage</u>: between 2 °C and 8 °C. Do not freeze; discard if vaccine has been frozen N Shanchol<sup>®</sup> vaccines used in controlled temperature chain (CTC) can be stored at temperatures of up to 40 °C for 14 days maximum. All vaccines removed from the cold chain and not used within 14 days or exposed to temperatures > 40 °C must be discarded.

# DIPHTERIA-TETANUS-PERTUSSIS VACCINE (DTP)

#### **Indications**

– Prevention of diphtheria, tetanus and pertussis in children under 7 years (primary vaccination and booster dose)

## Composition, forms, route of administration

- Trivalent vaccine combining diphtheria toxin, tetanus toxin and whole-cell (DTwP) or acellular (DTaP) pertussis vaccine
- Suspension for injection in multidose vial, for IM injection into the anterolateral part of the thigh in children < 2 years and in the deltoid muscle in children ≥ 2 years. **DO NOT ADMINISTER INTO THE GLUTEAL MUSCLE.**

## Dosage and vaccination schedule

- Child: 0.5 ml per dose
- Primary vaccination: 3 doses 4 weeks apart, preferably before the age of 6 months. It is recommended to administer the 1<sup>st</sup> dose at 6 weeks of age, the 2<sup>nd</sup> dose at 10 weeks of age and the 3<sup>rd</sup> dose at 14 weeks of age. If a child has not been vaccinated at 6 weeks of age, start vaccination as soon as possible.
- Booster: one dose between 12 and 23 months

- Do not administer in the event of allergic reactions to a previous dose of DTP vaccine or evolving neurological disease (encephalopathy, uncontrolled epilepsy).
- Vaccination should be postponed in the event of severe acute febrile illness; minor infections are not contra-indications.
- May cause: mild local reactions (redness and pain at the injection site), fever, fatigue, malaise; rarely: anaphylactic reactions, seizures.
- Respect an interval of 4 weeks between each dose of primary vaccination.
- If administered simultaneously with other vaccines, use different syringes and injection sites.

#### Remarks

- If the vaccination is interrupted before the complete series has been administered, it is not necessary to start again from the beginning. Continue the vaccination schedule from where it was interrupted and complete the series as normal.
- Also comes in:
- tetravalent vaccine (diphtheria, tetanus, pertussis, hepatitis B) and pentavalent vaccine (diphtheria, tetanus, pertussis, hepatitis B and *Haemophilus influenzae*) used for primary vaccination in children < 7 vears:
- bivalent Td vaccine containing a reduced dose of diphtheria toxoid (tetanus-diphtheria), used in children ≥ 4 years, adolescents and adults.
- Shake before use to homogenise the vaccine.
- <u>Storage</u>: between 2 °C and 8 °C. Do not freeze W

# DIPHTHERIA, TETANUS, PERTUSSIS, HEPATITIS B, Hib VACCINE

#### **Indications**

– Prevention of tetanus, diphtheria, pertussis, hepatitis B and severe *Haemophilus influenzae* type B infections in children from 6 weeks to 7 years of age (primary vaccination)

## Composition, forms, route of administration

- Pentavalent vaccine combining tetanus toxoid, diphtheria toxoid, whole-cell pertussis toxoid, recombinant adsorbed hepatitis B vaccine and *Haemophilus influenza*e type B polysaccharide
- Suspension for injection in multidose vial, for IM injection into the anterolateral part of the thigh in children < 2 years and into the deltoid muscle in children ≥ 2 years. **DO NOT ADMINISTER INTO THE GLUTEAL MUSCLE.**

## Dosage and vaccination schedule

- Neonate: 3 doses 4 weeks apart, preferably before the age of 6 months. It is recommended to administer the 1<sup>st</sup> dose at 6 weeks of age, the 2<sup>nd</sup> dose at 10 weeks of age and the 3<sup>rd</sup> dose at 14 weeks of age.
- If a child has not received the 1<sup>st</sup> dose by the age of 1 year, start vaccination as soon as possible according to the 0-1-6 schedule:
- 2 doses 4 weeks apart, then a 3<sup>rd</sup> dose 6 months after the 1<sup>st</sup> dose

- Do not administer in the event of allergic reactions to a previous dose of vaccine containing these strains.
- Do not administer at birth to vaccinate against hepatitis B.
- Vaccination should be postponed in the event of severe acute febrile illness; minor infections are not contra-indications.
- May cause: mild local reactions (redness, pain at the injection site), fever, pain, malaise, headache, myalgia; rarely: anaphylactic reactions.
- If administered simultaneously with other vaccines, use different syringes and injection sites.

#### Remarks

- Also comes in:
- a trivalent vaccine (diphtheria, tetanus, pertussis) and tetravalent vaccine (diphtheria, tetanus, pertussis, hepatitis B) used for primary vaccination in children < 7 years;
- a bivalent Td vaccine containing a reduced dose of diphtheria toxoid (tetanus-diphtheria), used in children ≥ 4 years, adolescents and adults.
- <u>Storage</u>: between 2 °C and 8 °C. Do not freeze 🌠

## **HEPATITIS B VACCINE**

#### **Indications**

- Prevention of hepatitis B

## Composition, forms, route of administration

- Recombinant hepatitis B vaccine
- Suspension for injection in monodose or multidose vial, for IM injection into the anterolateral part of the thigh in children < 2 years and into the deltoid muscle in children ≥ 2 years. DO NOT ADMINISTER INTO THE GLUTEAL MUSCLE.

#### Dosage and vaccination schedule

Dosage varies according to age and type of vaccine used: follow manufacturer's instructions.

Child: one dose = 5 to 10 micrograms

Adult: one dose = 10 to 20 micrograms

- Standard schedule
- Neonate and infant:

One dose as soon as possible after birth (preferably within the first 24 hours of life) then a 2<sup>nd</sup> dose at 6 weeks and a 3<sup>rd</sup> dose at 14 weeks

or

One dose as soon as possible after birth (preferably within the first 24 hours of life) then 3 doses administered 4 weeks apart with the 1<sup>st</sup> at 6 weeks, the 2<sup>nd</sup> at 10 weeks and the 3<sup>rd</sup> at 14 weeks

- Child, adolescent, adult: schedule 0-1-6
- 2 doses 4 weeks apart, then a 3<sup>rd</sup> dose 6 months after the 1<sup>st</sup> dose

Accelerated schedule, when rapid protection is required in the event of post-exposure prophylaxis
 3 doses administered during the same month on D0-D7-D21, then a 4<sup>th</sup> dose one year after the 1<sup>st</sup> dose

## Contra-indications, adverse effects, precautions

- Do not administer in the event of allergic reactions to a previous dose of hepatitis B vaccine.
- Vaccination should be postponed in the event of severe acute febrile illness; minor infections are not contra-indications.
- May cause: minor local reactions (pain or redness at injection site), fever, headache, myalgia; rarely: anaphylactic reaction.
- If administered simultaneously with other vaccines, use different syringes and injection sites.
- Pregnancy and breast-feeding: no contra-indication

#### Remarks

- At birth, use only the monovalent hepatitis B vaccine. For the following doses, administer a monovalent or tetravalent (diphtheria, tetanus, pertussis, hepatitis B) or pentavalent (diphtheria, tetanus, pertussis, hepatitis B and *Haemophilus influenzae*) vaccine.
- If an infant was not administered the birth dose, this dose can be administered at anytime during the first contact with health-care providers, up to the time of the next dose of the primary schedule.
- If the vaccination schedule is interrupted before the complete series has been administered, it is not necessary to start again from the beginning. Continue the vaccination schedule from where it was interrupted and complete the series as normal.
- SC route may be used, only if IM route is contra-indicated.
- Shake before use to homogenise the vaccine.
- Storage: between 2 °C and 8 °C. Do not freeze W

# JAPANESE ENCEPHALITIS VACCINE

#### **Indications**

- Prevention of Japanese encephalitis:
- in children from 1 year and adults in endemic countries (rural areas of Southeast and Southwest Asia and Western Pacific countries)
- in travellers spending more than 1 month in endemic countries, in rural areas and during the wet season

## Composition, forms, route of administration

- Inactivated virus vaccine
- Powder for injection in single-dose vial, to be dissolved with the entire vial of the diluent supplied by the manufacturer, for SC injection

#### **Dosage**

- Child from 1 to 3 years: 0.5 ml per dose
- Child over 3 years and adult: 1 ml per dose

There are several vaccination schedules. For information, for travellers:

3 doses on Day 0, Day 7 and Day 28; a booster dose every 3 years if risk persists.

An accelerated schedule is possible (3 doses on Day 0, Day 7 and Day 14) but this is likely to result in lower antibody levels than the standard schedule.

The 3<sup>rd</sup> dose should be given at least 10 days before departure to ensure an adequate immune response and access to medical care in the event of adverse reactions.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with history of an allergic reaction to a previous injection of Japanese encephalitis vaccine.
- Vaccination should be postponed in the event of severe acute febrile illness; minor infections are not contra-indications.
- May cause:
- redness and swelling at the injection site;
- fever, headache, chills, asthenia;
- hypersensitivity reactions (urticaria, angioedema), immediate or delayed (up to 2 weeks after injection);
- rarely: encephalitis, encephalopathy.
- Do not mix with other vaccines in the same syringe (inactivation of vaccines).
- If administered simultaneously with EPI vaccines, use different syringes and injection sites.
- <u>Pregnancy</u>: only administer if there is a high risk of contamination.
- Breast-feeding: no contra-indication

#### **Remarks**

- Protection lasts at least 2 years after 3 doses.
- Caution: there are different vaccines against EJ, with different dosages and administration schedules (e.g. suspension for injection in pre-filled syringe, administered in 2 doses (0.5 ml on D0 and D28) in adults, by IM route). For each vaccine, follow manufacturer's instructions.
- Storage: //
- Powder: between 2 °C and 8 °C. Do not freeze.
- Diluent: a cold chain is not required for storage. However, at least 12 hours before reconstitution of the vaccine, the diluent must be refrigerated between 2 °C and 8 °C so that the diluent and lyophilised powder are at the same temperature: a temperature difference during reconstitution may reduce vaccine efficacy. Do not freeze.
- Reconstituted vaccine: between 2 °C and 8 °C, for 6 hours maximum.

## **MEASLES VACCINE**

#### **Indications**

- Prevention of measles

#### Composition, forms, route of administration

- Live-attenuated virus vaccine, derived from different viral strains (Schwarz, Edmonston, CAM70, Moraten, etc.)
- Powder for injection in single multidose vial, to be dissolved with the diluent supplied by the manufacturer, for SC or IM injection into the anterolateral part of the thigh in children < 2 years and into the deltoid muscle in children ≥ 2 years

## Dosage and vaccination schedule

- Routine vaccination
- Child between 9 and 12 months: one dose of 0.5 ml. The WHO recommends a 2<sup>nd</sup> dose between 15 and 18 months. Respect an interval of at least 4 weeks between doses.
- Where there is high risk of infection (overcrowding, epidemics, malnutrition, infants born to a mother with HIV infection, etc.), administer a supplementary dose from 6 months of age then continue vaccination schedule.
- Catch-up vaccination

Children under 15 years who have missed either one or both doses of routine vaccination should be vaccinated when they come in contact with health services. Check national recommendations.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with severe immune depression or history of an allergic reaction to a previous injection of measles vaccine.
- Vaccination should be postponed in the event of severe acute febrile illness; minor infections are not contra-indications.
- May cause: mild local reaction (pain, redness at the injection site), fever, skin rash; rarely: seizures, encephalitis, anaphylactic reaction.
- If administered simultaneously with other vaccines, use different syringes and injection sites.
- Pregnancy and breast-feeding: avoid

#### **Remarks**

- Combination vaccines that include measles and rubella (MR) or measles, mumps and rubella (MMR) are also available in countries where these vaccines are included in the national immunization programme.
- Storage: V
- Powder: between 2 °C and 8 °C.
- Diluent: a cold chain is not required for storage. However, at least 12 hours before reconstitution of the vaccine, the diluent must be refrigerated between 2 °C and 8 °C so that the diluent and lyophilised powder are at the same temperature: a temperature difference during reconstitution may reduce vaccine efficacy. Do not freeze.
- Reconstituted vaccine: between 2 °C and 8 °C for 6 hours maximum.

# MENINGOCOCCAL A CONJUGATE VACCINE

#### **Indications**

- Prevention of meningitis due to meningococcus A in countries of the African meningitis belt

## Composition, forms, route of administration

- Inactivated bacterial vaccine, conjugated (Neisseria meningitidis group A)
- Powder for injection, to be dissolved with the entire vial of the diluent supplied by the manufacturer
- Vials of 10 doses of:
- 5 micrograms of meningococcal A antigen per 0.5 ml dose for children aged 3 to 24 months
- 10 micrograms of meningococcal A antigen per 0.5 ml dose for children from 1 year and adults up to 29

#### vears

– For deep IM injection, into the anterolateral part of the thigh in children < 2 years or into the deltoid muscle in children ≥ 2 years and adults

## Dosage and vaccination schedule

- Child 3 to < 9 months: 2 doses of 0.5 ml, to be administered at least 8 weeks apart
- Child 9 months and over: 0.5 ml single dose
- Adult: 0.5 ml single dose

## Contra-indications, adverse effects, precautions

- Do not administer to patients with history of an allergic reaction to a previous injection of meningococcal vaccine.
- Vaccination should be postponed in the event of severe acute febrile illness (minor infections are not contra-indications).
- May cause: mild local reaction, mild fever.
- Do not mix with other vaccines in the same syringe (inactivation of vaccines).
- If administered simultaneously with other vaccines, use different syringes and injection sites.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Immunity lasts at least 27 months.
- The WHO recommends this vaccine for routine vaccination in children aged 9 to 18 months, in catch-up or periodic campaigns in children from 1 year and in mass vaccination campaigns during outbreaks due to meningococcus A in children from 1 year and adults up to 29 years.
- Storage: do not freeze 🌽
- Powder: between 2 °C and 8 °C.
- Diluent: a cold chain is not required for storage. However, at least 12 hours before reconstitution of the vaccine, the diluent must be refrigerated between 2 °C and 8 °C so that the diluent and lyophilised powder are at the same temperature: a temperature difference during reconstitution may reduce vaccine efficacy.
- Reconstituted vaccine: up to 40 °C for 6 hours maximum.
- Controlled temperature chain (CTC): during mass vaccination campaigns only, the 10 microgram vaccine can be stored in temperatures of up to 40 °C for a period of 4 days maximum. Any vaccine removed from the cold chain and not used within 4 days or exposed to temperatures > 40 °C must be discarded.

## MENINGOCOCCAL A+C VACCINE

#### **Indications**

- Prevention of meningitis due to meningococci groups A and C:
- in mass immunisation campaigns in the event of an outbreak due to meningococcus A or C
- in travellers spending more than 1 month in hyperendemic areas

#### Composition, forms, route of administration

- Inactivated bacterial vaccine, polysaccharide
- Powder for injection in monodose or multidose vial, to be dissolved with the entire vial of the diluent supplied by the manufacturer, for deep SC or IM injection, into the deltoid muscle or the anterolateral part of the thigh in children (follow manufacturer's instructions)

## Dosage and vaccination schedule

- Child from 2 years and adult: 0.5 ml single dose

## Contra-indications, adverse effects, precautions

- Do not administer to patients with history of an allergic reaction to a previous injection of meningococcal vaccine.
- Vaccination should be postponed in the event of severe acute febrile illness; minor infections are not contra-indications.
- May cause: mild local reaction, mild fever.
- Do not mix with other vaccines in the same syringe (inactivation of vaccines).
- If administered simultaneously with EPI vaccines, use different syringes and injection sites.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Immunity develops 7 to 10 days after injection, and lasts for approximately 3 years.
- Storage: //
- Powder: between 2 °C and 8 °C.
- Diluent: a cold chain is not required for storage. However, at least 12 hours before reconstitution of the vaccine, the diluent must be refrigerated between 2 °C and 8 °C so that the diluent and lyophilised powder are at the same temperature: a temperature difference during reconstitution may reduce vaccine efficacy. Do not freeze.
- Reconstituted vaccine: between 2 °C and 8 °C, for 6 hours maximum.

## MENINGOCOCCAL A+C+W135 VACCINE

#### **Indications**

- Prevention of meningitis due to meningococci groups A, C and W135:
- in mass immunisation campaigns in the event of an outbreak due to meningococcus A, C or W135
- in travellers spending more than 1 month in hyperendemic areas

#### Composition, forms, route of administration

- Inactivated bacterial vaccine, polysaccharide
- Powder for injection in multidose vial, to be dissolved with the entire vial of the diluent supplied by the manufacturer, for SC injection only

## Dosage and vaccination schedule

- Child from 2 years and adult: 0.5 ml single dose

## Contra-indications, adverse effects, precautions

- Do not administer to patients with history of an allergic reaction to a previous injection of meningococcal vaccine.
- Vaccination should be postponed in the event of severe acute febrile illness; minor infections are not contra-indications.
- May cause: mild local reaction, mild fever.
- Do not mix with other vaccines in the same syringe (inactivation of vaccines).
- If administered simultaneously with EPI vaccines, use different syringes and injection sites.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Immunity develops 7 to 10 days after injection, and lasts for approximately 3 years.
- Storage: V
- Powder: between 2 °C and 8 °C.
- Diluent: a cold chain is not required for storage. However, at least 12 hours before reconstitution of the vaccine, the diluent must be refrigerated between 2 °C and 8 °C so that the diluent and lyophilised powder are at the same temperature: a temperature difference during reconstitution may reduce vaccine efficacy. Do not freeze.
- Reconstituted vaccine: between 2 °C and 8 °C, for 6 hours maximum.

# **HUMAN PAPILLOMAVIRUS VACCINE (HPV)**

#### **Indications**

- Prevention of premalignant anogenital lesions, mainly of the cervix, and of cervical cancer, due to certain types of papilloma viruses
- Prevention of anogenital warts due to certain types of papilloma viruses (particularly types 6 and 11) for the quadrivalent vaccine

## Composition, forms, route of administration

- Recombinant bivalent (HPV type 16 and 18) or quadrivalent (HPV type 6, 11, 16 and 18) vaccine
- Suspension for injection in monodose or multidose (only for bivalent vaccine) vials, for IM injection into the deltoid muscle

## Dosage and vaccination schedule

- Child from 9 to 14 years: 2 doses of 0.5 ml at least 6 months apart
   If the 2 doses are administered less than 5 months apart, a 3<sup>rd</sup> dose is administered at least 6 months and up to 12 months maximum after the 1<sup>st</sup> dose.
- Immunocompromised or HIV-infected individuals (under treatment or not): 2 doses of 0.5 ml 1 or 2 months apart then a  $3^{rd}$  dose 6 months after the  $1^{st}$  dose

Most vaccination programmes only target young females, the population group most at risk of papillomavirus infection complications. Acheiving high vaccination coverage in girls reduces the risk of infection for boys. For vaccination of boys, follow national recommendations.

## Contra-indications, adverse effects, precautions

- Do not administer in the event of allergic reactions to a previous dose of papillomavirus vaccine.
- Vaccination should be postponed in the event of severe acute febrile illness; minor infections are not contra-indications.
- May cause: mild reactions at the injection site (pain, redness at the injection site), fever, headache, myalgia; rarely: post-vaccination syncope, anaphylactic reactions.
- If administered simultaneously with other vaccines, use different syringes and injection sites.
- Pregnancy: avoid
- Breast-feeding: no contra-indication

#### Remarks

- In individuals 15 years or over, the vaccine is administered in 3 doses (as in immunocompromised individuals).
- Shake before use to homogenise the vaccine.
- <u>Storage</u>: between 2 °C and 8 °C. Do not freeze 🌠

Once opened, the multidose bivalent (Cervarix®) vaccine vials can be stored between 2 °C and 8 °C for 6 hours maximum.

Controlled temperature chain (CTC): the quadrivalent vaccine (Gardasil $^{\circ}$ ) can be stored at temperatures of up to 42  $^{\circ}$ C for 3 days maximum. All vaccines removed from the cold chain and not used within 3 days or exposed to temperatures > 42  $^{\circ}$ C must be discarded.

# PNEUMOCOCCAL CONJUGATE VACCINE (PCV)

#### **Indications**

– Prevention of invasive infections, pneumonia and acute otitis media due to *Streptococcus pneumoniae*, in children from 6 weeks of age

## Composition, forms, route of administration

- 10 or 13 valent pneumococcal polysaccharide conjugate vaccine
- Suspension for injection:
- 10 valent vaccine: in multidose vials
- 13 valent vaccine: in monodose and multidose vials
- For IM injection into the anterolateral part of the thigh in children < 2 years and into the deltoid muscle in children ≥ 2 years. DO NOT ADMINISTER INTO THE GLUTEAL MUSCLE.

## Dosage and vaccination schedule

- Child: 0.5 ml per dose
- Child from 6 weeks to < 12 months:
- 3p+0 schedule
- 3 doses 4 weeks apart at 6, 10 and 14 weeks of age

- 2p+1 schedule
- 2 doses 8 weeks apart and a booster dose between 9 and 15 months
- Child from 12 months to < 2 years: 2 doses 8 weeks apart</li>
- Child from 2 to 5 years: a single dose

- Do not administer in the event of allergic reactions to a previous dose of vaccine.
- Vaccination should be postponed in the event of severe acute febrile illness; minor infections are not contra-indications.
- May cause: mild local reactions (redness and pain at the injection site), fever, irritability, drowsiness, loss of appetite; rarely: seizures, anaphylactic reactions.
- If administered simultaneously with other vaccines, use different syringes and injection sites.

#### **Remarks**

- If the vaccination is interrupted before the complete series has been administered, continue the vaccination schedule from where it was interrupted, do not repeat administration of the previous dose.
- Choice of vaccines and vaccination schedule: follow national recommendations.
- Shake before use to homogenise the vaccine.
- Storage: between 2 °C and 8 °C. Do not freeze W
- 10 valent vaccine, 2 dose vial: if open vial is not used entirely within 6 hours it should be discarded.
- 10 and 13 valent vaccine, 4 dose vial: if open vial is not entirely used it can be stored for 28 days, providing the cold chain is respected.

# **INACTIVATED POLIOMYELITIS VACCINE (IPV)**

#### **Indications**

- Prevention of poliomyelitis, alone or in combination with the oral poliomyelitis vaccine (bOPV)

## Composition, forms, route of administration

- Inactivated virus vaccine, trivalent (poliovirus types 1, 2 and 3)
- Suspension for injection in multidose vial, for IM injection into the anterolateral part of the thigh in children < 2 years or deep SC injection into the deltoid muscle in children ≥ 2 years and adults

## Dosage and vaccination schedule

- bOPV + IPV schedule

Child: 0.5 ml single dose at 14 weeks, in combination with a dose of bOPV

- IPV only schedule

Child: 3 doses of 0.5 ml approximately 4 weeks apart, at 6, 10 and 14 weeks of age and a booster dose at least 6 months after the 3<sup>rd</sup> dose

- Vaccination should be postponed in the event of severe acute febrile illness (minor infections are not contra-indications).
- May cause: mild local reaction (pain, redness at the injection site), fever; exceptionally, anaphylactic reaction.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Protection against poliomyelitis lasts for life after 4 doses.
- In children who start routine vaccination late (after the age of 3 months), the dose of IPV is administered together with the 1<sup>st</sup> dose of bOPV, followed by 2 doses of bOPV alone administered 4 weeks apart.
- If there is a shortage of IPV the intradermal route is an alternative, if the operator is experienced in this administration technique. The vaccination schedule is: 2 doses of 0.1 ml at 6 and 14 weeks of age (the 2 doses must be administered at least 4 weeks apart).
- Certain countries have vaccination schedules for children and adults that use only the injectable vaccine and include booster doses: follow national recommendations.
- <u>Storage</u>: between 2 °C and 8 °C. Do not freeze 🌽

# ORAL POLIOMYELITIS VACCINE (OPV)

The bivalent vaccine bOPV replaces the trivalent vaccine tOPV (poliovirus types 1, 2 and 3).

#### **Indications**

- Prevention of poliomyelitis, in combination with the inactivated poliomyelitis vaccine (IPV)

## Composition, forms, route of administration

- Live-attenuated virus vaccine, bivalent (poliovirus types 1 and 3)
- Oral suspension in multidose vial, to be administered on the tongue, with dropper

## Dosage and vaccination schedule

One dose = 2 drops (approximately 0.1 ml)

– *In endemic areas or areas at risk of poliovirus importation, according to WHO recommendations* Child: 4 doses approximately 4 weeks apart, at birth then at 6, 10 and 14 weeks of age

The 4<sup>th</sup> dose at 14 weeks is administered in combination with a dose of the inactivated poliomyelitis vaccine (IPV).

- Other areas

Child: 3 doses approximately 4 weeks apart, at 6, 10 and 14 weeks of age

The 3<sup>rd</sup> dose at 14 weeks is administered in combination with a dose of the inactivated poliomyelitis vaccine (IPV).

- Do not administer in the event of severe immunodepression (risk of paralytic poliomyelitis): use the injectable vaccine IPV (asymptomatic HIV infection is not a contra-indication).
- Vaccination should be postponed in the event of severe acute febrile illness (minor infections are not contra-indications).
- May cause (exceptionally): paralytic poliomyelitis.
- In the event of vomiting or diarrhoea when the vaccine is administered, give the usual dose followed by an extra dose once gastrointestinal symptoms have improved.
- Respect an interval of at least 4 weeks between each dose.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Protection against poliomyelitis lasts for life after 3 doses.
- In children who start routine vaccination late (after the age of 3 months), the dose of IPV is administered together with the 1<sup>st</sup> dose of bOPV, followed by 2 doses of bOPV alone administered 4 weeks apart.
- For the vaccination schedule, follow national recommendations.
- Storage: V
- For prolonged storage: freeze (-20 °C).
- After defrosting: between 2 °C and 8 °C for 6 months maximum.

# **HUMAN RABIES IMMUNOGLOBULIN (HRIG)**

## Therapeutic action

- Neutralisation of rabies virus at wound sites

#### **Indications**

- Prevention of rabies after category III exposure (except in patients who have received a full course of pre-exposure prophylaxis against rabies), in combination with rabies vaccine
- Prevention of rabies after category II and III exposures in immunocompromised patients (even in patients who have received a full course of pre-exposure prophylaxis against rabies), in combination with rabies vaccine

## Forms and strengths, route of administration

– Solution for injection, 300 IU in 1 ml ampoule (300 IU/ml) and 1500 IU in 5 ml ampoule (300 IU/ml) for infiltration into and around the wound

## **Dosage and duration**

- Child and adult: 20 IU/kg single dose on D0, along with the first dose of rabies vaccine.
- Infiltrate as much of the dose as possible into and around the wound(s), which has been cleaned beforehand.
- In the event of multiple wounds, dilute the dose 2 to 3-fold with sterile 0.9% sodium chloride to obtain

a sufficient quantity to infiltrate all the sites.

– If HRIG is not available on D0, administer the first dose of rabies vaccine alone. Administer HRIG as soon as possible between D0 and D7; from D8, it is not necessary to administer rabies immunoglobulin as vaccine-induced antibodies begin to appear.

## Contra-indications, adverse effects, precautions

- May cause: fever, headache, gastrointestinal disturbances, joint pain, local reactions at the injection site (pain, inflammation); rarely: anaphylactic reactions.
- Aspirate prior to injection to confirm that the needle is not in a vein and ensure that the HRIG does not enter a blood vessel (risk of shock).
- For finger wounds, infiltrate with caution to avoid increased pressure in the tissue compartment.
- If administered simultaneously with rabies immunoglobulin and other vaccines, use different syringes and injection sites.
- Pregnancy and breast-feeding: no contra-indication

#### Remarks

- Purified equine rabies immunoglobulin F(ab')2 fragments may replace HRIG if unavailable. The method of administration is the same but the dose is 40 IU/kg.
- Storage: between 2 °C and 8 °C. Do not freeze W

## RABIES VACCINE

#### **Indications**

- Prevention of rabies after category II and III exposures

## Composition, forms, route of administration

- Inactivated virus vaccine, prepared from cell cultures (CCEEV): in embryonated egg or purified cells (chick embryo-cells, Vero-cells or human diploid-cells)
- Powder for injection in monodose vial, to be dissolved with the entire vial of the diluent (0.5 ml or 1 ml, supplied by the manufacturer)
- IM route: DO NOT ADMINISTER INTO THE GLUTEAL MUSCLE
- Child < 2 years: inject into the anterolateral part of the thigh
- Child ≥ 2 years and adult: inject into the deltoid muscle
- ID route:

Child and adult: inject into the deltoid muscle (or the anterolateral part of the thigh or the suprascapular region)

## Dosage and vaccination schedule

- Child and adult: one IM dose = 0.5 or 1 ml, depending on the vaccine used; one ID dose = 0.1 ml, whichever vaccine used
- Vaccination schedules may vary from country to country, check national recommendations. The schedule depends on the patient's vaccination status at the moment of exposure and the route of administration used (follow manufacturer's instructions).
- The first dose of vaccine should be administered as soon as possible after exposure, even if the patient seeks medical attention long after exposure (rabies incubation period may last several months). The

patient must receive all the recommended doses.

– If a vaccine dose is delayed or the route of administration is changed, continue vaccination according to the chosen route of administration and do not recommence the schedule.

The simplest vaccination schedules endorsed by the WHO are the following:

	No rabies vaccination or incomplete vaccination or complete vaccination with an NTV or unknown vaccination status			Complete vaccination with a CCEEV		
	IM route <sup>(a)</sup>		ID route	IM or ID route <sup>(d)</sup>		
DO	2 doses <sup>(b)</sup> (1 dose in each arm or thigh)	1 dose <sup>(b)</sup>	2 doses <sup>(b)</sup> (1 dose in each arm)	1 dose		
D3		1 dose	2 doses (1 dose in each arm)	1 dose		
D7	1 dose	1 dose	2 doses (1 dose in each arm)			
D14		1 dose <sup>(c)</sup>				
D21	1 dose					

<sup>(</sup>a) There are two possible schedules for the IM route: the Zagreb regimen (2-0-1-0-1) over 21 days or the 4-dose Essen regimen (1-1-1-1-0) over 14 to 28 days.

## Contra-indications, adverse effects, precautions

- Do not administer corticoids concomitantly (vaccine efficacy diminished).
- May cause: benign local reactions at the injection site (pain, induration), fever, malaise, headache, fatigue, gastrointestinal disturbances; rarely: anaphylactic reaction.
- Ensure that the vaccine does not enter a blood vessel (risk of shock): aspirate prior to injection to confirm that the needle is not in a vein.
- ID vaccination: incorrect ID technique results in treatment failure. If correct ID technique cannot be assured, use IM route.
- If administered simultaneously with rabies immunoglobulin and other vaccines, use different syringes and injection sites.
- <u>Pregnancy and breast-feeding</u>: no contra-indication

<sup>(</sup>b) As well as a single dose of rabies immunoglobulin into the wound in the event of category III exposure on D0.

<sup>(</sup>c) The last injection can be administered between D14 and D28.

<sup>(</sup>d) Another possible ID schedule: 4 ID doses (1 dose in each arm and 1 dose in each thigh) on D0.

<sup>–</sup> Immunocompromised patient: 1 dose on D0, D7 and between D21 and D28 by IM or ID route (as well as a single dose of rabies immunoglobulin)

#### Remarks

- Rabies vaccine is also used for pre-exposure vaccination in persons at high risk of infection (prolonged stay in rabies endemic areas, professionals in contact with animals susceptible of carrying the virus).
- Avoid the use of vaccines prepared from animal nerve tissue (NTVs): they are less immunogenic than CCEEV vaccines and more likely to cause severe adverse effects.
- Storage: 🖊
- Powder: between 2 °C and 8 °C. Do not freeze.
- Diluent: a cold chain is not required for storage. However, at least 12 hours before reconstitution of the vaccine, the diluent must be refrigerated between 2 °C and 8 °C so that the diluent and lyophilised powder are at the same temperature: a temperature difference during reconstitution may reduce vaccine efficacy. Do not freeze.
- Reconstituted vaccine: use immediately.

## ORAL ROTAVIRUS VACCINE

#### **Indications**

- Prevention of gastroenteritis due to rotavirus infection in infants

## Composition, forms, route of administration

- Live-attenuated monovalent human rotavirus vaccine (RV1, strain RIX4414, Rotarix®)
- Oral suspension, 1.5 ml in monodose plastic tube. DO NOT ADMINISTER BY PARENTERAL ROUTE.

#### Dosage and vaccination schedule

- Child from 6 weeks to 24 months: 2 doses at least 4 weeks apart. It is recommended to administer the  $1^{\text{st}}$  dose at 6 weeks of age and the  $2^{\text{nd}}$  dose at 10 weeks of age, at the same time as the first 2 doses of pentavalent vaccine (diphtheria, tetanus, pertussis, hepatitis B and *Haemophilus influenzae*).
- Shake the plastic tube, squeeze the entire content of the tube into the mouth.

## Contra-indications, adverse effects, precautions

- Do not administer in case of acute gastroenteritis, history of intussusception, severe immunodeficiency.
- Do not administer in the event of allergic reactions to a previous dose of vaccine.
- Vaccination should be postponed in the event of severe acute febrile illness; minor infections are not contra-indications.
- May cause: diarrhoea, abdominal pain, irritability; rarely: intussusception, anaphylactic reactions.
- If the patient vomits the dose of vaccine, wait a few minutes and re-administer the same dose.

#### Remarks

- Also comes in a monovalent human vaccine (RV1, strain 116E, Rotavac®) and pentavalent human-bovine vaccine (RV5), to be administered in 3 doses 4 week apart.
- Rotavirus vaccine can be administered concomitantly with oral polio vaccine (OPV).
- Storage: between 2 °C and 8 °C. Do not freeze W

# **HUMAN TETANUS IMMUNOGLOBULIN (HTIG)**

## Therapeutic action

- Neutralisation of tetanus toxin. HTIG provides passive immunization against tetanus for 3 to 4 weeks.

#### **Indications**

- Prevention of tetanus in wound management, in patients non immunised or incompletely immunised or in patients whose immunisation status is unknown, in combination with tetanus vaccine
- Treatment of clinical tetanus

#### Forms and strengths, route of administration

– Solution for injection, in 250 IU (250 IU/ml, 1 ml) or 500 IU (250 IU/ml, 2 ml) ampoule or single-dose syringe, for IM injection. DO NOT ADMINISTER BY IV ROUTE.

## **Dosage and duration**

- Prevention of tetanus

HTIG is administered in the event of tetanus-prone wounds, e.g. wounds with fracture, deep penetrating wounds, bite wounds, wounds containing foreign bodies, wounds contaminated with soil, infected wounds, extensive tissue damage (contusions, burns).

Child and adult: 250 IU single dose; 500 IU if more than 24 hours has elapsed HTIG should be administered as soon as possible after injury, along with the tetanus vaccine, in a separate syringe and injection site.

- Treatment of tetanus

Neonate, child and adult: 500 IU single dose, to be injected into 2 different sites

## Contra-indications, adverse effects, precautions

- Do not administer to patients with known allergy to HTIG.
- May cause (very rarely): allergic reactions.
- Ensure that the HTIG does not enter a blood vessel (risk of shock): aspirate prior to injection to confirm that the needle is not in a vein.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- For minor clean wounds, tetanus vaccine is administered alone.
- SC route may be used but only if IM route is contra-indicated.
- Storage: between 2 °C and 8 °C. Do not freeze 🌠

# **TETANUS VACCINE (TT)**

# **TETANUS-DIPHTHERIA VACCINE (Td)**

#### **Indications**

- Prevention of tetanus in wound management
- Prevention of tetanus and diphtheria in pregnant women or women of childbearing age
- Prevention of tetanus and diphtheria in children over 4 years and adolescents (booster dose after complete primary vaccination)

## Composition, forms, route of administration

- Bivalent vaccine combining tetanus toxoid and diphtheria toxoid (containing reduced dose of diphtheria toxoid)
- Suspension for injection in multidose vial, for IM injection into the deltoid muscle

## Dosage and vaccination schedule

- Child and adult: 0.5 ml per dose
- Prevention of tetanus in wound management

Type of		<b>te vaccination</b> (3 ce administration		Incomplete vaccination (less than 3 doses) or no vaccination	
wound	< 5 years	5-10 years	> 10 years	or <b>unknown status</b>	
Minor, clean	None	None	Td 1 booster dose	Initiate* or complete tetanus vaccination	
Other	None	Td 1 booster dose	Td 1 booster dose	Initiate* or complete tetanus vaccination and administer tetanus immunoglobulin	

<sup>\* 2</sup> doses 4 weeks apart then 3 additional doses administered according to the vaccination schedule below.

Prevention of tetanus in pregnant women and women of childbearing age
5 doses administered according to the schedule below:

Td1	On first contact with the health care system or as soon as possible during pregnancy
Td2	At least 4 weeks after Td1
Td3	6 months to 1 year after Td2 or during the following pregnancy
Td4	1 to 5 years after Td3 or during the following pregnancy
Td5	1 to 10 years after Td4 or during the following pregnancy

In pregnant women, administer at least 2 doses before delivery: the 1<sup>st</sup> dose as soon as possible during pregnancy and the 2<sup>nd</sup> dose at least 4 weeks after the 1<sup>st</sup> and at least 2 weeks before due date. After

delivery, continue vaccination as described in the table above until the required 5 doses have been administered.

- Prevention of tetanus in children over 4 years (after complete primary vaccination and 1<sup>st</sup> booster between 12 and 23 months)

Booster dose between 4 and 7 years then between 9 and 15 years

## Contra-indications, adverse effects, precautions

- Do not administer in the event of allergic reactions after a previous dose of tetanus or diphtheria vaccine.
- Vaccination should be postponed in the event of severe acute febrile illness; minor infections are not contra-indications.
- May cause: mild local reactions (redness, pain at the injection site), fever, pain, malaise; rarely: anaphylactic reactions.
- If administered simultaneously with other vaccines, use different syringes and injection sites.
- <u>Pregnancy and breast-feeding</u>: no contra-indication

#### Remarks

- The monovalent tetanus (TT) vaccine is used in certain national protocols. Use perferably the conjugate tetanus-diphtheria (Td) vaccine for the prevention of tetanus in children over 7 years, adolescents and adults.
- Tetanus vaccination in pregnant women and women of child bearing age protects neonates from tetanus.
- <u>Storage</u>: between 2 °C and 8 °C. Do not freeze **//**

# ! Tetanus antitoxin (equine)

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see TETANUS ANTITOXIN (EQUINE)(see page 329)

## TUBERCULOSIS VACCINE = BCG VACCINE

#### **Indications**

- Prevention of tuberculosis

## Composition, forms, route of administration

- Live attenuated bacterial vaccine
- Powder for injection in multidose vial, to be dissolved with the entire vial of the diluent supplied by the manufacturer, for intradermal injection into the external face of the left upper arm

## Dosage and vaccination schedule

- Child: 0.05 ml single dose as soon after birth as possible
- If child is over one year old: 0.1 ml single dose

## Contra-indications, adverse effects, precautions

- Do not administer to patients with immunodeficiency (symptomatic HIV infection, immunosuppressive therapy, etc.) and malignant haemopathy.
- Vaccination should be postponed in the event of evolutive extensive dermatosis, acute complicated malnutrition (vaccine should be given just before the child is discharged from the nutrition centre) and severe acute febrile illness (minor infections are not contra indications).
- May cause:
- normal local reaction 2 to 4 weeks after injection: papule which changes to an ulcer, that usually heals spontaneously (dry dressing only), leaving a permanent scar;
- occasionally: persistent ulcer with serous discharge up to 4 months after injection, non-suppurative adenitis, keloid formation, abscess at the injection site;
- exceptionally: suppurative lymphadenitis, osteitis.
- Clean the injection site with boiled and cooled water and allow drying. Do not use antiseptics (risk of inactivation of live vaccine).
- Do not mix with other vaccines in the same syringe (inactivation of vaccines).
- If administered simultaneously with EPI vaccines, use different syringes and injection sites.
- <u>Pregnancy</u>: **CONTRA-INDICATED**
- Breast-feeding: no contra-indication

#### Remarks

- Inject the vaccine in the same place for each child to make it easy to find the BCG scar subsequently.
- If the injection is correctly performed an "orange-skin" papule, measuring 5-8 mm in diameter, should appear at the injection site.
- Duration of protection is not known, and decreases over time.
- Storage: W
- Powder: between 2 °C and 8 °C. Freezing is possible but unnecessary
- Diluent: a cold chain is not required for storage. However, at least 12 hours before reconstitution of the vaccine, the diluent must be refrigerated between 2 °C and 8 °C so that the diluent and lyophilised powder are at the same temperature: a temperature difference during reconstitution may reduce vaccine efficacy. Do not freeze.
- Reconstituted vaccine: between 2 °C and 8 °C for 6 hours maximum.

# **TYPHOID CONJUGATE VACCINE (TCV)**

#### **Indications**

- Prevention of typhoid fever in children as of 6 months and adults up to 45 years of age:
- in endemic areas
- in mass immunisation campaigns in the event of an outbreak or humanitarian emergency context, based on risk assessment

#### Composition, forms, route of administration

- Typhoid (polysaccharide) conjugate vaccine
- Suspension for injection in multidose vial, for IM injection into the anterolateral part of the thigh in children < 2 years and into the deltoid muscle in children ≥ 2 years. **DO NOT ADMINISTER INTO THE GLUTEAL MUSCLE.**

## Dosage and vaccination schedule

- Child and adult: 0.5 ml single dose
- Routine vaccination

Child at 9 months or during the 2<sup>nd</sup> year of life: one single dose at the same time as other recommended vaccines. Follow national recommendations.

- Catch-up vaccination

Child up to 15 years: one single dose. Follow national recommendations.

## Contra-indications, adverse effects, precautions

- Do not administer in case of allergic reactions to any component of the vaccine.
- Vaccination should be postponed in the event of severe acute febrile illness; minor infections are not contra-indications.
- May cause: mild reactions at the injection site (pain, redness at the injection site), fever, headache, myalgia; rarely: anaphylactic reactions.
- If administered simultaneously with other vaccines, use different syringes and injection sites.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Typhoid conjugate vaccine does not protect against *Salmonella* Paratyphi or other types of non-typhi salmonella.
- Shake before use to homogenise the vaccine.
- <u>Storage</u>: between 2 °C and 8 °C. Do not freeze **V** Once opened, store vial between 2 °C and 8 °C for 6 hours maximum.

## YELLOW FEVER VACCINE

#### **Indications**

- Prevention of yellow fever:
- in children from 9 months of age and adults living in or travelling to or from endemic areas
- in mass immunisation campaigns in the event of an outbreak

## Composition, forms, route of administration

- Live-attenuated virus vaccine, prepared by culturing the virus in embryonated chicken eggs
- Powder for injection in monodose and multidose vials, to be dissolved with the entire vial of diluent

supplied by the manufacturer, for IM injection into the anterolateral part of the thigh in children < 2 years and into the deltoid muscle in children ≥ 2 years and adults

## Dosage and vaccination schedule

- Child and adult: 0.5 ml single dose
- In routine immunisation (EPI), the vaccine is usually administered between 9 and 12 months of age, along with the measles vaccine.
- Vaccination is contra-indicated in children less than 6 months. In children between 6 and 9 months, vaccination is only recommended in epidemics, as the risk of virus transmission may be very high.

## Contra-indications, adverse effects, precautions

- Do not administer to patients with history of allergy to egg; to immunocompromised patients or patients with symptomatic HIV infection or under immunosuppressive treatment.
- Vaccination should be postponed in the event of severe acute febrile illness; minor infections are not contra-indications.
- May cause: mild reactions at the injection site (redness, pain at the injection site), mild fever, headache, myalgia; rarely: hypersensitivity reactions, neurological disorders (especially in children < 9 months and adults > 60 years), multiple organ failure (especially in adults > 60 years).
- If administered simultaneously with other vaccines, use different syringes and injection sites.
- <u>Pregnancy</u>: not recommended. However, given the severity of yellow fever, the vaccine is administered when the risk of contamination is very high (epidemics, unavoidable travel to regions of high endemicity).
- Breast-feeding: no contra-indication

#### Remarks

- A standard 0.5 ml single dose by IM injection is sufficient to confer life-long immunity. A booster dose is no longer recommended.
- Only in the event of limited vaccine supply during yellow fever outbreaks and according to national recommendations, vaccination may be administered by SC or IM injection in children over 2 years and adults with a fractional dose of 1/2 or 1/5 of the standard dose (minimum 0.1 ml) using vials containing a maximum of 10 standard doses. Children < 2 years, pregnant women and HIV positive individuals are administered a standard 0.5 ml dose by IM injection.
- Storage: 🖊
- Powder: between 2 °C and 8 °C.
- Diluent: a cold chain is not required for storage. However, at least 12 hours before reconstitution of the vaccine, the diluent must be refrigerated between 2 °C and 8 °C so that the diluent and lyophilised powder are at the same temperature: a temperature difference during reconstitution may reduce vaccine efficacy. Do not freeze.
- Reconstituted vaccine: between 2 °C and 8 °C, for 6 hours maximum.

# Drugs for external use, antiseptics and disinfectants

- ACICLOVIR, eye ointment(see page 285)
- ALCOHOL-BASED solution or gel(see page 286)
- ARTESUNATE rectal(see page 287)
- BENZOIC acid + SALICYLIC acid ointment = Whitfield's ointment(see page 288)
- BENZYL BENZOATE, lotion(see page 289)
- CALAMINE lotion(see page 290)
- CHLORHEXIDINE 5% solution(see page 291)
- CHLORHEXIDINE 7.1% dermal gel(see page 292)
- CHLORHEXIDINE 0.2% mouthwash(see page 292)
- CHLORINE-RELEASING COMPOUNDS (NaDCC, HTH, bleach, chlorinated lime)(see page 293)
- CIPROFLOXACIN, ear drops(see page 295)
- CLOTRIMAZOLE, vaginal tablet(see page 296)
- DIMETICONE, lotion(see page 297)
- ETHANOL(see page 297)
- ETHYL ALCOHOL = ETHANOL(see page 298)
- FLUORESCEIN, eye drops(see page 299)
- ! Gentian violet = GV = Crystal violet(see page 299)
- HYDROCORTISONE, cream and ointment(see page 300)
- LEVONORGESTREL intrauterine device(see page 301)
- MALATHION, lotion(see page 302)
- ! Methylrosanilinium chloride = Gentian violet = Crystal violet(see page 303)
- MICONAZOLE, cream(see page 303)
- MUPIROCIN, ointment(see page 304)
- NaDCC(see page 305)
- NYSTATIN, vaginal tablet(see page 305)
- OXYBUPROCAINE, eye drops(see page 305)
- PERMETHRIN 1%, lotion(see page 306)
- PERMETHRIN 5%, cream(see page 307)
- PILOCARPINE, eye drops(see page 308)
- PODOPHYLLOTOXIN 0.5%, solution or gel(see page 309)
- PODOPHYLLUM resin, solution(see page 310)
- POVIDONE IODINE = POLYVIDONE IODINE = PVI, aqueous solution(see page 311)
- POVIDONE IODINE = POLYVIDONE IODINE = PVI, scrub solution(see page 312)
- SILVER SULFADIAZINE, cream(see page 313)
- SODIUM DICHLOROISOCYANURATE = NaDCC(see page 314)
- TETRACYCLINE, eye ointment(see page 315)
- ZINC OXIDE, ointment(see page 316)

# **ACICLOVIR**, eye ointment

Prescription under medical supervision

#### Therapeutic action

- Antiviral active against herpes virus

#### **Indications**

- Treatment of herpes keratitis
- Prevention of herpes keratitis in neonate born to a mother suffering from genital herpes at the moment of childbirth

#### Forms and strengths

- 3% ointment, tube

#### **Dosage and duration**

Treatment of herpes keratitis
 Child and adult: one application 5 times daily into the conjunctival sac of both eyes for 14 days or for 3 days after lesions have healed

Prevention of herpes keratitis in neonate
 Immediately after birth: one single application of aciclovir into the conjunctival sac of both eyes (after washing eyes with sterile 0.9% sodium chloride)

#### Contra-indications, adverse effects, precautions

– In neonates, wait 12 hours after application of aciclovir 3% then apply tetracycline eye ointment 1% to prevent gonococcal neonatal conjunctivitis.

#### Remarks

Storage: below 25 °C
 Use within 30 days after first opening.

# **ALCOHOL-BASED** solution or gel

## Therapeutic action

- Antiseptic

#### **Indications**

- Antiseptic hand rub, before and after procedures, whether gloves are used or not

#### Forms and strengths

- Ready to use alcohol-based hand rub solution or gel

#### Use

- Alcohol-based hand rubs can only be used if hands are not visibly dirty or soiled with organic matter. There must be no residual powder on hands (use powder-free gloves) and hands must be dry.
- Apply 3 ml of solution or gel in a cupped hand and spread to cover the entire surface of hands. Rub hands for 20-30 seconds, palm to palm, palm over dorsum, between fingers (fingers interlaced), around the thumbs and nails, until hands are completely dry. Do not dilute the product. Do not rinse off or dry hands.
- As long as hands are not visibly soiled, the product may be reapplied as many times as necessary without handwashing before or after applying the product.

## Contra-indications, adverse effects, precautions

- Do not use if:
- hands are visibly dirty or soiled with organic matter (wash hands);
- there is residual powder on hands (wash hands);
- hands are wet (water dilutes alcohol and impedes drying).
- Do not use after direct contact with a patient with a parasitic skin infection (scabies, lice): wash hands.
- Do not use simultaneously with soap or another antiseptic (antagonism, inactivation, etc.).
- Do not use for disinfection of material, patient's skin or mucous membranes.
- May cause: stinging sensation on broken skin.
- In case of eye contact flush immediately with plenty of water.

#### Remarks

- Dose required and duration of handrubbing may vary depending on the product used. Read the manufacturer's instructions carefully.
- To avoid difficulty in putting on gloves, rub hands until the product is completely dry.
- Use of alcohol-based hand rubs may result in a sticky residue on hands after several applications. In this event, wash hands.
- Some alcohol-based hand rubs can be used for surgical hand antisepsis, however the technique is not the same as for antiseptic hand rub.
- Storage: below 25°C 🌽

Close bottles tightly to avoid evaporation. Keep away from sources of ignition (flame, spark, incandescent material).

## **ARTESUNATE** rectal

Prescription under medical supervision

#### Therapeutic action

– Antimalarial

#### **Indications**

– Pre-referral treatment of suspected or confirmed severe malaria, in children less than 6 years, before transfer to a facility where parenteral antimalarial treatment can be administered

## Forms and strengths, route of administration

- 100 mg rectal capsule

## **Dosage and duration**

- 10 mg/kg as a single dose before transferring the patient
- Child 2 months to < 3 years (≤ 10 kg): 1 rectal capsule single dose (100 mg)</li>
- Child 3 to < 6 years (≤ 20 kg): 2 rectal capsules single dose (200 mg)

## Contra-indications, adverse effects, precautions

- May cause: gastrointestinal disturbances, headache.
- Buttocks should be held together for at least 1 minute to ensure retention. If capsules are expelled from the rectum within 30 minutes of insertion, re-administer the treatment.

#### Remarks

- Up to 2 capsules can be administered simultaneously.
- <u>Storage</u>: between 15 °C and 25 °C. Avoid temperature excursions above 30 °C. Do not refrigerate. Do not freeze V

# BENZOIC acid + SALICYLIC acid ointment = Whitfield's ointment

## Therapeutic action

- Fungistatic and keratolytic agent

#### **Indications**

- Dermatophyte infection of the scalp (tinea capitis), in combination with a systemic antifungal
- Dermatophyte infection of the glabrous skin and skin folds:
- alone, if lesions are localised, non-extensive
- in combination with a systemic antifungal, if the lesions are extensive

#### Forms and strengths

- Benzoic acid 6% + salicylic acid 3% ointment, tube or jar

#### **Dosage**

- Child and adult: one application 2 times daily, in a thin layer, to clean and dry skin

#### **Duration**

- 3 to 6 weeks, depending on clinical response

## Contra-indications, adverse effects, precautions

- Do not apply to exudative lesions, mucous membranes or eyes.
- May cause: skin irritation, local benign inflammation.
- In case of secondary bacterial infection, start appropriate local or systemic treatment before applying Whitfield's ointment.
- In case of contact with eyes or mucous membranes, flush immediately with plenty of water.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

### Remarks

- Whitfield's ointment is not included in the WHO list of essential medicines.
- Storage: below 25 °C 7

Once the ointment has been exposed to a high temperature, the active ingredients are no longer evenly distributed: the ointment must be homogenized before using.

# **BENZYL BENZOATE, lotion**

# Therapeutic action

Scabicide

## **Indications**

- Scabies (preferably use 5% permethrin cream for this indication)

## Forms and strengths

- 25% lotion

## Preparation and use

- Shake the bottle before application or dilution.
- Dilute the lotion, as required, according to age. Use drinking or boiled water.
- Apply the lotion to the whole body, including scalp, postauricular areas, palms of the hands and soles of the feet, paying particular attention to skin creases and interdigital web spaces. Leave on for recommended contact time, then rinse thoroughly with water.
- In children under 2 years: wrap hands to avoid accidental ingestion and contact with eyes.

	Child < 2 years	Child 2 to 12 years	Child > 12 years and adult	Pregnant woman
Preparat ion	1 part of 25% lotion + 3 parts of water	1 part of 25% lotion + 1 part of water	Undiluted 25% lotion	Undiluted 25% lotion

Contact time	12 hours (6 hours in children < 6 months)	24 hours	24 hours	12 hours
Number of applicati ons	One application only	Two applications (e.g. 24 hours apart, with a rinse between the two applications; or two successive applications 10 minutes apart, when the first application has dried, then rinse after 24 hours)		One application only

# Contra-indications, adverse effects, precautions

- Do not apply to broken skin (risk of systemic absorption), the face or mucous membranes.
- May cause: burning sensation; contact dermatitis in case of repeated applications; seizures in the event of marked transcutaneous absorption; rarely: hypersensitivity reactions.
- Avoid contact with eyes. In case of accidental contact, flush immediately with plenty of water.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication. Do not apply to the breasts.

## Remarks

- Close contacts should be treated at the same time regardless of whether they have symptoms or not. Decontaminate, after each treatment, the clothes and bed linen of patients and close contacts: wash ≥ 60 °C and dry in the sun, or leave in direct sunlight or seal in a plastic bag for 72 hours.
- Itching may persist for up to 4 weeks after the end of treatment (allergic reaction to dead parasites). Do not re-treat during this period. The treatment may be repeated if specific scabies lesions (scabious burrows) are still present after this period.
- Prepare dilution in a glass container. The lotion may damage certain plastics.
- Storage: below 25 °C V

# **CALAMINE lotion**

# Therapeutic action

- Antipruritic drug

## **Indications**

- Symptomatic treatment of pruritus

# Forms and strengths

- Calamine 8% or 15% lotion, bottle

## **Dosage**

- Child and adult: one application 3 to 4 times daily in a thin layer

## **Duration**

- According to clinical response

## Contra-indications, adverse effects, precautions

- Clean the skin before applying the lotion.
- Do not apply to exudative and/or superinfected lesions, mucous membranes or eyes.
- In case of contact with eyes or mucous membranes, flush immediately with plenty of water.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication. Do not apply to the breasts.

## Remarks

- Shake the lotion well before using.
- Storage: below 25°C 🌽

# **CHLORHEXIDINE 5% solution**

## Therapeutic action

- Antiseptic

## **Indications**

- Antisepsis of minor and superficial wounds and burns

## Forms and strengths

– 5% concentrated solution of chlorhexidine gluconate, corresponding to 2.8% chlorhexidine, to be diluted before use

# **Preparation**

- Use as a 0.05% aqueous solution:

For one litre: 10 ml of 5% concentrated solution + 990 ml of clear water, boiled a few minutes and cooled

## **Dosage**

– Apply diluted solution to minor and superficial wounds and burns.

- Do not use undiluted solution.
- Do not bring into contact with body cavities, eyes (risk of corneal damage), brain and meninges, middle ear (risk of deafness if ear drum is perforated).
- Do not use with soap or a different type of antiseptic, e.g. povidone iodine (incompatibility).
- May cause: skin and mucous membrane irritation; rarely allergic reactions.

- Avoid applications to mucous membranes, especially to genital mucous membranes.
- Do not use cork stoppers (decreases the antibacterial activity of chlorhexidine).

- <u>Storage</u>: below 25 °C - **V** Once diluted, the solution must be used immediately; do not store the diluted solution (risk of contamination).

# **CHLORHEXIDINE 7.1% dermal gel**

## Therapeutic action

- Antiseptic

## **Indications**

- Antisepsis of umbilical cord

## Forms and strengths

- 7.1 % chlorhexidine digluconate dermal gel, delivering 4% chlorhexidine, in 3 g sachet and 20 g tube

## **Dosage and duration**

- One application of 3 g of gel to the umbilical cord stump immediately after cutting the cord or during the first post-natal visit within the first 7 days of life if the neonate was born at home
- In settings where traditional unhygienic practices are common: one application daily for the first 7 days of life

# Contra-indications, adverse effects, precautions

- Do not bring into contact with body cavities, eyes (risk of corneal damage), brain and meninges, middle ear (risk of deafness if ear drum is perforated).
- Do not use with soap or a different type of antiseptic, e.g. povidone iodine (incompatibility).
- May cause: skin and mucous membrane irritation; rarely allergic reactions.
- Avoid applications to mucous membranes, especially to genital mucous membranes.

### Remarks

- <u>Storage</u>: below 25 ℃ - 🏸

# **CHLORHEXIDINE 0.2% mouthwash**

# Therapeutic action

- Antiseptic

## **Indications**

- Antisepsis of noma mouth ulcers

## Forms and strengths

- 0.2% mouthwash solution of chlorhexidine digluconate, ready to use

## **Dosage**

– Child: one application 4 to 6 times daily to oral mucosa, using a clean gauze swab wrapped around a tongue depressor

#### **Duration**

- According to clinical response

# Contra-indications, adverse effects, precautions

- Do not swallow.
- Do not bring into contact with eyes (risk of corneal damage), middle ear (risk of deafness if ear drum is perforated).
- May cause: reversible brown discoloration of the tongue and teeth, taste disturbances; rarely allergic reactions.

## Remarks

Storage: below 25 °C - V
 Once open, the mouthwash solution keeps for 4 weeks maximum.

# CHLORINE-RELEASING COMPOUNDS (NaDCC, HTH, bleach, chlorinated lime)



# Therapeutic action

- Disinfectants

## **Indications**

- Disinfection of medical devices, instruments, linen, floors and surfaces

## Forms and strengths

- The potency of chlorine disinfectants is expressed in terms of active chlorine in either:
  - percentage (%)
  - g/litre or mg/litre
  - parts per million (ppm)
  - chlorometric degree (1°chl. = approximately 0.3% active chorine)

- The most widely used chlorine disinfectants are:
  - Sodium dichloroisocyanurate (NaDCC), 1,67 g tab......1 g active chlorine/tab
  - Calcium hypochlorite (HTH), granules.......65-70% active chlorine
  - Sodium hypochlorite solutions (liquid bleach):
  - Chlorinated lime, powder ......25-35% active chlorine

## Preparation and use

- The concentration required depends on the amount of organic material present (how clean/unclean the surface is).
- The active chlorine content must always be checked on the product packaging in order to adjust the dilution if necessary.
- Prepare solutions with cold water in non-metallic containers.
- A deposit in HTH solutions and chlorinated lime solutions is normal (use only the supernatant).

	Clean medical devices, equipment, surfaces and linen (after cleaning)	Surfaces, beds, utensils in case of cholera (after cleaning)	Surfaces, equipment contaminated with blood and other body fluid spills (before cleaning)	Corpses, excreta, boots in case of cholera
Concentration required, expressed in active chlorine	<b>0.1%</b> = 1000 ppm	<b>0.2%</b> = 2000 ppm	<b>0.5%</b> = 5000 ppm	<b>2%</b> = 20 000 ppm
NaDCC (1 g active chlorine/tablet	1 tab/litre water	2 tab/litre water	5 tab/litre water	20 tab/litre water
Calcium hypochlorite (70% active chlorine)	15 g/10 litres = 1 level tablespoon for 10 litres water	30 g/10 litres = 2 level tablespoons for 10 litres water	7.5 g/litre = ½ tablespoon for 1 litre water	300 g/10 litres = 20 level tablespoons for 10 litres water

For more information, see Antiseptiques et désinfectants(see page 343), Part two.

## **Precautions**

- Handle concentrated products with caution (avoid jolts and exposure to high temperatures or flames).
- Do not bring dry products, particularly HTH and chlorinated lime, in contact with organic materials (e.g. corpses): risk of explosion.
- Avoid inhaling vapours and dust when opening or handling the containers.

#### Remarks

- Sodium dichloroisocyanurate (NaDCC) is less corrosive than the other products.
- Bleach or concentrated bleach, or if not available HTH, may be used to prepare an antiseptic solution at 0.5% active chlorine (as substitute to Dakin's solution), provided sodium bicarbonate (one tablespoon per litre) is added to the final solution to neutralise the alkalinity (e.g. for one litre: 200 ml of bleach 2.6% + 800 ml distilled or filtered water, or if not available, boiled and cooled water + 1 tablespoon of sodium bicarbonate).
- Chloramine T (powder or tablet, 25% active chlorine) is another chlorine-releasing compound used above all as an antiseptic.
- Trichloro-isocyanuric acid (TCCA), in powder or granules (90% active chlorine), is very similar to NaDCC, but its use is limited due to its poor solubility.
- <u>Storage</u>: in airtight, non-metallic containers, protected from light, heat (and humidity for dry products)

Chlorinated lime, bleach and concentrated bleach are unstable. HTH is more stable. NaDCC is by far the most stable

# CIPROFLOXACIN, ear drops

Prescription under medical supervision

# Therapeutic action

- Fluoroquinolone antibacterial

## **Indications**

- Acute otitis externa
- Chronic suppurative otitis media

## Forms and strengths

- 0.3% ear drops

## **Dosage**

- Child ≥ 1 year: 3 drops 2 times daily
- Adult: 4 drops 2 times daily

To administer drops in the affected ear(s), pull back the auricle and maintain the head to one side for a few minutes.

#### **Duration**

- Acute otitis externa: 7 days; chronic suppurative otitis media: until no more drainage is obtained (approximately 2 weeks, max.4 weeks)

## Contra-indications, adverse effects, precautions

- May cause: headache, local skin eruption or pruritus.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

### Remarks

- Do not touch let the dropper touch either hands or the ear.
- <u>Storage</u>: below 25 °C

Once the bottle has been opened, solution keeps for 4 weeks.

# **CLOTRIMAZOLE**, vaginal tablet

## Therapeutic action

- Antifungal

#### **Indications**

- Vaginal candidiasis

## Forms and strengths, route of administration

- 500 mg vaginal tablet, with applicator

## **Dosage and duration**

– Adult: one vaginal tablet single dose, at bedtime, preferably lying down Place the tablet on the applicator. Insert the applicator high into the vagina. Push the plunger then remove the applicator.

- May cause: local irritation; allergic reactions.
- Inform patients that the oil-based vaginal tablet may damage the latex in condoms and diaphragms and reduce their effectiveness.

- <u>Pregnancy</u>: no contra-indication (do not use the applicator to avoid damage to the cervix)
- Breast-feeding: no contra-indication

- Also comes in 100 mg vaginal tablets, applied once daily at bedtime for 6 days. Do not interrupt treatment during menstruation. Clean the applicator with water after each use.
- Storage: below 25°C 🌽

# **DIMETICONE**, lotion

## Therapeutic action

- Pediculicide by physical mode of action

## **Indications**

- Head pediculosis (lice)

# Forms and strengths

-4% lotion

#### Use

- Child 6 months and over and adult: apply lotion to scalp and entire length of the hair shaft, paying particular attention to the areas behind the ears and around the nape of the neck. Leave on hair for 8 hours (e.g. overnight), then rinse throughly with water.
- Repeat the application after 7 days.

## Contra-indications, adverse effects, precautions

- May cause: scalp and eye irritation.
- Keep away from flames and/or heat sources during application and until rinsing (risk of ignition).
- Avoid contact with eyes. In case of accidental contact, flush immediately with plenty of water.
- Pregnancy: no contra-indication
- Breast-feeding: no contra-indication

## Remarks

- Examine everyone in contact with a patient and only treat those with live lice and/or live nits. Preventive treatment of noninfected persons is ineffective.
- Wash combs and decontaminate headwear, bedding: wash ≥ 60 °C, iron or dry in the sun or, if not feasible, seal in a plastic bag for 2 weeks.
- Storage: below 25 °C W

# **ETHANOL**

See ETHYL ALCOHOL(see page 298)

# ETHYL ALCOHOL = ETHANOL

## Therapeutic action

- Antiseptic and disinfectant

## **Indications**

- Antisepsis of intact skin prior to injections and venopunctures
- Disinfection of latex stopper of infusion bottles and drug vials (except vaccines), latex injection sites of infusion sets

## Forms and strengths

- Mixtures of alcohol (ethanol) and water in different concentrations (e.g. 95% v/v ethanol), sometimes containing additives to avoid their ingestion.
- Alcoholic strength is expressed:
- preferably as a percentage by volume of alcohol (% v/v); e.g. 1000 ml of 95% v/v alcohol contains 950 ml of absolute alcohol.
- sometimes as a percentage by *weight* of alcohol (% w/w). The % w/w is not equal to the % v/v because the mixture of water and alcohol produces a reduction in volume.
- sometimes in *degrees* (°) but this should be discouraged as it is a source of error. There are at least 3 different definitions of degrees: the old UK definition (° British proof), the American (° proof) and the one used in French speaking countries (1° = 1% v/v). For example:  $40\% \text{ v/v} = 70^\circ \text{ proof}$  (British system) =  $80^\circ \text{ proof}$  (American system) =  $40^\circ \text{ in French speaking countries}$ .

# **Preparation**

- Use 70% v/v ethanol, which is more effective than higher concentrations.
- To obtain 1 litre of 70% v/v ethanol:
- take 785 ml of 90% v/v ethanol, or 730 ml of 95% v/v ethanol, or 707 ml of 99% v/v ethanol;
- add distilled or filtered water to make up a volume of 1 litre;
- leave to cool and top up with water again to bring the volume back to 1 litre (mixing water and ethanol together produces a reaction whereby volume is reduced).

## **Precautions**

- Do not apply to mucous membranes, wounds or burns: it is painful, irritating and slows the healing process.
- Do not apply on neonatal skin.

## Remarks

- Ethanol can be used for disinfection of non-critical medical items (items that are in contact with intact skin only) that are not soiled by blood or other body fluids.
- Critical medical items (surgical instruments, etc.) cannot, under any circumstances, be "sterilized" by alcohol flaming, immersion in ethanol or wiping with ethanol.
- Storage: below 25 °C 🌠

Close bottles tightly to avoid evaporation. Keep away from sources of ignition (flame, spark, incandescent material).

# FLUORESCEIN, eye drops

## Therapeutic action

- Ophthalmic diagnostic staining agent

## **Indications**

- Detection of corneal or conjunctival epithelial damage

## Forms and strengths

- 0.5% or 2% eye drops in single use vial

## **Dosage and duration**

- Instill 1 or 2 drops into the conjunctival sac.
- Ask patient to blink a few times to spread the dye around; remove excess fluorescein and proceed with the examination.

## Contra-indications, adverse effects, precautions

- May cause: local allergic reaction (rare).
- Wait 15 minutes before administering any other kind of eye drops.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- To facilitate the examination, use an ophthalmoscope with a blue filter (increases fluorescence).
- Under normal light, large lesions are visible but small lesions cannot be detected.
- Storage: below 25 °C V

Vials are designed for single use only; they must be discarded after use.

# ! Gentian violet = GV = Crystal violet

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see METHYLROSANILINIUM CHLORIDE = GENTIAN VIOLET(see page 324)

# **HYDROCORTISONE**, cream and ointment

Prescription under medical supervision

# Therapeutic action

- Topical corticosteroid

## **Indications**

- Atopic eczema, contact eczema, seborrhoeic dermatitis
- Reactions to insect bites

# Forms and strengths

- 1% cream and ointment

## **Dosage and duration**

– Child and adult: one application once daily or 2 times daily to the affected area only, in thin layer, for 7 days maximum

# Contra-indications, adverse effects, precautions

- Do not use:
- for more than 7 days;
- in case of acne, rosacea, perioral dermatoses, untreated bacterial (impetigo, etc.), fungal (candidiasis and dermatophytosis) and viral (herpes) skin infections;
- under occlusive dressing, on large areas of skin or on wounds, especially in infants and children (increased local and systemic adverse effects).
- May cause:
- irritations, pruritus, burning sensations, skin eruptions, hypopigmentation, contact eczema and urticaria;
- skin atrophy, dilation of small blood vessels (telangiectasia), stretch marks, skin fragility, delayed wound healing in case of prolonged treatment.
- Apply with precaution to:
- the eyelids and around the eyes (risk of glaucoma and cataract);
- the face (risk of rosacea and thinning of the skin);
- the skin folds (increased adverse effects).
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication. Do not apply to the breasts.

### Remarks

- The cream and ointment are interchangeable. However, preferably use the cream on moist lesions and the ointment on dry and scaly lesions.
- Storage: below 25 °C 🌽

# **LEVONORGESTREL** intrauterine device

Prescription under medical supervision

# Therapeutic action

- Hormonal contraceptive, progestogen

## **Indications**

- Long-acting contraception
- Menorrhagia

# Forms and strengths

– Intrauterine device (IUD) containing 52 mg of levonorgestrel and releasing 20 micrograms daily on insertion

## **Dosage**

- The IUD may be inserted at any moment of the cycle if it is reasonably certain the woman is not pregnant, including when switching from another form of contraception.

  Use condoms for 7 days after the insertion of the IUD if it is inserted:
- over 7 days after the start of menstrual period;
- over 28 days postpartum if not breastfeeding;
- over 7 days after an abortion.

## **Duration**

- As long as desired and well tolerated, for max. 5 years after which it must be changed.

- Do not use in patients with breast cancer, cervical cancer, severe or recent liver disease, unexplained vaginal bleeding, genital infection, active thromboembolic disorders, hydatidiform mole or other gestational trophoblastic disease.
- May cause:
- changes in bleeding patterns: amenorrhoea, irregular lighter bleeding; rarely: heavy prolonged bleeding;
- abdominal pain, headache, nausea, breast tenderness, acne, weight gain, mood change.
- IUD insertion-related complications: expulsion of IUD, pelvic infection, risk of uterine perforation during insertion.
- The contraceptive efficacy of levonorgestrel-releasing IUD does not seem to be reduced in women taking enzyme-inducing drugs.
- Pregnancy: CONTRA-INDICATED
- Breast-feeding: no contra-indication

- Fertility returns rapidly after removal of the IUD.
- The IUD can be inserted into the uterus within 48 hours after childbirth. If not inserted within 48 hours, delay insertion until after 28 days postpartum.
- For details on insertion and removal of IUD, read manufacturer's instructions carefully.
- <u>Storage</u>: below 25 °C 🌽

# **MALATHION**, lotion

# Therapeutic action

- Pediculicide (organophosphorus insecticide)

## **Indications**

- Head pediculosis (lice)

## Forms and strengths

- 0.5% lotion

#### Use

- Apply lotion to hair and scalp; pay particular attention to the areas behind the ears and around the nape of the neck.
- Leave on hair for:
- 8 hours in children from 6 months to 2 years;
- 12 hours in children over 2 years and adults.
- Rinse with plenty of water.
- It is recommended to repeat the application after 10 days.

## Contra-indications, adverse effects, precautions

- Use with caution and under medical supervision in children under 2 years.
- May cause: scalp irritation.
- Avoid contact with eyes. In the event of product entering the eye, rinse with plenty of water.
- DO NOT SWALLOW. The first signs of poisoning after accidental ingestion are gastrointestinal disturbances (vomiting, diarrhoea). Dyspnoea, seizures or coma are signs of severe intoxication. As soon as the first signs appear, administer injectable atropine as an antidote.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Examine everyone in contact with a patient and treat only those infected. Preventive treatment of noninfected persons is ineffective and increases the risk of resistance.
- Malathion is flammable. Keep medication away from heat sources.

- Malathion is not included in the WHO list of essential medicines.
- <u>Storage</u>: below 25 °C 🖊

# ! Methylrosanilinium chloride = Gentian violet = Crystal violet

This drug is either potentially dangerous and forbidden in certain countries, or obsolete or ineffective.

This drug is still widely used, attention is therefore drawn to the risk of prescription.

For more information, see METHYLROSANILINIUM CHLORIDE = GENTIAN VIOLET(see page 324)

# MICONAZOLE, cream

## Therapeutic action

- Antifungal

## **Indications**

- Cutaneous candidiasis (groin, abdominal folds, intergluteal fold, sub-mammary folds, interdigital spaces of the toes or fingers)
- Candidal balanitis
- Mild dermatophyte infection of the glabrous skin and skin folds

## Forms and strengths

- 2% cream, tube

## **Dosage**

- Child and adult: one application 2 times daily, in a thin layer, to clean and dry skin

## **Duration**

- Cutaneous candidiasis: 2 to 4 weeks
- Candidal balanitis: one week
- Dermatophyte infection: 2 to 3 weeks

- May cause: local irritation; allergic reactions.
- In the event of genital candidiasis, inform patients that the oil-based cream may damage the latex in condoms and diaphragms and reduce their effectiveness.

- <u>Pregnancy</u>: no contra-indication
- <u>Breast-feeding</u>: no contra-indication. In the event of mammary candidiasis, clean the breast before nursing and apply cream after nursing.

- For the treatment of vulvovaginal candidiasis, miconazole cream may complement, but does not replace, treatment with clotrimazole vaginal tablets.
- Storage: below 25 °C W

# **MUPIROCIN**, ointment

Prescription under medical supervision

Mupirocin should not be used in patients with extended impetigo (more than 5 lesions or more than one skin area involved), bullous impetigo, ecthyma, impetigo with abscess, and in immunodeficient patients: in such cases, oral antibiotic therapy is required.

## Therapeutic action

- Antibacterial

## **Indications**

- Localized non bullous impetigo (less than 5 lesions in a single area)

## Forms and strengths

- 2% ointment, tube

## **Dosage and duration**

– Child and adult: one application 3 times daily, to clean and dry skin, for 7 days The patient should be reassessed after 3 days. If there is no response, switch to oral antibiotic therapy.

## Contra-indications, adverse effects, precautions

- May cause: pruritus and burning sensation; allergic reactions.
- If applying to the face, avoid contact with eyes.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication. Do not apply to the breasts.

## Remarks

- Do not mix with other ointments (effect of mupirocin decreased).
- Avoid touching the lesions; keep them covered with gauze if possible.
- Storage: below 25 °C W

# **NaDCC**

See SODIUM DICHLOROISOCYANURATE(see page 314)

# **NYSTATIN**, vaginal tablet

## Therapeutic action

- Antifungal

## **Indications**

- Vaginal candidiasis

# Forms and strengths, route of administration

- 100 000 IU vaginal tablet

## **Dosage and duration**

- Adult: one tablet once daily at bedtime for 14 days

Tablets must be moistened and inserted high into the vagina.

# Contra-indications, adverse effects, precautions

- May cause (rarely): local irritation, allergic reactions.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

### Remarks

- Do not interrupt treatment during menstruation.
- Prefer clotrimazole 500 mg vaginal tablet as a single dose for this indication.
- Storage: below 25 °C V

Once a tablet is removed from the packaging, it must be used immediately.

# **OXYBUPROCAINE**, eye drops

Prescription under medical supervision

# Therapeutic action

- Local anaesthetic

## **Indications**

- Short-term anaesthesia of conjunctiva and cornea

## Forms and strengths

- 0.4% eye drops in single use vial

## **Dosage and duration**

- Removal of foreign bodies

Up to 3 drops into the conjunctival sac, administered one to two minutes apart

- Measurement of intraocular pressure

1 drop into the conjunctival sac

# Contra-indications, adverse effects, precautions

- Do not use repeatedly (risk of severe and permanent corneal damage).
- May cause: stinging on instillation.
- Wait 15 minutes before administering any other kind of eye drops.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

## Remarks

- Anaesthesia is produced within one minute and lasts 10 to 20 minutes.
- Anaesthetic eye drops (oxybuprocaine, tetracaine, etc.) are intended for specific therapeutic or diagnostic procedures. They must not be given to the patient for home use. In the event of intense ocular pain, prescribe an appropriate oral analgesic.
- *− Storage: below 25 °C*

Vials are designed for single use only; they must be discarded after use.

# **PERMETHRIN 1%, lotion**

## Therapeutic action

- Pediculicide (pyrethroid insecticide)

## **Indications**

- Head pediculosis (lice)

## Forms and strengths

- 1% lotion

#### Use

- Child 2 months and over and adult: apply lotion to scalp and entire length of the hair shaft, paying particular attention to the areas behind the ears and around the nape of the neck. Leave on hair for 10 minutes, then rinse throughly with water.
- Repeat the application after 7 days.

## Contra-indications, adverse effects, precautions

- Use with caution and under medical supervision in children under 6 months.
- May cause: scalp irritation, pruritus, skin rash and redness; rarely: oedema, hypersensitivity reactions.
- Avoid contact with eyes. In case of accidental contact, flush immediately with plenty of water.
- <u>Pregnancy and breast-feeding</u>: prefer dimeticone

## Remarks

- Examine everyone in contact with a patient and only treat those with live lice and/or live nits. Preventive treatment of noninfected persons is ineffective and increases the risk of resistance.
- Wash combs and decontaminate headwear and bedding: wash ≥ 60 °C, iron or dry in the sun or, if not feasible, seal in a plastic bag for 2 weeks.
- Use the lotion rather than the shampoo that is less effective as the contact time is usually shorter.
- Permethrin 5% cream is used for the treatment of scabies in children 2 months and over and adults.
- Storage: below 25°C 🌽

# PERMETHRIN 5%, cream

## Therapeutic action

- Scabicide (pyrethroid insecticide)

## **Indications**

- Scabies

## Forms and strengths

- 5% cream

#### Use

- Child 2 months and over and adult: apply the cream to the whole body, including scalp, postauricular areas, palms of the hands and soles of the feet, paying particular attention to skin creases and interdigital web spaces. Leave on for at least 8 hours (e.g. overnight) then rinse thoroughly with water.
- In child under 2 years: wrap hands to avoid accidental ingestion and contact with eyes.
- Repeat the application after 7 days.

# Contra-indications, adverse effects, precautions

- Do not use in children under 2 months.
- Do not apply to the face and mucous membranes, nor on broken skin.
- May cause: paraesthesia, pruritus, redness, burning sensation, skin dryness; rarely: oedema, hypersensitivity reactions.
- Avoid contact with eyes. In case of accidental contact, flush immediately with plenty of water.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication. Do not apply to the breasts.

### Remarks

- Close contacts should be treated at the same time regardless of whether there have symptoms or not. Decontaminate, after each treatment, clothes and bed linen of patients and close contacts: wash ≥ 60  $^{\circ}$ C and dry in the sun, or expose to sunlight or seal in a plastic bag for 72 hours.
- Itching may persist for up to 4 weeks after the end of treatment (allergic reaction to dead parasites): do not re-treat during this period. The treatment may be repeated if specific scabies lesions (scabious burrows) are still present after this period.
- 1% permethrin lotion is used for the treatment of head lice in children 2 months and over and adults.
- Storage: below 25°C 🖊

# PILOCARPINE, eye drops

Prescription under medical supervision

## Therapeutic action

- Cholinergic anti-glaucoma agent, miotic

## **Indications**

- Chronic open-angle glaucoma

## Forms and strengths

- 2% eye dropsAlso comes in 4% eye drops.

## **Dosage**

- Adult: 1 drop into the conjunctival sac 4 times daily

## **Duration**

- Life-long treatment

- Do not administer to children.
- Do not administer to patients with iridocyclitis and some forms of secondary glaucoma.

- Do not administer to patients with history of retinal detachment (trauma or family history) nor to myopic patients, except if it is possible to examine the peripheral retina (fundus examination) prior to the initiation of therapy and routinely thereafter.
- May cause:
- transient blurred vision, visual field modification, difficulty with dark adaptation (inform patients, especially drivers);
- retinal detachment in patients with myopia;
- ocular irritation, headache (decreasing after 2 to 4 weeks); rarely, allergic reactions.
- In case of treatment with another eye drop, wait 5 minutes before instilling the second eye drop treatment.
- Patients should have regular monitoring of intraocular pressure during therapy.
- <u>Pregnancy</u>: no contra-indication
- Breastfeeding: no contra-indication

- Do not touch the dropper with the hands.
- Storage: below 25 °C

Once the bottle has been opened, solution keeps for 2 weeks.

# PODOPHYLLOTOXIN 0.5%, solution or gel

Prescription under medical supervision

## Therapeutic action

- Antiviral, antimitotic, cytolytic agent active against human papillomaviruses (HPVs)

## **Indications**

- External genital warts, perianal warts and vaginal warts

## Forms and strengths

- 0.5% solution or gel, with applicator tips

## **Dosage**

- One application to warts 2 times daily
- For vaginal warts, allow to dry before removing the speculum.

## **Duration**

- 3 consecutive days per week, for a maximum of 4 weeks

- Do not use to treat genital warts in children.
- Do not apply to warts > 3 cm.
- Do not apply to cervical, urethral, anorectal or oral warts.
- Do not apply to healthy skin.

- May cause local reactions: erythema, ulceration, pain in area where applied.
- Use a new applicator tip for each application.
- Avoid contact with eyes. In case of eye contact flush immediately with plenty of water.
- <u>Pregnancy</u>: **CONTRA-INDICATED**
- Breast-feeding: CONTRA-INDICATED

- When treatment is contra-indicated or has failed after 4 weeks, change treatment method (cryosurgery, electrosurgery, surgical removal).
- <u>Storage</u>: below 25 °C 🖊

# **PODOPHYLLUM resin, solution**

Prescription under medical supervision

## Therapeutic action

- Antiviral, antimitotic, cytolytic agent active against human papillomaviruses (HPVs)

## **Indications**

- External genital warts, perianal warts and vaginal warts

# Forms and strengths

– Podophyllum resin in alcohol or compound benzoin tincture, 10%, 15% and 25% solution for topical application

#### Use

- Always apply a protective layer of vaseline or zinc oxide ointment on the surrounding skin prior to treatment.
- Apply podophyllum resin to warts:
- For external warts, leave on the warts for 1 to 4 hours then wash with soap and water.
- For vaginal warts, allow to dry before removing the speculum.

#### **Duration**

- Apply once weekly if necessary, for a maximum of 4 weeks.

- Do not use to treat genital warts in children.
- Do not apply to healthy skin or mucous membranes, or to warts > 3 cm, or to cervical, urethral, anorectal or oral warts.
- May cause:
- local reactions: erythema, ulceration, pain in area where applied;
- systemic adverse effects: gastrointestinal disturbances, haematological and neurological disorders (possibly severe) in the event of prolonged or excessive application, or when applied to bleeding lesions.

- Avoid contact with eyes. In case of eye contact flush immediately with plenty of water.
- <u>Pregnancy</u>: **CONTRA-INDICATED**
- Breast-feeding: CONTRA-INDICATED

- Use by preference 0.5% podophyllotoxin solution: it is as effective as podophyllum resin, but less irritant and toxic. Another advantage is that the patient may apply the solution to the warts himself; whereas the resin must always be applied by medical staff.
- When treatment is contra-indicated or has failed after 4 weeks, change treatment method (cryosurgery, electrosurgery, surgical removal).
- Storage: below 25 °C 🌽

# POVIDONE IODINE = POLYVIDONE IODINE = PVI, aqueous solution

## Therapeutic action

- Antiseptic and disinfectant

## **Indications**

- Antisepsis of intact or broken skin and mucous membranes
- Disinfection of latex stopper of infusion bottles and drug vials (except vaccines), latex injection sites of infusion sets

## Forms and strengths

- 10% aqueous solution

#### Use

- Antisepsis of intact skin (injections, punctures)

Apply 10% solution to the puncture/injection site and allow to dry before inserting the needle. The skin should be cleaned beforehand if soiled or if the procedure is invasive (lumbar puncture, epidural/spinal anaesthesia, etc.).

- Preoperative skin antisepsis

Apply 10% solution twice. Allow to dry between each application (do not dab to accelerate drying). Incise once the 2<sup>nd</sup> application has dried. The surgical site should be cleaned beforehand with PVI scrub solution.

- Wound antisepsis

Apply 10% solution to small superficial wounds.

For large wounds and burns, wound irrigation, etc., dilute PVI ( $\frac{1}{4}$  of 10% PVI and  $\frac{3}{4}$  of 0.9% NaCl or sterile water) then rinse with 0.9% NaCl or sterile water.

# Contra-indications, adverse effects, precautions

- Do not use with other antiseptics such as chlorhexidine (incompatibility) or mercury compounds (risk of necrosis).
- Do not use in preterm neonates and neonates < 1.5 kg.
- Due to the risk of transcutaneous resorption of iodine, do not use repeatedly nor on large areas, especially in pregnant and lactating women and infants < 1 month.
- May cause: local skin reactions; exceptionally, allergic reactions.

## Remarks

- The antiseptic effect of PVI begins after 30 seconds of contact. However, a minimum contact time of 1 minute is recommended to eliminate bacteria.
- Storage: below 25°C 🌽

Once the bottle has been opened, solution keeps 30 days.

# POVIDONE IODINE = POLYVIDONE IODINE = PVI, scrub solution

## Therapeutic action

Antiseptic

## **Indications**

- Antiseptic hand wash and surgical hand antisepsis
- Preoperative skin preparation (patient preoperative showering, antiseptic cleansing of the surgical site)
- Cleansing of contaminated wounds

## Forms and strengths

7.5% scrub solution
Also comes in 4% scrub solution.

#### Use

- Antiseptic hand wash

Wet hands; pour 5 ml of solution, rub hands for 1 min; rinse thoroughly; dry with a clean towel.

- Surgical hand antisepsis

There are different protocols, for information:

Wet hands and forearms; spread 5 ml of solution on hands and forearms and rub for 1 or 2 min (i.e. 30 seconds or 1 min for each side); brush the nails of each hand for 30 seconds; rinse.

Spread again 5 ml of solution on hands and forearms and rub for 2 min; rinse thoroughly; dry with a sterile towel.

- Patient preoperative showering

Wet the whole body including hair; apply the solution and rub until the foam is white, start at the head

and move down, finishing with the feet. Pay special attention to hair, armpit, hands, perineum, genitals and toes. Leave in contact a few minutes and rinse; dry with a clean towel; put on clean clothes.

- Antiseptic cleansing of surgical site

Rub for 1 min the surgical site, using sterile gauze soaked with sterile water and solution; rinse with sterile water; dry with sterile gauze.

- Cleansing of contaminated wounds

Prepare a diluted solution:

With 7.5% solution: 1 part of solution + 4 parts of sterile 0.9% NaCl or water With 4% solution: 1 part of solution + 2 parts of sterile 0.9% NaCl or water

Clean the wound; rinse thoroughly.

# Contra-indications, adverse effects, precautions

- Do not use with others antiseptics such as chlorhexidine (incompatibility) or mercury compounds (risk of necrosis). Given the possible interactions between different groups of antiseptics, PVI scrub solution must only be used with products of the same group (i.e. PVI aqueous or alcoholic solutions).
- Do not use in preterm neonates and neonates < 1.5 kg (use ordinary soap).
- May cause: local skin reactions (contact dermatitis); exceptionally: allergic reactions.
- <u>Pregnancy and breast-feeding</u>: no contra-indication for brief application; no prolonged use.

## Remarks

- For preoperative skin preparation, cleansing of the surgical site is followed by the application of 10% PVI solution.
- <u>Storage</u>: below 25 °C 🌽

# SILVER SULFADIAZINE, cream

Prescription under medical supervision

## Therapeutic action

- Antibacterial (sulfonamide group)

## **Indications**

- Prophylaxis and treatment of infections of in severe burns
- Treatment of infections in leg ulcers

## Forms and strengths

- 1% sterile cream, tube or jar

#### Use

- Child 2 months and over and adult: clean the wound then apply a 3 to 5 mm layer of silver sulfadiazine cream to the wound once daily and cover with sterile compresses.

#### **Duration**

– Until wound has healed or until skin graft, when required.

# Contra-indications, adverse effects, precautions

- Do not use in patients with allergy to sulfonamides; in children under 2 months.
- Do not apply other topical treatments to wounds where silver sulfadiazine is applied.
- Use with caution in children under 2 years (risk of systemic absorption); in patients with severe renal or hepatic impairment.
- May cause:
- skin reactions, grey skin discoloration, skin photosensitivity; rarely: allergic reactions, sometimes severe (Lyell's and Stevens-Johnson syndromes).
- systemic adverse effects related to sulfonamides (haematological, renal, cutaneous disorders, etc.) when applied to a large surface area, mucous membranes or prolonged use.
- <u>Pregnancy</u>: avoid if possible during the 3<sup>rd</sup> trimester of pregnancy (risk of jaundice in the neonate)
- Breast-feeding: CONTRA-INDICATED if the child is under one month

#### Remarks

- <u>Storage</u>: between 8 °C and 25 °C -  $\sqrt{N}$ After use, keep the tube or jar tightly closed to avoid exposure to light.

# SODIUM DICHLOROISOCYANURATE = NaDCC



## Therapeutic action

- Disinfectant (chlorine-releasing compound)

## **Indications**

- Disinfection of medical devices, instruments, linen, floors and surfaces

# Forms and strengths

– 1.67 g NaDCC effervescent tablet, releasing 1 g active chlorine when dissolved in water. Also comes in different strengths and in granules and powder.

# **Preparation and use**

- Pre-disinfection of soiled instruments
- 0.1% active chlorine solution (1000 ppm): 1 tablet of 1 g active chlorine per litre Immediately after use, soak instruments for 15 minutes, then clean instruments.
- Disinfection of clean instruments
- 0.1% active chlorine solution (1000 ppm): 1 tablet of 1 g active chlorine per litre Soak previously cleaned instruments for 20 minutes, rinse thoroughly and dry.

- Disinfection of linen

0.1% active chlorine solution (1000 ppm): 1 tablet of 1 g active chlorine per litre Soak for 15 minutes, rinse thoroughly (at least 3 times).

General disinfection (surfaces, floors, sinks, equipment, etc.)
 See Chlorine-releasing compounds(see page 293) and Antiseptics and disinfectants(see page 343), Part two.

## **Precautions**

- Prepare solutions with cold water, in non metallic containers.
- NaDCC can corrode metal. The risk is limited for good quality stainless steel instruments if concentration, contact time (20 minutes maximum) and thorough rinsing recommendations are respected.
- For disinfection of linen: use only for white cotton or linen (risk of discolouration).
- Do not expose the product to flames. Do not incinerate.
- DO NOT SWALLOW. Do not store NaDCC tablets near oral tablets.
- Avoid inhaling vapours and dust when opening or handling the containers.
- Do not mix with acid solutions such as urine, etc. (release of toxic chlorine gas) and detergents.

#### Remarks

– NaDCC may be used for wound antisepsis but only if the formulation is intended for this purpose: 0.1% active chlorine solution (1000 ppm): 1 tablet of 1 g active chlorine per litre. For prolonged use, protect the healthy skin around the wound with vaseline.

Caution: some formulations used for disinfecting floors contain additives (detergents, colouring, etc.) and cannot be used on wounds. Check label or leaflet.

- Some formulations can be used for the disinfection of drinking water (Aquatabs®, etc.). Follow manufacturer's instructions.
- NaDCC is also called sodium troclosene, sodium dichloro-s-triazinetrione.
- <u>Storage</u>: in airtight container, protected from light, heat and humidity, in a well ventilated room  $\mathscr{U}$  -

# TETRACYCLINE, eye ointment

## Therapeutic action

- Antibacterial

# **Indications**

- Treatment of bacterial conjunctivitis
- Treatment of trachoma (by preference use oral azithromycin for this indication)
- Prevention of neonatal conjunctivitis

## Forms and strengths

- 1% ointment, tube

## **Dosage and duration**

- Wash the eyes with boiled and cooled water before each application. Use sterile sodium chloride 0.9% for newborns.
- Apply tetracycline 1% into the conjunctival sac of both eyes:
- Conjunctivitis: one application 2 times daily for 7 days
- Trachoma: one application 2 times daily for 6 weeks
- Prevention of neonatal conjunctivitis: one single application immediately after birth

# Contra-indications, adverse effects, precautions

- Do not use in patients with hypersensitivity to tetracyclines.
- May cause allergic reactions; stop treatment in the event of serious reaction.

### **Remarks**

- Neonatal conjunctivitis must be treated with systemic antibiotic therapy. When it is not immediately available, apply tetracycline eye ointment to both eyes every hour until systemic treatment is available.
- Oxytetracycline and chlortetracycline are used in the same way as tetracycline.
- In the event of eye infection, use only eye ointment; dermal ointment must never be applied to the eyes.
- <u>Storage</u>: below 25 °C **//** Do not use after expiry date.

# ZINC OXIDE, ointment

## Therapeutic action

- Skin protector

## **Indications**

- Dermatosis of kwashiorkor
- Nappy rash
- Eczema
- First-degree burns
- Protection of healthy skin when caustic products such as podophyllum resin or podophyllotoxin are to be applied

## Forms and strengths

- 10% zinc oxide ointment, tube or jar

## **Dosage**

- Child and adult: one application 1 to 3 times daily

## **Duration**

- According to clinical response

# Contra-indications, adverse effects, precautions

- Clean the skin before applying the ointment.
- Do not apply to exudative and/or superinfected lesions.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication. Do not apply to the breasts.

#### Remarks

- Storage: below 25 °C - 🖊

Once the ointment has been exposed to a high temperature the active ingredients are no longer evenly distributed: the ointment must be homogenized before using.

# Drugs potentially dangerous or obsolete or ineffective

- AMODIAQUINE = AQ oral(see page 318)
- ARTEMETHER injectable(see page 319)
- ARTESUNATE = AS oral(see page 320)
- ARTESUNATE + SULFADOXINE/PYRIMETHAMINE = AS + SP oral(see page 321)
- Long-acting oily CHLORAMPHENICOL injectable(see page 322)
- MEFLOQUINE = MQ oral(see page 323)
- METHYLROSANILINIUM CHLORIDE = GENTIAN VIOLET = GV = CRYSTAL VIOLET(see page 324)
- METAMIZOLE = DIPYRONE = NORAMIDOPYRINE oral(see page 326)
- METAMIZOLE = DIPYRONE = NORAMIDOPYRINE injectable(see page 326)
- PROMETHAZINE injectable(see page 327)
- QUININE injectable(see page 328)
- TETANUS ANTITOXIN (EQUINE)(see page 329)

# AMODIAQUINE = AQ oral

Prescription under medical supervision

Do not administer the combination artesunate-amodiaquine as separate tablets (i.e. artesunate tablets + amodiaquine tablets). Use co-formulated tablets.

# Therapeutic action

- Antimalarial

## **Indications**

- Treatment of uncomplicated falciparum malaria, in combination with artesunate
- Treatment of uncomplicated malaria due to other Plasmodium species, in combination with artesunate, when chloroquine cannot be used
- Completion treatment following parenteral therapy for severe malaria, in combination with artesunate

# Forms and strengths

- 200 mg amodiaquine hydrochloride tablet, containing 153 mg amodiaquine base

# **Dosage and duration**

- Child and adult: 10 mg base/kg once daily for 3 days, in combination with artesunate

## Contra-indications, adverse effects, precautions

- Do not administer in the event of previous severe adverse reaction to treatment with amodiaquine (e.g. hypersensitivity reaction, hepatitis, leucopenia, agranulocytosis).
- Do not administer to patients taking efavirenz.
- May cause: gastrointestinal disturbances, pruritus, cough, insomnia.
- <u>Pregnancy:</u> no contra-indication
- Breast-feeding: no contra-indication

## **Remarks**

- Also comes as co-packaged dispersible tablets for seasonal malaria chemoprevention in children: amodiaquine 153 mg + sulfadoxine/pyrimethamine 500 mg/25 mg and amodiaquine 76.5 mg + sulfadoxine/pyrimethamine 250 mg/12.5mg.
- Storage: below 25 °C 📝

# **ARTEMETHER** injectable

Prescription under medical supervision

# Therapeutic action

Antimalarial

## **Indications**

- Alternative to injectable artesunate (when it is not available) in the:
- Treatment of severe malaria
- Initial treatment of uncomplicated malaria, when persistent vomiting precludes oral therapy

# Forms and strengths, route of administration

– 80 mg in 1 ml ampoule (80 mg/ml), oily solution for IM injection. NEVER ADMINISTER BY IV ROUTE. When the dose required is less than 1 ml, use a 1 ml syringe graduated in 0.01 ml.

# **Dosage and duration**

- Child and adult:
- 3.2 mg/kg by IM injection on the first day followed by 1.6 mg/kg once daily

	80 mg ampoule		
Weight	Loading dose	maintenance dose	
3-4 kg	0.2 ml	0.1 ml	
5-6 kg	0.3 ml	0.15 ml	
7-9 kg	0.4 ml	0.2 ml	

10-14 kg	0.6 ml	0.3 ml
15-19 kg	0.8 ml	0.4 ml
20-29 kg	1.2 ml	0.6 ml
30-39 kg	1.6 ml	0.8 ml
40-49 kg	2 ml	1 ml
50-59 kg	2.5 ml	1.2 ml

<sup>-</sup> Treat parenterally for at least 24 hours (2 doses), then, if the patient can tolerate the oral route, change to a complete 3-day course of an artemisinin-based combination. If not, continue parenteral treatment once daily until the patient can change to oral route (without exceeding 7 days of parenteral treatment).

# Contra-indications, adverse effects, precautions

- May cause: gastrointestinal disturbances, dizziness.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

## **Remarks**

– <u>Storage</u>: below 25°C - 📈

# **ARTESUNATE = AS oral**

Prescription under medical supervision

Oral artesunate must always be administered in combination with another antimalarial in coformulated tablets: artesunate/amodiaquine or artesunate/mefloquine.

# Therapeutic action

– Antimalarial

## **Indications**

- Treatment of uncomplicated falciparum malaria, in combination with another antimalarial
- Treatment of uncomplicated malaria due to other Plasmodium species, in combination with another antimalarial, when chloroquine cannot be used
- Completion treatment following parenteral therapy for severe malaria, in combination with another antimalarial

# Forms and strengths

- 50 mg tablet

## **Dosage and duration**

- Child and adult: 4 mg/kg once daily for 3 days in combination with another antimalarial

# Contra-indications, adverse effects, precautions

- May cause: gastrointestinal disturbances, dizziness.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

#### Remarks

- Storage: below 25 °C - ₩ - Ť

# ARTESUNATE + SULFADOXINE/ PYRIMETHAMINE = AS + SP oral

Prescription under medical supervision

## Therapeutic action

Antimalarial

## **Indications**

- Treatment of uncomplicated falciparum malaria
- Completion treatment following parenteral therapy for severe falciparum malaria

## Forms and strengths

- Artesunate (AS) tablets and sulfadoxine/pyrimethamine (SP) tablets, in blister packs, for a complete treatment for one individual
- There are 4 different blister packs:
- Child < 25 kg:
- blister pack with 3 tab AS 50 mg and 1 tab SP 500/25 mg
- Child 25 to < 50 kg:
- blister pack with 6 tab AS 50 mg and 2 tab SP 500/25 mg
- Child ≥ 50 kg and adult:
  - blister pack with 12 tab AS 50 mg and 3 tab SP 500/25 mg or blister pack with 6 tab AS 100 mg and 3 tab SP 500/25 mg

# **Dosage and duration**

– Artesunate is administered once daily for 3 days. Sulfadoxine/pyrimethamine is administered as a single dose on D1, with the first dose of artesunate.

Weight	Bliste	r pack D1	D2	D3
--------	--------	-----------	----	----

5 to < 10 kg	3 tab AS50 + 1 tab SP	½ tab AS + ½ tab SP	½ tab AS	½ tab AS
10 to < 25 kg		1 tab AS + 1 tab SP	1 tab AS	1 tab AS
25 to < 50 kg	6 tab AS50 + 2 tab SP	2 tab AS + 2 tab SP	2 tab AS	2 tab AS
≥ 50 kg and adult	12 tab AS50 + 3 tab SP	4 tab AS + 3 tab SP	4 tab AS	4 tab AS
	6 tab AS100 + 3 tab SP	2 tab AS + 3 tab SP	2 tab AS	2 tab AS

# Contra-indications, adverse effects, precautions

- Do not administer to patients with allergy to sulfonamides.
- May cause: see artesunate and sulfadoxine/pyrimethamine.
- Do not use in combination with co-trimoxazole.
- Do not give folic acid on the same day SP is administered, or within 2 weeks thereafter.
- <u>Pregnancy</u>: **CONTRA-INDICATED** during the first trimester (risk of neural tube defects); no contraindication during the 2<sup>nd</sup> and 3<sup>rd</sup> trimester
- Breast-feeding: no contra-indication

## **Remarks**

- <u>Storage</u>: below 30 °C - **∅** - **†** 

Leave tablets in blisters until use. Once a tablet is removed from its blister, it must be administered immediately.

If half tablets are used, remaining half tablets may be given to another patient if administered within 24 hours.

# Long-acting oily CHLORAMPHENICOL injectable

Prescription under medical supervision



## Therapeutic action

- Phenicol antibacterial, with prolonged effect

## **Indications**

- Treatment of meningococcal meningitis during epidemics

# Forms and strengths, route of administration

– 500 mg oily suspension in 2 ml ampoule (250 mg/ml) for IM injection only. NEVER FOR IV INJECTION.

## **Dosage**

- Child over 2 years and adult: 100 mg/kg single dose (max. 3 g per dose)

Age	Weight	Dose	Volume
2 to < 6 years	13 to < 21 kg	1.5 g	6 ml
6 to < 10 years	21 to < 31 kg	2 g	8 ml
10 to < 15 years	31 to < 54 kg	2.5 g	10 ml
≥ 15 years and adult	≥ 54 kg	3 g	12 ml

- If necessary, administer half the dose into each buttock.

## **Duration**

– Single dose. If there is no improvement after 24 hours, a second dose may be administered.

# Contra-indications, adverse effects, precautions

- Do not administer to patients with:
- history of allergic reaction or bone marrow depression during a previous treatment with chloramphenicol;
- G6PD deficiency.
- May cause:
- dose-related haematological toxicity (bone marrow depression, anaemia, leucopenia, thrombocytopenia), allergic reactions. In these events, stop treatment immediately;
- gastrointestinal disturbances, peripheral and optic neuropathies.
- Avoid or monitor combination with potentially haematotoxic drugs (carbamazepine, co-trimoxazole, flucytocine, pyrimethamine, zidovudine, etc.).
- Pregnancy: CONTRA-INDICATED
- Breast-feeding: CONTRA-INDICATED

#### Remarks

- Oily chloramphenicol is not recommended as chemoprophylaxis for meningitis contacts during epidemics.
- Shake the injection suspension before administration.
- Storage: below 25 °C 7

# **MEFLOQUINE = MQ oral**

Prescription under medical supervision



Do not administer the combination artesunate-mefloquine as separate tablets (i.e. artesunate tablets + mefloquine tablets). Use co-formulated tablets.

# Therapeutic action

– Antimalarial

#### **Indications**

- Treatment of uncomplicated falciparum malaria
- Treatment of uncomplicated malaria due to other Plasmodium species, when chloroquine cannot be used
- Completion treatment following parenteral therapy for severe malaria

# Forms and strengths

- 250 mg scored tablet

## **Dosage and duration**

– Child 6 months and over (≥ 5 kg) and adult: 8 mg/kg once daily for 3 days (in combination with artesunate)

# Contra-indications, adverse effects, precautions

- Do not administer to patients with neuropsychiatric disorders (or history of), seizures, hypersensitivity to mefloquine or quinine; mefloquine treatment in the previous 4 weeks.
- For completion treatment following parenteral therapy for severe malaria: do not administer if the patient developed neurological signs during the acute phase.
- May cause:
- gastrointestinal disturbances, dizziness, headache, sleeping disorders;
- more rarely: neuropsychiatric reactions, heart rhythm disorders, hypo or hypertension, skin allergies.
- If the patient vomits less than 30 minutes after administration, repeat the full dose. If the patient vomits within 30 to 60 minutes, re-administer a half the dose.
- Do not combine with anti-epileptics (risk of seizures), co-artemether, chloroquine (risk of seizures, cardiac toxicity).
- Do not administer simultaneously with quinine (risk of seizures, cardiac toxicity). If mefloquine is used after quinine IV, administer mefloquine 12 hours after the last dose of quinine.
- Administer with caution to patients taking antiarrhythmics, beta-blockers, calcium-channel blockers or digitalis (risk of heart rhythm disorders).
- Pregnancy: no contra-indication
- <u>Breast-feeding</u>: no contra-indication

## **Remarks**

- Also comes in co-formulated tablets containing artesunate 25 mg/mefloquine 50 mg and artesunate 100 mg/mefloquine 200 mg.
- Storage: below 25 °C Ţ

# METHYLROSANILINIUM CHLORIDE = GENTIAN VIOLET = GV = CRYSTAL VIOLET

Carcinogenic effects have been demonstrated in animals. As a precaution, this product should not be used in humans if an alternative is available.

## **Action thérapeutique**

- Antifongique, antiseptique faible, asséchant

#### **Indications**

- Candidose oropharyngée, candidose mammaire chez la femme allaitante
- Certaines lésions cutanées humides (impétigo, dermatophytoses suintantes)

#### **Présentation**

- Poudre à dissoudre

## **Préparation**

- Dissoudre 2,5 g de poudre (= une demi cuillère à café) dans un litre d'eau claire (préalablement bouillie pendant quelques minutes et refroidie) pour obtenir une solution à 0,25%.
- Bien agiter et laisser décanter : la solution doit être limpide, filtrer ou transvaser dans un autre flacon pour éliminer un éventuel dépôt.
- Laver soigneusement à l'eau chaude les flacons servant à la dilution et ceux servant à la conservation. Les laisser sécher avant chaque remplissage.

#### **Utilisation**

- Une application 2 fois par jour pendant quelques jours

## Contre-indications, effets indésirables, précautions

- Ne pas appliquer sur les plaies et ulcérations.
- Ne pas appliquer sur le visage et les muqueuses génitales.
- Peut provoquer:
- irritation, ulcérations, réactions allergiques ;
- pigmentation persistante de la peau.
- La solution ne doit pas être avalée.
- L'application d'huile alimentaire ou de vaseline autour des lèvres, avant l'application du violet de gentiane dans la bouche, peut limiter le risque de coloration de la peau.
- Arrêter les applications en cas de réactions allergiques ou d'apparition de nouvelles ulcérations.
- En cas de contact accidentel avec les yeux, rincer abondamment à l'eau.
- Eviter le contact avec les vêtements (coloration indélébile du tissu).

## Remarques

- Le violet de gentiane ne fait plus partie de la liste des médicaments essentiels de l'OMS.
- Conservation : T
- Poudre à dissoudre : conservation illimitée
- Solution diluée : 1 semaine maximum

# METAMIZOLE = DIPYRONE = NORAMIDOPYRINE oral

Prescription under medical supervision



Given the potentially serious adverse effects and that safer alternatives exist, this drug should not be prescribed as first choice treatment.

## Therapeutic action

- Analgesic, antipyretic

#### **Indications**

- Pain, fever

## Forms and strengths

- 500 mg tablet

## Dosage

- Adult: 500 mg to 1 g 2 to 3 times daily

#### **Duration**

- As short as possible.

## Contra-indications, adverse effects, precautions

- May cause:
- severe agranulocytosis, potentially fatal, regardless of dose or duration of treatment;
- allergic reactions, anaphylactic shock.
- Pregnancy: CONTRA-INDICATED
- Breast-feeding: CONTRA-INDICATED

#### **Remarks**

- Metamizole is not included in the WHO list of essential medicines.
- Storage: below 25 °C

# METAMIZOLE = DIPYRONE = NORAMIDOPYRINE injectable

Prescription under medical supervision



Given the potentially serious adverse effects and that safer alternatives exist, this drug should not be prescribed as first choice treatment.

## Therapeutic action

- Analgesic, antipyretic

#### **Indications**

- Pain, fever

## Forms and strengths, route of administration

– 1 g in 2 ml ampoule (500 mg/ml) for IM, SC or slow IV injection or infusion

## **Dosage**

- Adult: 500 mg every 8 hours if necessary

#### **Duration**

- As short as possible.

## Contra-indications, adverse effects, precautions

- May cause
- severe agranulocytosis, potentially fatal, regardless of dose or duration of treatment;
- allergic reactions, anaphylactic shock.
- Pregnancy: CONTRA-INDICATED
- Breast-feeding: CONTRA-INDICATED

#### **Remarks**

- Metamizole is not included in the WHO list of essential medicines.
- Storage: below 25 °C

# **PROMETHAZINE** injectable

Prescription under medical supervision



## Therapeutic action

- Sedating H1 antihistamine

### **Indications**

- Symptomatic treatment of allergic reactions, when oral administration is not possible

## Forms and strengths, route of administration

- 50 mg in 2 ml ampoule (25 mg/ml) for deep IM injection

## **Dosage and duration**

- Adult: 25 to 50 mg single dose

## Contra-indications, adverse effects, precautions

- Administer with caution and monitor use:
- in elderly patients;
- in patients with prostate disorders, closed-angle glaucoma, epilepsy, orthostatic hypotension, severe renal or hepatic impairment;
- in patients taking CNS depressants (opioid analgesics, antipsychotics, sedatives, antidepressants, etc.) or drugs known to have an anticholinergic effect (atropine, amitriptyline, chlorpromazine, etc.).
- May cause:
- drowsiness, dizziness, headache, confusion, hypotension, photosensitivity (protect skin from sun exposure);
- anticholinergic effects (dry mouth, constipation, blurred vision, tachycardia, disorders of micturition);
- rarely: seizures, extrapyramidal syndrome, neuroleptic malignant syndrome (unexplained hyperthermia with neuromuscular disorders), allergic reactions.
- Avoid alcohol during treatment.
- Pregnancy and breast-feeding: avoid

#### Remarks

- Storage: below 25 °C - ₩

# **QUININE** injectable

Prescription under medical supervision



## Therapeutic action

Antimalarial

### **Indications**

- Alternative to injectable artesunate, when it is not available, in the treatment of severe malaria

## Forms and strengths, route of administration

– 600 mg of quinine dihydrochloride in 2 ml ampoule (300 mg/ml), to be diluted in 5% glucose, for slow infusion. NEVER ADMINISTER BY IV INJECTION.

## Dosage

The dosage is expressed in terms of salt:

- Child and adult:
- loading dose: 20 mg/kg administered over 4 hours, then keep the vein open with an infusion of 5% glucose over 4 hours
- maintenance dose: 8 hours after the start of the loading dose, 10 mg/kg every 8 hours (alternate quinine over 4 hours and 5% glucose over 4 hours)

For adults, administer each dose of quinine in 250 ml. For children under 20 kg, administer each dose of quinine in a volume of 10 ml/kg.

Do not administer a loading dose to patients who have received oral quinine or mefloquine within the previous 24 hours: start with maintenance dose.

#### **Duration**

- Treat parenterally for at least 24 hours, then, if the patient can tolerate the oral route, change to a complete 3-day course of an artemisinin-based combination (or if not available oral quinine to complete 7 days of quinine treatment). If not, continue parenteral treatment until the patient can change to oral route (without exceeding 7 days of parenteral treatment).

## Contra-indications, adverse effects, precautions

- May cause: hypoglycaemia; auditory and visual disturbances, cardiac disorders (especially in the event of overdose), hypersensitivity reactions, cardiac depression if injected undiluted by IV route.
- In patients with acute renal failure, reduce the dose by one-third if the parenteral treatment lasts more than 48 hours.
- Monitor blood glucose (reagent strip test).
- Do not administer simultaneously with mefloquine (risk of seizures, cardiac toxicity). Administer mefloquine 12 hours after the last dose of quinine.
- <u>Pregnancy</u>: no contra-indication. The risk of quinine-related hypoglycaemia is very high in pregnant women.
- Breast-feeding: no contra-indication

#### **Remarks**

- 10 mg quinine dihydrochloride = 8 mg quinine base.
- Administration by IM deep injection (into the anterior thigh only) is possible when infusion cannot be performed (e.g. before transferring a patient). However this may cause numerous complications. Doses are the same as for the IV route. Quinine should be diluted (1/2 or 1/5). For the loading dose, administer half the dose into each thigh.
- Storage: below 25 °C V

## **TETANUS ANTITOXIN (EQUINE)**



Equine tetanus antitoxin should no longer be used, as there is a risk of hypersensitivity and serum sickness.

It should be replaced by human tetanus immunoglobulin.

## Therapeutic action

– Neutralisation of tetanus toxin. Tetanus antiserum provides temporary passive immunity against tetanus for 2 weeks.

#### **Indications**

- Prevention of tetanus in wound management, in patients non immunised or incompletely immunised or in patients whose immunisation status is unknown, in combination with tetanus vaccine
- Treatment of clinical tetanus

## Composition, forms and strengths, route of administration

- Solution prepared from the serum of horses immunised against tetanus toxin
- 1500 IU in 1 ml ampoule, for IM injection. DO NOT ADMINISTER BY IV ROUTE.

## **Dosage and duration**

- Prevention of tetanus

Tetanus antiserum is administered in the event of tetanus-prone wounds, e.g. wounds with fracture, deep penetrating wounds, bite wounds, wounds containing foreign bodies, wounds contaminated with soil, infected wounds, extensive tissue damage (contusions, burns).

Child and adult: 1500 IU single dose; 3000 IU if more than 24 hours has elapsed

It is administered as soon as possible after injury, along with the tetanus vaccine, in a separate syringe and injection site.

Treatment of tetanusNeonate: 1500 IU single dose

Child and adult: 10 000 IU single dose

## Contra-indications, adverse effects, precautions

- Do not administer to patients with known allergy to tetanus antiserum.
- May cause: hypersensitivity reactions, anaphylactic shock, Quinke oedema; serum sickness up to 10 days after injection.
- Administer following Besredka's method: inject 0.1 ml by SC route and wait 15 minutes; if no local or general allergic reactions occur, inject 0.25 ml by SC route and wait 15 minutes; if no reactions, administer the injection by IM route.
- Ensure that the injection does not enter a blood vessel (risk of shock): aspirate prior to injection to confirm that the needle is not in a vein.
- <u>Pregnancy</u>: no contra-indication
- Breast-feeding: no contra-indication

### Remarks

- Equine tetanus antitoxin is not included in the WHO list of essential medicines.
- <u>Storage</u>: between 2 °C and 8 °C. Do not freeze **%**

## Part two

- Organization and management of a pharmacy(see page 331)
- Drug quality and storage(see page 339)
- Prescription, cost, compliance(see page 342)
- Antiseptics and disinfectants(see page 343)

# Organization and management of a pharmacy

- Preliminary information(see page 331)
  - Drug designation(see page 331)
  - Selection of essential medicines(see page 332)
  - Drug classification(see page 332)
  - Levels of use(see page 332)
  - Quantitative evaluation of needs when launching a programme(see page 332)
- Layout of a pharmacy(see page 333)
  - Premises(see page 333)
  - Characteristics of a warehouse(see page 333)
  - Interior layout of a warehouse(see page 333)
  - Arrangement of drugs and supplies(see page 335)
- Management of a pharmacy(see page 336)
  - Organization of activities(see page 336)
  - Stock management(see page 336)
  - Donations of recuperated medicines and medical samples(see page 339)

Organization and rigorous management of the pharmacy are crucial in all health facilities in order to:

- maintain a permanent stock of essential medicines and supplies of quality;
- reduce costs:
- save time and optimise the work of the staff;
- facilitate management and continuous consumption evaluation.

In any case, national pharmaceutical policies and regulations must be taken into account when implementing pharmaceutical activities.

## **Preliminary information**

## **Drug designation**

All active ingredients have an *international nonproprietary name* (INN). Drugs are designated by their INN in all standardised lists. The INN should also be used in standard therapeutic regimens and management documents, in order to avoid confusion, since drugs are sold under their INN or a variety of brand names, depending on the manufacturer (e.g. ampicillin may be sold as Britapen®, Penbritin®, Pentrexyl®, Totapen®, etc.).

Generic drugs are copies of drugs whose patents have expired. They can therefore be made by any pharmaceutical laboratory and are most often sold under their INN or occasionally under a new brand name.

#### Selection of essential medicines

Most countries have a national list of essential medicines. If there is no national list, refer to the latest WHO list.

The use of such a list presents several advantages:

- it simplifies supply and reduces costs: most drugs on the WHO list are available in generic forms at affordable prices;
- it facilitates co-ordination of international aid and obtains approval from organizations which subsidise projects (United Nations, European Union, etc.).

The list of selected drugs is drawn in accordance with pre-established standardised therapeutic regimens. This offers two major advantages:

- better treatments due to more rational use of a restricted number of essential drugs;
- economic and administrative improvements concerning purchasing, storage, distribution and control.

Proposing the same drug in many different strengths or forms should be avoided. In most cases, one form/strength for adults and one paediatric form/strength are sufficient. This facilitates management and avoids confusion in prescriptions.

At times, local prescription usages should be taken into account, e.g. in French-speaking Africa, 500 mg aspirin tablets are used; in English-speaking Africa, 300 mg tablets.

*Note*: medical supplies (dressing, injections, sutures, etc.) should be limited to essentials and the object of a standardised list.

#### **Drug classification**

In the WHO list, drugs are classified according to their therapeutic action. This classification presents a certain pedagogical advantage but cannot be used as the basis of a storage arrangement system (e.g. a drug may appear in several classes).

Médecins Sans Frontières recommends a storage arrangement system according to the route of administration and in alphabetical order.

Drugs are divided into 6 classes and listed in alphabetical order within each class:

- oral drugs
- injectable drugs
- infusion fluids
- vaccines, immunoglobulins and antisera
- drugs for external use and antiseptics
- disinfectants

This classification should be used at every level of a management system (order forms, stock cards, inventory lists, etc.) in order to facilitate all procedures.

#### Levels of use

More limited lists should be established according to the level of health structures and competencies of prescribers. Restricted lists and the designation of prescription and distribution levels should be adapted to the terminology and context of each country.

## Quantitative evaluation of needs when launching a programme

Once standard therapeutic regimens and lists of drugs and supplies have been established, it is possible to calculate the respective quantities of each product needed from the expected number of patients and from a breakdown of diseases.

Several methods have been suggested (see *Estimating drug requirements*, WHO). Quantities calculated may differ from those corresponding to true needs or demands (this can be the case when the number of consultations increases or when prescribers do not respect proposed therapeutic regimens).

In an emergency situation (especially with displaced population), the *Emergency Health Kit*, developed in collaboration with the WHO, UNHCR, MSF, etc., is designed to meet the care needs of a displaced population of 10,000 people for 3 months. Afterwards, specific local needs should be evaluated in order to establish a suitable supply.

Routine evaluation of needs and consumption allows verification of how well prescription schemes are respected and prevents possible stock shortages.

## Layout of a pharmacy

Whether constructing a building, converting an existing building, central pharmacy or health facility pharmacy, the objectives are the same only the means differ.

#### **Premises**

Functional premises should be designed in order to ensure:

- the safe keeping of stocks;
- correct storage of drugs and supplies;
- rational and easy management.

#### Characteristics of a warehouse

Dimensions of warehouse are determined by storage needs, which depend on:

- the number of drugs and supplies to be stocked;
- the number and activities of facilities;
- distribution and receiving frequency: the lesser the frequency the greater the volume needed, thus the greater the space needed.

It is better to have too much space than not enough: a cramped warehouse is difficult to work, and any increases in stock or activity are also difficult. For  $1 \text{ m}^2$  of storage space count  $3 \text{ m}^2$  of floor space.

Security of stocks requires solid doors, locks, windows and ceilings.

Correct preservation of drugs depends on temperatures and humidity, conditions that are very often difficult to control in tropical countries.

- Correct ventilation is necessary; fans mainly reduce humidity, air-conditioning reduces heat and humidity.
- A ceiling underneath the roof is essential in order to reduce the ambient temperature; the space between the ceiling and roof must be ventilated.
- Windows and openings should be shaded to avoid exposure of drugs to direct sunlight.
- Floors should be covered in cement (slightly inclined, if possible, to facilitate cleaning).

#### Interior layout of a warehouse

The organization should be logical and correspond to the circuit "reception, storage, distribution".

#### **Shelves and pallets**

Solid and stable shelves are indispensable. In tropical countries where termites attack wood, metal structures are preferred. As they can be dismantled, it is easy to adjust spaces between shelves and alleys to better accommodate goods to be stored.

Space between shelves and walls improves ventilation.

No products or packaging, even large-sized, should be stored on the floor, but on pallets which permit air circulation and protect against humidity.

#### **Stocking areas**

Within a warehouse, or close by, stocking areas should be provided.

- Receiving area: for stocking parcels before unpacking and checking freight and quality control.
- Distribution area: for stocking peripheral orders before distribution. Each destination should have a designated area where parcels may be stocked before distribution.

Receiving and distribution areas should be near access doors in order to facilitate handling.

It is also recommended to plan a stocking area for empty boxes, used to prepare orders for peripheral health facilities.

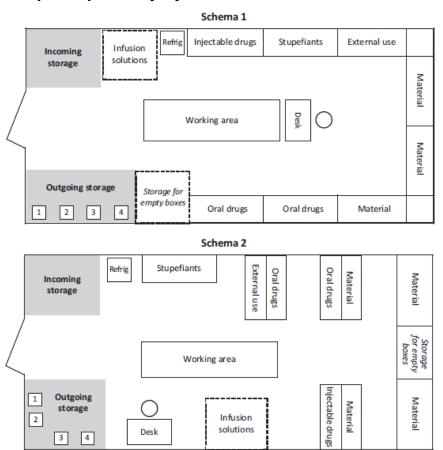
#### Workspace(s)

A workspace should be set up in the receiving area and in the distribution area to verify deliveries and prepare orders.

#### Desk

For the person in charge of the pharmacy, a desk near a light source should be set up for administrative work and for keeping documents.

#### **Examples of pharmacy layout**



The arrangement of shelves, tables or other furniture, varies according to the layout of the premises.

For larger stocks or central pharmacies, use several rooms and apply the same principles by adapting layouts to needs: administration, cold room, refrigerators, etc.

#### Arrangement of drugs and supplies

#### Storage of drugs not requiring a cold chain

Drugs are arranged according to the classification adopted:

- oral drugs
- injectable drugs
- infusions
- drugs for external use and antiseptics
- disinfectants

In each category of products (oral, injectable, etc.) are classified alphabetically.

Each product should have a designated place, well identified by a fixed label indicating the INN, form and strength. By attributing a specific place to each item it is possible to immediately see the quantity available and to react quickly to avoid stock shortages.

Provide for sufficient space between and for each product.

Clearly indicate expiry dates on boxes (large marker). Arrange products with the earliest expiry date at the front of the shelves and those with the latest at the back. This is essential to avoid drugs expiring during storage.

So that persons not familiar with the INN system can find their way around in case of emergency or replacement, a list of commercial names and the corresponding INN can be put up, e.g.:

Bactrim® see co-trimoxazole Clamoxyl® see amoxicillin Flagyl® see metronidazole Valium® see diazepam

#### Storage of controlled substances

Narcotics and other controlled substances should be placed under lock and key.

#### Storage of products requiring a cold chain

Products needing a cold chain should be stored in a refrigerator (between 2-8 °C): vaccines, immunoglobulins, serums, insulin, ergometrine, oxytocin, dinoprostone, certain laboratory tests, etc.

#### **Storing medical materials/supplies**

Given the diversity of items, do not to use alphabetical ordering, but group articles by category: injections, dressings, sutures, reagents and laboratory material, etc.

#### **Storing bulky materials**

Put a few boxes in their normal place and, on a label, indicate where the rest of the stock is kept. Do not disperse the rest of the stock in several places.

- The storage arrangement should allow a 'visual stock check':
- It should be possible to quickly count the number of boxes for each product and evaluate, in a few minutes, the number of weeks or months that can be covered with the stock available.
- An empty space behind a label immediately shows that the product is out of stock.
- Only a few hours should be needed to perform a complete inventory.

## Management of a pharmacy

### **Organization of activities**

The management of the pharmacy should be entrusted to a single person having received adequate training. This person is the only person possessing keys to the pharmacy and narcotics cupboard and is helped by one or more assistants, depending on the workload.

Tasks and responsibilities should be clearly defined. One assistant should be able to replace the person in charge if necessary.

It is important to draw up a work calendar (orders, distributions, inventories, management of expired drugs, etc.) in order to spread out the workload.

#### **Stock management**

#### **Stock cards**

The stock card is the principle instrument for stock control. A stock card is established for each product (drugs and supplies) and updated at each movement. Stock cards are used to:

- identify all stock movements: in and out;
- determine at any moment the theoretical level of stocks;
- follow-up the consumption of different facilities;
- correctly plan and prepare orders;
- determine losses (differences between theoretical stock and actual stock).

#### Example of a stock card

Item: AMOXICILLIN		Dosage/Form: 250 mg, tab					
Code:		Packaging unit: box 1,000 tab					
AMC = 9,00	00						
Date	Origin/Destination	IN	OUT	STOCK	Remarks/Signature		
01/06/19	Brought forward (previous stock card)			20,000			
01/06/19	Central warehouse	80,000		100,000	Exp. 12/2021		
02/06/19	Health centre 1		5,000	95,000			
06/06/19	Health centre 2		2,000	93,000			
06/06/19	Health centre 3		2,000	91,000			
01/07/19	Inventory			91,000	10,000 (07/19) 11,000 (05/20) 70,000 (12/21)		
02/07/19	Health centre 1		6,000	85,000			
05/07/19	Health centre 2		2,000	83,000			
05/07/19	Health centre 3		1,000	82,000			
31/07/19	Expired July 19		1,000	81,000	Exp. 07/2019		
01/08/19	Health centre 1		6,000	75,000			
06/08/19	Health centre 2		1,000	74,000			
06/08/19	Health centre 3		2,000	72,000			

The following should be noted on stock cards:

- the INN, form and strength;
- all movements (in, out, origin, destination, loss due to expiration, damages) and dates;
- inventories and dates.

The following may also be included:

- average monthly consumption;
- stock levels: buffer stock, running stock;
- other stock areas for a product;
- unit price;
- current orders and dates.

Quantities in and out are always recorded in units (e.g. 5,000 tablets, 80 ampoules) and never in number of boxes.

Write a single operation per line, even if several operations take place the same day.

Note: stock cards are always equired, even when computer assisted stock management is used.

#### Quantities to retain and order (stock level)

- Average monthly consumption (AMC)

Calculated from outgoing stock recorded on stock cards: add the quantities of several months (3, 6 or 12) in the out column and divide the total by the number of months considered.

- Running stock = consumption between two supply deliveries

Running stock corresponds to the quantity of each drug consumed between two supply deliveries (e.g. if deliveries are quarterly, running stock = AMC x 3).

- Buffer stock

This stock is planned to compensate for possible late deliveries, losses, and increases in consumption. It is calculated according to the delivery delay of orders.

Buffer stock quantities are generally evaluated as half of the consumption during the period between two deliveries. It depends on risks that a programme may run: stock shortages or drug expiration in specific situations (resources, seasonal supply problems, etc.).

For example, if the delivery delay is two months, the buffer stock corresponds to the quantity consumed in one month.

- Quantities to be ordered

Quantities to order are based on data from stock cards:

- actual stock level (inventory) on the day of the order
- running stock
- buffer stock
- delay period between order and delivery
- orders not yet delivered

Order = (running stock + buffer stock + probable consumption during delivery delay) – (inventory + orders not yet delivered).

#### Order and delivery forms

Concerning orders from peripheral facilities to the central pharmacy, it is recommended to use preprinted order forms which indicate the INN, form (tablet, capsule, vial, ampoule, etc.) and strength. The following may also be included:

- stock levels,
- AMC.

Orders should be in triplicate, dated and countersigned by the person in charge of the health facility. Two copies are sent to the central pharmacy: one serves as a way bill and may also be used for invoicing, the second stays with the central pharmacy. The third copy stays at the health facility.

#### Example:

Health facility order form, 6-month supply period, minimum stock of 3 months (2 month delivery delay +

Health structure: Beboro											
Head of structure: Jacques Pinel, Ph											
Date: 26.06.19	Signature: $\mathcal{XXX}$										
ORAL DR	UGS										
NAME	PRESENTATION	Price	Stock	Monthly consump.	Qty ordered	Qty delivered					
ACETYLSALICYLIC ACID	300 mg tab	0.01	55,000	10,000	5,000						
ASCORBIC ACID	250 mg tab	0.04	-	-	_						
ALUMINIUM HYDROXYDE	500 mg tab	0.03	15,000	6,000	21,000						
AMOXICILLIN	250 mg tab	0.18	16,000	4,000	8,000						

1 month buffer stock)

#### **Receiving orders**

All orders should be accompanied by a way bill or invoice and packing list.

On reception, the number of parcels should be checked, then their contents should be verified:

- ensure that products delivered correspond to products ordered, and that the quantities conform to those on the packing list;
- packaging, labelling and expiry dates of each product should be checked, as well as the aspect of the product;
- look for special storage conditions (cold chain).

The supplier should be notified of all irregularities.

Then, drugs and material are integrated into stocks at their designated places. Incoming quantities are recorded on stock cards.

Way bills, invoices and packing lists are to be classed with orders in an "orders" file and kept for 3 years or more according to current regulations.

#### **Inventory**

An inventory of current stock quantities and expiry dates should be done before each order.

Stock cards give a theoretical figure of stock quantities, but actual quantities of each product should be verified (physical stock). Differences may arise due to errors in recording or due theft. These differences should be clarified.

An inventory may only be easily done if the pharmacy is correctly arranged. It is an indispensable task. During an inventory there should be no stock movements, i.e. incoming or outgoing stock.

#### Distribution

- Distribution to health facilities

Each health facility sends the central pharmacy two copies of the order form.

On both copies, actual quantities supplied by the central pharmacy are recorded in the "Qty delivered" column.

One on these copies is sent with the delivery.

After verifying that all products have been correctly recorded on their respective stock cards, the second copy is placed in a file established for health facility. The exit date on the stock card should be the same as the date on the order form.

- Dispensing drugs to patients

Drug packaging should be presentable. Use plastic bags that can be resealed by pressure (Minigrip®). Prepare labels for each drug, clearly showing:

- the name of the drug (INN), form and strength;
- the dosage written out in full or in symbols.

Put the number of tablets corresponding to a complete treatment and the label into the bag. In busy centres it is better to have two people responsible for dispensing drugs in order to double check prescription deliveries; the first collects the drugs prescribed, the second verifies and gives them to patients with all necessary explanations, slightly away from other patients.

So that patients correctly follow treatment, adequate explanations should be given:

- how to take the drug,
- · for how long,
- possible adverse effects (e.g. drowsiness caused by anti-histamines),
- precautions to be taken (e.g. avoid alcohol with metronidazole).

Persons dispensing drugs should be able to give patients the information they need. Interpreters are needed if several languages exist in the same region

#### Donations of recuperated medicines and medical samples

It is not recommended to solicit or accept supplies coming from collections of drugs recuperated from consumers in industrialised countries, or free samples distributed by manufacturers.

They are very often specialised drugs unknown to prescribers and unsuitable for local pathologies. The multiplication of different drugs supplied interfere with the implementation of standardised therapeutic regimens and makes any form of management impossible.

## Drug quality and storage

- Quality standards(see page 339)
- Storage conditions(see page 340)
- Deterioration(see page 341)
- Expiration(see page 341)

Drug quality influences treatment efficacy and safety. Quality depends on correct manufacturing and storage: high-quality drugs are available when using rational buying procedures and when suppliers are reliable. It is also essential to ensure optimum transportation and storage conditions.

## **Quality standards**

Each drug is characterised by particular norms written in pharmacopoeia or files presented by manufacturers and recognised by competent authorities in each country. These norms concern aspects (colour, odour, etc.), physicochemical properties, analysis procedures, shelf life and storage conditions.

Analysis certificates guarantee that products from one batch (products from the same production cycle) conform to official quality standards in the country of manufacture. These certificates are provided for each product by manufacturers.

Every unit (box and bottle) should be clearly labelled; each label should clearly indicate the:

- INN.
- form and dosage,
- number of units (tablets, ampoule, etc.) or the volume (syrup, etc.),

- name and address of the manufacturer,
- batch number,
- expiry date.

## **Storage conditions**

Stability of drugs depends on both environmental factors such as temperature, air, light and humidity, and drug-related factors such as the active ingredient itself, the dosage form (tablet, solution, etc.) and the manufacturing process. It is therefore necessary to respect storage instructions given in this guide or by manufacturers (on notices and labels) if the recommendations are not identical.

#### **Temperature**

The temperature in the store should not be above 25 °C.

Storage temperatures are defined by European pharmacopoeia as follows:

freezer  $-15 \text{ to } 0 \,^{\circ}\text{C}$ refrigerator  $+2 \text{ to } +8 \,^{\circ}\text{C}$ cool  $+8 \text{ to } +15 \,^{\circ}\text{C}$ ambient temperature  $+15 \text{ to } +25 \,^{\circ}\text{C}$ 

During transit and transportation temperatures may attain 50 to 60 °C inside vehicles, shipping containers or on docks and, in this case, shelf life and expiry dates may no longer be guaranteed.

Freezing may be detrimental, particularly for solutions, leading to the deterioration or precipitation of active ingredients as well as the breaking of ampoules and vials.

Vaccines, immunoglobulins and antisera are products that are sensitive to heat and light. Even though new techniques produce vaccines that are less sensitive to heat (called "thermostable"), they still have to be stored in the refrigerator between 2 °C and 8 °C, and the cold chain must be strictly respected during transport.

The vaccine vials may have a heat-sensitive monitor (VVM). The square on the monitor changes colour when exposed to heat over a period of time: if the square is lighter than the circle, the vaccine can be used. If the square is the same colour or darker than the circle, the vial must be destroyed. The monitor registers cumulative exposure to heat.

## **Controlled temperature chain (CTC)**

In certain mass vaccination campaigns only, certain vaccines licensed for use in a CTC can be transported and used out of the cold chain within a specified time limit.

To qualify for use in a CTC the vaccine must be able, once out of the cold chain (2 °C to 8 °C), to tolerate temperatures of up to 40 °C for at least 3 days. The maximum temperature of 40 °C is monitored by a peak threshold indicator in each vaccine carrier used for transport and vaccination in the field.

## Air and humidity

In a store, relative humidity should not be above 65% (there are several devices for humidity measurement).

Air is a factor of deterioration due to its content of oxygen and humidity. All containers should remain closed. In airtight and opaque containers (hospital type), drugs are protected against air and light. Opening containers long before the use of drugs should be avoided.

Patients should be informed that tablets should not be removed from blisters until immediately before administration.

#### Light

Drugs should be protected from light, particularly solutions. Parenteral forms should be preserved in their packaging. Coloured glass may give illusory protection against light.

#### **Deterioration**

It is important to be familiar with the normal aspects of each drug (colour, odour, solubility, consistency) in order to detect changes, which may indicate its deterioration. It is important to know that deterioration does not always lead to a detectable external modification.

The principal consequence of deterioration is a *reduction of therapeutic activity*, which leads to more or less grave consequences for the individual and/or community.

For example, the use of expired antibacterials does not cure an infection and also favours the emergence of resistant strains.

It is not recommended to compensate for a possible reduction of activity by a random increase in the usual dose, as there is a real danger of overdose when using toxic drugs.

Over time, certain drugs undergo a deterioration leading to the development of substances much more dangerous, thus an *increase in toxicity*. Tetracycline is the main example: the pale, yellow powder becomes brownish and viscous, its use therefore being dangerous even if before the expiry date.

An increase in allergen strength has been observed in certain drugs such as penicillins and cephalosporins.

Suppositories, pessaries, creams and ointments that have been melted under heat should not be used. The active ingredient is no longer distributed in a homogenous manner.

Oral rehydration salts may be used as long as they keep their aspect of white powder. Humidity transforms them into a compact mass, more or less brownish and insoluble. They are therefore unfit for consumption, whatever their expiry date.

## **Expiration**

Drugs deteriorate progressively and according to various processes, even if stored in adequate conditions. In most countries, regulations impose an obligation on manufacturers to study the stability of their products in standardised conditions and to guarantee a minimum shelf life period. The expiry date indicated by manufacturers designates the date up to and including which the therapeutic effect remains unchanged (at least 90% of the active ingredient should be present and with no substantial increase in toxicity).

The expiry date indicated on the label is based on the stability of the drug in its original and closed container. Shelf life period currently usually guaranteed is 3 and 5 years. Less stable substances are only guaranteed for 1 or 2 years.

The expiry date should be indicated on the label with storage instructions.

### **Expired drugs**

Expiry dates are to be respected due to legal obligations and considerations of therapeutic responsibility In cases where the only available drugs have expired, a doctor may be led to take on the responsibility of using these drugs.

It is evident that a drug does not become unfit for consumption the day after its expiry date. If a product has been stored in adequate conditions (protected from humidity and light, packaging intact and at a medium temperature) and if modification of aspects or solubility have not been detected, it is often preferable to use the expired drug than to leave a gravely ill patient without treatment.

Expiry dates for drugs that require very precise dosage should be strictly respected due to a risk of underdosage. This is the case for cardiotonic and antiepilectic drugs, and for drugs that risk becoming toxic, such as cyclines.

#### Destruction of expired or unusable drugs and material

It is dangerous to throw out expired or unusable drugs or to bury them without precaution. For more information about destruction of drugs and material see *Interagency Guidelines For Safe Disposal of Unwanted Pharmaceuticals in and after emergencies*, WHO/99.2.

## Prescription, cost, compliance

- Limiting the use of injectable drugs(see page 342)
- Limiting the use of syrups and oral suspensions(see page 342)
- Studying the choice of treatment regimens(see page 343)
- Considering non-essential medicines and placebos(see page 343)

#### SOME SUGGESTIONS FOR

Reducing risks - Reducing costs - Facilitating compliance

It is possible to promote a more rational use of medicines, as much for safety as for cost, by a judicious choice of therapeutic regimens and the resulting lists of medicines.

## Limiting the use of injectable drugs

Numerous patients demand treatment with injectable drugs, which they imagine to be more effective. Certain prescribers also believe that injections and infusions are more technical acts and thus increase their credibility.

Parenteral treatment is always more costly than oral treatment. The price of the drug itself is higher for an equal dose of active ingredient. It requires costly disposable material. It exposes patients to complications due to poorly tolerated products (abscesses, necrosis due to IM quinine injections or antibacterials, etc.) or badly performed injection techniques (symptoms of overdose after a IV injection given too rapidly, sciatic nerve damage, etc.). If disposable injection supplies are re-used, there is a risk of bacterial or viral contamination (tetanus, hepatitis, HIV, etc.).

When both oral and injectable drugs are equally effective, parenteral administration is only justified in case of emergency, digestive intolerance or when a patient is unable to take oral medication. Oral drugs should replace injectable drugs as soon as possible during the course of treatment.

## Limiting the use of syrups and oral suspensions

Taking liquid drugs is often easier, especially for young children and more so if they are sweetened or flavoured. It is, however, recommended to limit their use for numerous reasons:

#### - Risk of incorrect usage

Outside of hospitals, determining the correct dosage is hazardous: spoons never contain standard volumes (soup spoons, dessert spoons, tea spoons). Oral suspensions should be prepared with a specified amount of clean water, and well shaken prior to administration. There is therefore a risk of overdose or giving an insufficient dosage.

Some oral suspensions must be kept refrigerated; their storage at room temperature is limited to a few days, and with syrups there is a risk of fermentation.

In numerous countries syrups are thought of as "cough medicine". Confusion between cough mixtures and antibacterial suspensions or syrups is common.

#### - Economic considerations

Compared to the price of tablets or capsules, the price of syrups and oral suspensions is considerably higher. Even using a powder for subsequent reconstitution, the costs may be 2 to 7 times higher than an equivalent dose due to the cost of the bottle itself and higher transportation costs due to weight and volume.

## Studying the choice of treatment regimens

The choice of a treatment regimen often influences compliance and cost. The shortest and least divided (1 to 2 doses per day) treatments are most often recommended. Single dose treatments are ideal, when indicated.

For the treatment of malaria, tuberculosis and HIV infection, fixed-dose combinations (coformulated tablets) should preferably be used in order to improve compliance.

## Considering non-essential medicines and placebos

In developing countries as in industrialised countries, patients with psychosomatic complaints are numerous. The problems that motivate their consultations may not necessarily be remedied with a drug prescription. Is it always possible or desirable to send these patients home without a prescription for a symptomatic drugs or placebo? If so, what placebo should be prescribed?

When national drug policy is strict and allows neither the use of placebos nor non-essential symptomatic drugs, other products are often used in an abusive manner, such as chloroquine, aspirin, and even antibacterials.

Conversely, a placebo may take the place of an effective and needed drug. This risk is real, but seems less frequent, which makes the introduction of placebos on a list of essential drugs relevant. Multivitamins may present a type of harmless and inexpensive placebo. Their composition generally corresponds to preventive treatment of vitamin deficiency and they have no contra-indications.

Numerous non-prescription drug products (tonics, oral liver treatments presented in ampoules) have no therapeutic value and, due to their price, cannot be used as placebos.

# **Antiseptics and disinfectants**

- Definitions(see page 344)
- Selection(see page 344)
  - Recommended products(see page 344)
  - Non-recommended products(see page 345)
- Preparation and use of antiseptic solutions(see page 345)
  - Preparation(see page 345)
  - Use(see page 346)
- Preparation and use of disinfectant solutions(see page 346)
  - Preparation(see page 346)
  - Disinfection of floors and surfaces(see page 346)
  - Disinfection of linen(see page 347)
  - Pre-disinfection of reusable medical devices/instruments(see page 347)
  - Washing-disinfection of reusable medical devices/instruments(see page 347)

#### **Definitions**

Antiseptics are used to kill or eliminate microorganisms and/or inactivate viruses on living tissues (intact or broken skin and mucous membranes).

Disinfectants are used to kill or eliminate microorganisms and/or inactivate viruses on inanimate objects and surfaces (medical devices, instruments, equipment, walls, floors).

Certain products are used both as an antiseptic and as a disinfectant (see specific information for each product).

#### Selection

#### **Recommended products**

#### 1) Core list

No single product can meet all needs with respect to cleaning, disinfection and antisepsis. However, use of a limited selection of products allows greater familiarity by users with the products in question and facilitates stock management:

- ordinary soap;
- a detergent and, if available, a detergent-disinfectant for instruments and a detergent-disinfectant for floors and surfaces;
- a disinfectant: chlorine-releasing compound (e.g. NaDCC);
- an antiseptic: 10% povidone iodine or chlorhexidine.

#### 2) Complementary list

Other products can be used, according to the activities carried out, resources, and options for obtaining the product, locally or otherwise:

#### - Ethanol and isopropanol

By virtue of its rapid action (< 30 seconds), alcohol, if available locally, is useful to disinfect:

- intact skin, before taking a blood sample or performing an injection (except vaccines),
- latex stoppers of injection vials.

Alcohol acts faster than polyvidone iodine, but its duration of action is shorter.

Application to mucous membranes or broken skin is contra-indicated, however, alcohol may be used on broken skin in the event of accidental exposure to blood.

Alcohol is more effective at 60-70% concentration than at 90-95%.

#### Alcohol-based hand rub solutions

Alcohol-based hand rubs (ABH) are used for standard hand antisepsis. Some, but not all, ABH may also be used for surgical hand antisepsis.

Not all ABH preparations are equivalent. For example, for antiseptic hand rub, depending on the product specifications:

- Bactericidal effect may be achieved with a single application of 30 seconds duration, or 2 consecutive applications of 30 seconds each, or a single application of 60 seconds duration.
- The volume of rub required per application may be 3 or 5 ml.

Thus, when purchasing locally, it is important to verify the quality of the product and specific instructions for use (number of applications, duration of application, and volume to be used per application).

For surgical activity, ensure that the product is suitable for use as a surgical hand rub. Follow manufacturer's instructions for use.

All alcohols and alcohol-based products are flammable. Precautions should be taken during storage and use to avoid contact with a heat source (flame, electrocautery, etc.).

#### - Povidone iodine (PVI) scrub solution

7.5% or 4% PVI scrub solution is used for antiseptic cleansing of healthy skin, contaminated wounds and surgical site, as well as antiseptic hand wash and surgical hand wash.

Given the possible interactions between different groups of antiseptics, antiseptic cleansing and

antisepsis should only be carried out using products from the same class. For example, for pre-operative skin preparation, PVI scrub solution is used for cleansing, then PVI 10% dermal solution is used for antisepsis.

#### - Glutaraldehyde (2% solution)

Glutaraldehyde is used for high-level disinfection of heat-sensitive items, which cannot withstand heat sterilisation, notably endoscopes/endoscopy equipment.

Instructions for glutaraldehyde use must be followed scrupulously:

- 1) two preliminary washes of the equipment through immersion in a detergent-disinfectant solution for instruments, followed each time by rinsing;
- 2) complete immersion of the equipment in a 2% glutataldehyde solution for 20 minutes;
- 3) thorough final rinsing, with filtered water (or sterile water for endoscopes introduced into a sterile cavity) to eliminate any residue;
- 4) thorough drying with a sterile towel;
- 5) sterile wrapping and use within 24 hours.

Glutaraldehyde is available as 2% ready-to-use solution (e.g. Korsolex RTU®, Steranios 2%®); concentrated solution that must be diluted to obtain a 2% solution (e.g. 25% or 38.5% solutions); preparations requiring « activation » (alkalinisation) before use, through addition of the agent provided with the product (e.g. Cidex®, Glutrex®).

Glutaraldehyde solution is irritating to skin and mucous membranes, and releases toxic vapours. Personnel exposed to glutaraldehyde should take precautions to protect skin and eyes and avoid inhalation of vapours (risk of nausea, headache, breathing disorders, rhinitis, eye irritation, dermatitis). Glutaraldehyde solutions are flammable. Precautions should be taken during storage and use to avoid contact with a heat source.

#### Non-recommended products

- Hydrogen peroxide (3% or 10 volumes) has limited efficacy as antiseptic agent but can be useful to clean contaminated wounds. In addition, concentrated solutions are dangerous to transport and handle.
- Mercury compounds such as phenylmercuric borate, merbromin (Mercurochrome®), mercurobutol (Mercryl®), thimerosal (Merthiolate®, Timerosal®) have limited efficacy, may cause serious adverse effects (toxic for kidneys, central nervous system and digestive tract; allergies) and pollute the environment. Their use must be abandoned.
- Hexachlorophene is toxic for the central nervous system and its efficacy is limited.
- Ether is often wrongly used as an antiseptic; it removes sticky residues of plaster.
- Eosin is often wrongly used as an antiseptic; it is a colouring agent used for staining as well as a drying agent.

None of these products is included in the WHO list of essential medicines.

## Preparation and use of antiseptic solutions

#### **Preparation**

Aqueous solutions of many antiseptics can be contaminated by pathogens (especially *Pseudomonas aeruginosa*) during handling. To avoid this, the following precautions must be taken:

- Prepare all aqueous antiseptic solutions with clean water that has been boiled for a few minutes and cooled.
- Prepare solutions immediately before use.
- Only prepare small amounts at a time to avoid wastage and the temptation to keep expired and/or contaminated solutions.

- Wash bottles with hot water and leave to dry before each refill.
- Never use a cork stopper (it promotes contamination; cork inactivates certain antiseptics such as chlorhexidine).
- Mark on the bottles:
- the name of the product,
- its concentration,
- the date and time of preparation.

Every medical facility should define a clear policy concerning the renewal of antiseptic solutions.

#### Use

- Do not use antiseptic solutions belonging to different classes for the same procedure: incompatibilities between different compounds exist.
- Antiseptics should be used when wounds are contaminated or infected. Clean, non-infected wounds may be cleaned with 0.9% sodium chloride; it is not necessary to apply an antiseptic.
- In case of accidental exposure to blood (needlestick or broken skin): the injured area should be washed well with soap and water. No evidence exists that antiseptics reduce the risk of transmission, however, their use after thorough cleaning is not contraindicated. Use 2.6% bleach diluted 1/5 or 1/10, or 70% alcohol, or 10% povidone iodine solution and leave in contact for 5 minutes.
- Disinfection of skin when administrating a vaccine is not recommended; rather, simply clean the injection site with clean water. Certain vaccines (for example, BCG) may be inactivated in the presence of an antiseptic. If an antiseptic is used despite this recommendation, it must be allowed to dry before vaccine injection.

## Preparation and use of disinfectant solutions

The effectiveness of disinfection can be impaired by error in preparation (concentration, temperature), failure to follow recommended contact times, or deterioration of the product due to poor storages conditions.

Personnel carrying out disinfection should wear protective clothing when preparing or using disinfectant solutions: gown, rubber apron, gloves with long cuffs, goggles and mask.

#### **Preparation**

Solutions should be prepared with clean water (chlorine solutions should be prepared with cold water only, in non-metal containers).

- Solution for disinfecting floors and surfaces: prepare just before use, and discard any unused solution.
- Solution for pre-disinfection of medical devices and instruments: replace daily. The solution may be used for a maximum of 24 hours; if visibly soiled, discard and replace with fresh soaking solution before 24 hours are up.
- Solution for disinfection of medical devices and instruments: prepare just before and discard after use.

Do not add any product (e.g. a detergent, descaling agent) to disinfectant solutions.

#### Disinfection of floors and surfaces

- Apply detergent-disinfectant intended for floors and surfaces (see page 0), without rinsing. Follow manufacturer's instructions for dilution and specific preparation procedures.

  Or
- After cleaning with a detergent (cleaning product without an antimicrobial agent) and rinsing with

water, apply a 0.1% active chlorine solution. Preliminary washing and rinsing are essential: the activity of chlorine is reduced in the presence of organic material (sputum, vomit, faeces, pus, blood and other body fluids), and the detergent used may be incompatible with chlorine. Contact time is 15 minutes. Stainless steel surfaces should be rinsed with water after disinfection with chlorine solution.

The use of detergent-disinfectant products reduces workload (cleaning and disinfection are carried out as a single procedure), but they have the disadvantage of being weak detergents and leaving a film, which causes dirt to build up on the floors. It is thus necessary to alternate their use with that of a detergent alone. Each medical facility should establish a clear policy addressing this issue.

#### **Disinfection of linen**

After hand washing, followed by rinsing: soak the clean linen in a solution of 0.1% active chlorine for 15 minutes and rinse thoroughly (3 rinses).

After machine-washing at 60 °C: soak the linen in a 0.1% active chlorine solution for 2 to 3 minutes and rinse thoroughly (3 rinses).

#### Pre-disinfection of reusable medical devices/instruments

- After use, soak medical devices (disassembled, forceps and scissors opened):
- In a detergent-disinfectant solution intended for medical devices and instruments seepage of . Use a syringe to irrigate the cavities of hollow devices with the same solution. For correct dilution and soak times, follow manufacturer 's instructions; use a timer.

Or

• In 0.1% available chlorine solution for 15 minutes (use a timer). Use a syringe to irrigate the cavities of hollow devices with the solution.

Comply with recommended soaking times and concentrations (risk of corrosion of metal instruments). Soaking for too long (> 15 minutes) and/or in a solution that is too concentrated will increase the risk of corrosion.

- Rinse with clean water, using a syringe for hollow cavities.
- Dry with a clean, dry, lint-free cloth.

## Washing-disinfection of reusable medical devices/instruments

After the pre-disinfection step:

- Immerse the material in a detergent-disinfectant solution intended for medical devices and instruments (for correct dilution and soak times, follow manufacturer's directions). Scrub with a soft, non abrasive brush. Use a bottle brush for hollow devices, or irrigate with a syringe. Rinse with clean water, drain and dry with a clean, dry, lint-free cloth.

  Or
- Wash (as above) with detergent and rinse with clean water. Then soak in 0.1% available chlorine solution for 20 minutes (use a timer). Comply with recommended soak times and concentrations (risk of corrosion of metal instruments). Rinse with clean water, drain and dry with a clean, dry, lint-free cloth.

For example a quaternary ammonium detergent-disinfectant. [ a(see page 0) b(see page 0) c(see page 0) ]

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