



Patient Information Leaflet

1. Name of the Product

Chloramphenicol Capsules BP 250 mg

2. Description of the Product

Size 2 white cap and white body hard gelation capsule. Containing white to off white colour powder and granules free from black particles

3. What is in the medicine?

Chloramphenicol Capsules BP 250 mg contains Chloramphenicol BP

4. Strength of the medicine

Each Hard Gelatin Capsule Contains:

Chloramphenicol BP..... 250 mg

Excipients..... q.s.

Approved Colour Used in Empty Gelatin Capsule Shells.

5. What is this medicine used for?

Typhoid fever and life-threatening infections, particularly those caused by *Haemophilus influenzae* where other antibiotics will not suffice.

6. How much and how often should you use this medicine?

Posology

Adults and elderly

The normal dose is 50 mg/kg body weight daily in 4 divided doses. For severe infections (meningitis, septicaemia) this dose may be doubled initially, but it must be reduced as soon as clinically practical.

Paediatric population

The safety and efficacy of Chloramphenicol Capsules BP 250 mg have not yet been established in children.

Method of administration



For oral administration.

7. When should you not take this medicine?

Chloramphenicol is contra-indicated in prophylaxis or treatment of minor infections; during active immunisation; and in porphyria patients.

Chloramphenicol is contra-indicated in patients taking drugs liable to depress bone marrow function

Chloramphenicol must not be used in breast-feeding mothers and during pregnancy or labour, due to a risk of foetal/ infant damage (Gray Baby syndrome).

8. Undesirable Effects

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as follows: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/100,000$), not known (cannot be estimated from the available data).

Blood and lymphatic disorders

Rare: (i) A reversible dose related bone marrow depression.
(ii) An irreversible aplastic anaemia

Not known: Increase in bleeding time.

Immune system disorders

Not known: Hypersensitivity reactions including allergic skin reactions.

Eye disorders

Not known: Optic neuritis leading to blindness.

Ear and labyrinth disorders

Not known: Ototoxicity.

Vascular disorders

Not known: Acidotic cardiovascular collapse.

Gastrointestinal disorders

Not known: Nausea, vomiting, glossitis, stomatitis, diarrhoea, enterocolitis.

Pregnancy, puerperium and perinatal conditions

9. What other medicine or food should be avoided whilst taking this medicine

Warfarin, phenytoin, sulphonylureas and tolbutamide



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Chloramphenicol prolongs the elimination, increasing the blood levels, of drugs including warfarin, phenytoin, sulphonylureas, tolbutamide.

Anticonvulsants and anticoagulants

Doses of anticonvulsants and anticoagulants may need to be adjusted if given concurrently.

Penicillins and rifampicin

Complex effects (including reduced / increased plasma levels) requiring monitoring of chloramphenicol plasma levels have been reported with co-administration of penicillins and rifampicin.

Paracetamol

Concurrent administration of paracetamol should be avoided as this prolongs chloramphenicol half-life.

Calcineurin Inhibitors (CNIs) Ciclosporin and Tacrolimus

Treatment with chloramphenicol possibly increases the plasma levels of the CNIs ciclosporin and tacrolimus.

Barbiturates

The metabolism of chloramphenicol is accelerated by barbiturates, such as phenobarbitone, leading to reduced plasma concentrations. There is a possible decrease in the metabolism of phenobarbitone with concomitant chloramphenicol administration.

Oestrogens

There is a small risk that chloramphenicol may reduce the contraceptive effect of oestrogens.

Hydroxocobalamin

Chloramphenicol reduces the response to hydroxocobalamin.

Drugs causing agranulocytosis

Chloramphenicol is contra-indicated in patients taking drugs liable to suppress bone marrow function. These include:

- Carbamazepine
- Sulphonamides
- Phenylbutazone
- Penicillamine
- Cytotoxic agents
- Some antipsychotics, including clozapine and particularly depot antipsychotics

Module 1: Administrative Information and Product Information



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- Procainamide
- Nucleoside reverse transcriptase inhibitors
- Propylthiouracil

10. What should you do if you miss a dose?

Try to make sure that you do not miss any doses. However, if you do forget a dose of these, take the missed dose as soon as you remember unless it is almost time for your next dose. Then take your next dose at the usual time. Ask your doctor for advice. Do not take a double dose to make up for a forgotten dose.

11. How should you keep this medicine?

Keep this medicine out of the sight and reach of children.

Do not use these capsules after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not use these if you notice that the pack is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

12. Signs and Symptoms of Overdosage

here adverse effects show signs of developing administration must be stopped immediately and treatment is mainly supportive. If an allergy develops, oral antihistamines may be used. In severe overdosage e.g. Gray Baby Syndrome, there is a need for a rapid reduction in plasma levels and it has been reported that resin haemoperfusion (XAD-4) substantially increases Chloramphenicol clearance.

13. What to do when you have taken more than the recommended dosage

If you have accidentally taken too many capsules, talk to your doctor straight away, or go to your nearest emergency unit. You may require medical attention. Remember to take your medicine with you, and show it to your doctor or the staff of the emergency unit.



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14. Name/Logo of Manufacturer/Importer/Marketing Authorisation Holder

Sun Enterprises LTD

BP 1952

Kigali, Rwanda

15. Care that should be taken while taking this medicine

Pregnancy

Chloramphenicol crosses the placenta. Therefore chloramphenicol is contraindicated during pregnancy

Breast-feeding

Chloramphenicol is excreted in breast milk. Therefore chloramphenicol is contraindicated during breast-feeding

Fertility

No human data on the effects of chloramphenicol on fertility is available.

16. Date of Revision of PIL
