

Package leaflet: Information for the user
CHLORAMPHENICOL EYE DROPS 0.5% W/V

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse after 48 hours.

What is in this leaflet

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1. What Chloramphenicol Eye Drops are and what they are used for

Chloramphenicol Eye Drops contain an antibiotic called chloramphenicol. It is used to treat bacterial infections that affect the front surfaces of the eye.

The most common type of infection in this area is called acute bacterial conjunctivitis. When you have this condition, the white part of one or both of your eyes will be red and /or your eyelids will be red or swollen. There will be a sticky discharge, which can make the eye difficult to open in the morning and the eye may feel 'gritty' or 'irritated'.

Chloramphenicol Eye Drops are not suitable for treating eye infections that have spread to the deeper layers of the eye coverings or into the fluid within the eyeball. Antibiotic tablets or injections are needed to treat these deeper, more serious infections.

2. What you need to know before you use Chloramphenicol Eye Drops

Chloramphenicol Eye Drops are recommended for use in **children aged 2 years and over, in adults** and the **elderly**. A child below the age of 2 years with an eye infection should be seen by a doctor.

Do not use this product if you:

- are **allergic to Chloramphenicol** or any of the ingredients of this medicine (listed in section 6).
- have ever had **problems with your blood** (in particular very low number of blood cells) **during previous treatment** with chloramphenicol
- have a family history of blood problems such as low white blood cell, red blood cell, or platelet counts

Do not use this product and seek advice from your doctor if:

- your **eyesight is affected** (loss of sight, reduced vision, blurred vision or halos around lights)
- you have **pain** within the eye
- your eye has suffered a blow or other **injury**
- your eye is **inflamed** and you have a rash on the scalp or face
- the **pupil** of your eye looks **unusual** or your eye looks **cloudy**
- your eyes are **sensitive to light**
- you have (or think you have) a **foreign body** in your eye, which has not been removed
- you have recently had an **eye infection**
- you suffer from or have suffered from **glaucoma** or **dry eye syndrome**
- you **wear contact lenses**. If you wear contact lenses and your contact lens practitioner or doctor has advised you to use this product, **do not wear your lenses during the course of treatment**. Wear your glasses instead. Soft contact lenses should not be used for 24 hours after completing treatment.
- you are using any other **eye drops** or **eye ointment**
- you have had **eye surgery or laser treatment** in the last 6 months

Tell your pharmacist before using this product if you:

- are taking any **other medicines**
- suffer from any other **eye problems**.

Other medicines and Chloramphenicol Eye Drops

If you are taking bone marrow depressant medicines (medicines which decrease the activity of the bone marrow, causing low blood cell counts) such as azathioprine or are receiving chemotherapy, seek the advice of your pharmacist or your doctor before using this product.

Pregnancy and breast-feeding

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

After using the drops, you may temporarily get blurred vision. Do not drive or operate machinery until your vision is clear. If in doubt, talk to your pharmacist or doctor.

Chloramphenicol Eye Drops contains phenylmercuric nitrate

Phenylmercuric nitrate may cause allergic reactions.

3. How to use Chloramphenicol Eye Drops

Instructions for use

To be used in the eye(s) only

- Check that the seal is not broken before the first use.
- Wash and dry your hands
- Tilt your head back while seated or lie down on your back
- Gently pull the lower eyelid downwards and look up
- Place the tip of the bottle close to your eye. Squeeze the bottle and let one drop fall into the space between the lower eyelid and the eye. Take care that the tip of the bottle does not touch your eye, the skin around your eye or your fingers.
- Close your eye for a moment.
- When both eyes are to be treated, repeat for the other eye
- Replace and tighten the cap immediately after use.

Whilst applying the drops, **do not**

- breathe on or touch the dropper nozzle
- touch the eyes or eyelids (or any other surface) with the tip of the bottle
- share your eye drops with anyone else.

For external use only.

Dose

Apply **one drop** to the affected eye(s) **every 2 hours for the first two days and every 4 hours thereafter**. Use during waking hours only.

Length of treatment

The course of treatment is 5 days. **Keep using** these eye drops for **5 days**. Do not stop just because you feel better, this could make your condition worse.

If your symptoms **do not improve within 48 hours**, consult your doctor. If your symptoms **get worse** seek medical advice **at once**.

Do not use Chloramphenicol Eye Drops for **more than 5 days** without consulting doctor. Dispose of any remaining eye drops appropriately after the 5 day course of treatment (see section 5).

If you forget to use your drops

If you have only just missed a dose and it is a long time before the next dose is due, put in the missed dose of drops straight away. If it is nearly time for your next dose, skip the missed dose and just put in the next dose of drops at the usual time. **Do not take a double dose** to make up for a forgotten dose.

4. Possible side effects

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

Some people may get one or more of these side effects. Some effects happen straight away but do not last long - others may only happen after several days of use.

- **Allergic reactions** such as itching or rashes. If you get a severe reaction, with swelling or breathing problems get medical help straight away.
- Changes in the blood (anaemia) leading to **severe tiredness or easy bruising**. If you experience these effects, stop using the drops immediately and tell your doctor.
- **Discolouration or clouding of the eye surface (cornea) or lens** due to preservative.
- The use of topical Chloramphenicol may occasionally result in the over growth of other non susceptible organisms including fungi. If any new infection appears during treatment you should tell your doctor.
- **Blurred vision** or mild **burning or stinging** when you put the drops in. These should subside quickly.
- **Irritation of the skin** around the eyes, **mercurialentis** (brown discolouration of the lens) and **atypical band keratopathy** (appearance of calcium on the cornea). These may be due to the preservative in the drops called phenylmercuric nitrate.

If you do not feel well or are worried about your health, talk to a pharmacist or doctor.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting 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 the 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 Eye Drops

Replace the cap securely after use. **Store at 2°C to 8°C.**

This is the **temperature** of most domestic **refrigerators**.

Keep this and all medicines out of the sight and reach of children.

Do not use after the expiry date which is stated on the bottle and on the carton the bottle is packed in.

Dispose of any medicine left at the end of a 5 day course of treatment.

Do not throw away any medicines via waste water 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 Eye Drops contains

- The active substance is Chloramphenicol 0.5% w/v.
- The other ingredients are: borax, boric acid 15mg/ml, phenyl mercuric nitrate (as preservative) 0.002% w/v and water for injections.

What Chloramphenicol Eye Drops looks like and contents of the pack

Each bottle contains 10 ml of drops.

The drops contain 0.5% w/v chloramphenicol, which is equivalent to 5 mg of chloramphenicol per millilitre.

Chloramphenicol Eye Drops is a clear, colourless, sterile solution.

Marketing Authorisation Holder

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