

Package leaflet: Information for the patient

Chloramphenicol Capsules BP 250 mg

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- Chloramphenicol Capsules BP 250 mg will be referred to as Chloramphenicol capsules throughout this package leaflet.

What is in this leaflet:

- 1. What Chloramphenicol capsules are and what they are used for**
- 2. What you need to know before you take Chloramphenicol capsules**
- 3. How to take Chloramphenicol capsules**
- 4. Possible side effects**
- 5. How to store Chloramphenicol capsules**
- 6. Contents of the pack and other information**

1. What Chloramphenicol capsules are and what they are used for

Chloramphenicol capsules contain chloramphenicol which is an antibiotic for specific uses. They are used for treatment of typhoid fever and other dangerous infections where other antibiotics are not effective.

2. What you need to know before you take Chloramphenicol capsules

Do not take Chloramphenicol capsules:

- if you are allergic to chloramphenicol or any of the other ingredients (listed in section 6)
- if you have recently been vaccinated
- if you have porphyria (a metabolism disorder which causes abdominal pains and mental disorder)
- if you have a minor infection
- if you are taking medicines that may suppress your bone marrow
- if you are pregnant or breast-feeding.

If any of the above apply to you, speak to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Chloramphenicol capsules

- if you have liver or kidney problems
- if you are elderly
- if you are taking any of the medicines listed in the next section “Other medicines and Chloramphenicol capsules”.

Children

Do not give this medicine to children because it is unlikely to be safe.

Other medicines and Chloramphenicol capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may be affected by chloramphenicol or they may affect how well chloramphenicol will work.

Tell your doctor or pharmacist if you are taking:

- paracetamol
- medicines that thin the blood (e.g. warfarin)
- antidiabetics (sulphonylureas such as gliclazide)
- medicines that may suppress the bone marrow (e.g. carbamazepine, penicillamine, sulphonamides, phenylbutazone)
- medicines to treat cancer
- antipsychotic drugs (e.g. clozapine, flupenthixol, fluphenazine, procainamide)
- sulphonamide antibiotics (e.g. co-trimoxazole)
- anticonvulsants for epilepsy or related conditions (e.g. phenytoin)
- barbiturates (e.g. phenobarbitone)
- immunosuppressants (e.g. ciclosporin or tacrolimus)
- penicillin or rifampicin type antibiotics
- vitamin B12 (hydroxocobalamin)
- oral contraceptives containing oestrogen (the pill)
- medicines that treat over-active thyroid disease (e.g. carbimazole, propylthiouracil)
- anti-retroviral medicines that treat HIV infection (e.g. zidovudine).

Pregnancy, breast-feeding and fertility

Do not take Chloramphenicol capsules if you are pregnant, planning to become pregnant or breast-feeding as they may harm the baby.

Chloramphenicol may cause a condition called Grey Baby Syndrome, where the baby's skin appears grey and the baby is listless and weak. This may be fatal and requires immediate medical attention.

Ask your doctor, pharmacist or nurse for advice before taking any medicine.

Driving and using machines

Chloramphenicol capsules have no or negligible influence on the ability to drive and use machines.

Chloramphenicol capsules contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Chloramphenicol Capsules

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the capsules whole with a drink of water.

Adults and elderly

The usual dose is 500 mg (2 capsules) every 6 hours or 50 mg per kg body weight daily in divided doses.

Blood tests may be carried out to check the level of chloramphenicol in your body and to make sure your blood is functioning properly, as chloramphenicol can damage blood cells.

Use in children

This medicine is not suitable for children.

If you take more Chloramphenicol capsules than you should

It is likely that you will be taking these capsules in hospital and, therefore, it is unlikely that you will overdose.

However, if you do take more capsules than you should:

1. Tell your doctor, pharmacist, nurse or nearest hospital casualty department immediately.
2. Take the container and any remaining capsules with you so that people can see what you have taken.
3. Do this even if you feel well.

If you forget to take Chloramphenicol capsules

If you forget to take a dose take it as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual.

Do not take a double dose to make up for a forgotten dose.

Tell the doctor if you miss a dose.

If you stop taking Chloramphenicol capsules

Do not stop just because you feel better. If you stop too soon, the infection may come back.

Keep taking your capsules until the prescribed course is finished.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

STOP taking the capsules and seek medical help immediately if you have any of the following **allergic reactions**:

- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised lumps
- blistering of the mouth, eyes, or genital region, patchy areas of rash, peeling skin.

Seek immediate medical attention if you have any of the following symptoms:

- drowsiness, feeling faint, sudden loss of consciousness, shortness of breath, nausea, vomiting
- unusual or increased bleeding or bruising
- fever, sore throat, mouth ulcers, repeated infections or infections that will not go away
- feeling tired, breathless, and looking pale
- sudden loss or blurring of vision, loss of colour vision, eye pain which worsens with eye movement
- ringing in the ears or temporary hearing loss, head-spins (vertigo), dizziness.

The side effects listed below have been reported:

Not known: frequency cannot be estimated from the available data

- inflamed, sore and swollen tongue, sore mouth, difficulty chewing and eating
- fever, nausea, vomiting, diarrhoea, abdominal pain and/or bloating, blood in stool, fatigue, dehydration, swelling.

Use of chloramphenicol in **pregnancy** and in **newborn babies** can result in Grey Baby Syndrome, where the baby's skin appears grey and the baby is listless and weak. This may be fatal and requires immediate medical attention.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card

Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Chloramphenicol Capsules

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

Do not take after the expiry date which is stated on the label and on the carton after EXP. The expiry date refers to the last day of that month.

Store in a cool dry place in the original package.

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.

6. Contents of the pack and other information

What Chloramphenicol Capsules contain

- The active substance is chloramphenicol (250 mg).
- The other ingredients are starch, talc, magnesium stearate and sodium lauryl sulphate (see end of section 2 for further information on sodium).
- The capsule shell is gelatin and titanium dioxide (E171).

What Chloramphenicol Capsules look like and contents of the pack

Chloramphenicol Capsules are off-white, hard gelatin capsules.

They are available in packs of 30, 50, 60, 100 or 1000 hard capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Chemidex Pharma Ltd., trading as Essential Generics, 7 Egham Business Village, Crabtree Road, Egham, Surrey TW20 8RB, UK.

Manufacturer

Delpharm L'Aigle. Zone Industrielle No1, Route de Crulai, L'Aigle 61300, France.

This leaflet was last revised in

May 2020