

Package leaflet: Information for the user
Chloramphenicol eye drops BP 0.5% w/v
(Chloramphenicol)

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- The medicine will be called Chloramphenicol in this leaflet.

What is in this leaflet

- 1. What Chloramphenicol is and what it is used for**
- 2. What you need to know before you use Chloramphenicol**
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1. What chloramphenicol is and what it is used for

Chloramphenicol belongs to a group of medicine called antibiotics.

Chloramphenicol is used in both adults and children to treat bacterial conjunctivitis, which is an infection of the outer surfaces of the eye. The infected eye will probably be red, gritty or itchy. In the morning there will be a sticky discharge which may make it difficult to open the eye. When put in the eye, chloramphenicol works by helping kill the bacteria (germs) and allow the body to overcome the infection.

2. What you need to know before you use chloramphenicol

Do not use chloramphenicol

- If you are allergic (hypersensitive) to chloramphenicol or to any other ingredients of this medicine (see section 6 for more details)
- If you or someone in your family ever had a blood disorder or bone marrow disease including anemia (decrease in the number of red blood cells) when using chloramphenicol in the past.
- If you have a family history of “dyscrasias”, a condition which can cause tiredness, bruising and an increased risk of infections

Take special care

- If you develop a new eye infection during this treatment, you should stop using the drops and speak to your doctor.
- If you use chloramphenicol eye drops for a long time, your doctor may do some blood tests to check for any problems.

Warnings and precautions

Talk to your doctor or pharmacist before using chloramphenicol

- if you have visual disturbances
- if you have severe pain in the eye
- if you are sensitive to light
- if your eye is inflamed and you have a rash on the scalp or face
- if your eye looks cloudy
- if your black or coloured part of the eye looks unusual
- if you have a foreign body in the eye
- if you have an eye infection that keeps coming back
- if you have glaucoma (raised pressure in the eye)
- if you have dry eyes
- if you have eye injury or eye surgery
- if you are currently using any other eye drops or eye ointment

Other medicines and chloramphenicol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including using eye drops or eye ointment and medicines obtained without a prescription before you start to use this medicine. Your medicine may affect their action and could alter their effect.

In particular, tell your doctor if you are taking any of the following:

- medicines for cancer such as methotrexate
- medicines for the immune system such as azathioprine

Pregnancy and breast-feeding

Chloramphenicol should not be used during pregnancy and breast-feeding unless considered essential by your doctor, as the effects are unknown.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

No effects on ability to drive and use machines have been reported. However do not drive or operate machines if you experience any visual disturbance after using the product. Wait until this clears before driving or using machines.

Contact lenses Contact lenses should not be worn in an infected eye. Your doctor will ask you to remove your contact lenses prior to the administration of the drops. Do not wear contact lenses during treatment.

3. How to use chloramphenicol

Always use Chloramphenicol exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is two drops applied to the affected eye(s) every three hours. Use during waking hours only. Continue treatment at least 48 hours after the eye appears normal, or as directed by your doctor.

Use in children:

Dosage adjustment may be necessary in newborn infants because of reduced systemic elimination due to immature metabolism and the risk of dose - related adverse effect .The maximum duration of treatment is 10-14 days

If you are using in combination with another eye drop medicine, wait 5-15 minutes before applying the second eye drop.

Instructions for use:

(Please also refer to pictograms at the end of the leaflet)

- First wash your hands
- Avoid touching the eye (or any other surface) with the tip of the bottle
- These drops are supplied as a sealed bottle with a spiked cap. When using the bottle for the first time, screw the cap down tightly in order to pierce the tip of the bottle
- Tilt your head back and look at the ceiling
- Pull the lower eyelid gently downwards
- Hold the bottle upside down above the eye and gently squeeze the bottle to release a drop into your eye
- Keep the affected eye closed and press your fingertip against the inside corner of the closed eye, and hold for 1 minute
- Repeat for the other eye if necessary
- Replace and tighten the cap immediately after use.

Be careful not to touch the tip of the bottle on your eye or on any other surface.

Ocular solutions, if handled wrongly, can become contaminated by common bacteria and cause eye infections. If you do develop any other eye condition whilst using this product, see your doctor immediately.

If you use more chloramphenicol than you should

If you accidentally apply too much drops, you should wash your eye with plenty of water, if any painful symptoms continue after this, you should tell your doctor immediately.

If you forget to use Chloramphenicol

Apply the drops as soon as you remember. However, if it is almost time for your next dose, do not double your dose and carry on with the normal schedule dose.

If you stop using chloramphenicol

To be effective chloramphenicol must be used every day. Do not stop using chloramphenicol until your doctor tells you so.

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

4. Possible side effects

Like all medicines, Chloramphenicol can cause side effects, although not everybody gets them. Some people find that their eyes sting or their sight is blurred immediately after using the drops. These effects should wear off after a short time. If prolonged irritation, swelling, watery eyes or sensitivity to light occurs, then exposed eye should be washed with water for 15 minutes. If the symptoms continue after this, an eye examination may be required.

Stop using your medicine and tell **your doctor or pharmacist immediately if you experience the following side effects:**

- Wheeziness (shortness of breath), fever, swelling of your face, lips or tongue, itching or rash with swelling of skin (the rash could be puffy (swollen) or blotchy, or look like little blisters.
- A sore throat, bruising or being unable to overcome an infection. On very rare occasions, patients using chloramphenicol have had changes in their blood cells causing severe tiredness or easy bruising.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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

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

Store in a refrigerator at a temperature between 2°C and 8°C.

Protect from light.

Discard the bottle 28 days after opening, even if there is solution remaining.

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

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 pack and other information

What Chloramphenicol contains

The active substance is chloramphenicol 0.5% w/v.

The other ingredients are borax, boric acid- and water for injection.

What Chloramphenicol looks like and contents of the pack

Each bottle contains 5ml or 10ml of Chloramphenicol Eye Drops.

Your medicine is a bright, colourless to faint yellow aqueous solution.

Marketing Authorisation Holder and Manufacturer

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PL number: 15872/0003

Hard to see or read the leaflet? Call + 44(0) 1489 565222 for help.

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MODE OF USE



The spike in the cap will pierce the tip of the bottle.

Tilt head backwards. Dispense drops with gentle pressure. Do not touch dropper tip to the surface of the eye.

Replace cap after every use, and screw the cap down