

Chloramphenicol Antibiotic 0.5% w/v Eye Drops

Chloramphenicol

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. See section 4.
- 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

- 1. What Chloramphenicol Antibiotic Eye Drops is and what it is used for
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1. What Chloramphenicol Antibiotic Eye Drops is and what it is used for

Chloramphenicol Antibiotic Eye Drops contains an antibiotic called chloramphenicol. It is used in both adults and children aged 2 years and over 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 Antibiotic Eye Drops is 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 Antibiotic Eye Drops

Chloramphenicol Antibiotic Eye Drops is 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 see a doctor due to necessary dosage adjustment.

Do not use Chloramphenicol Antibiotic Eye Drops if

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

Warnings and precautions

Talk to your doctor or pharmacist before using Chloramphenicol Antibiotic Eye Drops if

- your **eyesight is affected** (loss of sight, reduced vision, blurred or double vision, or halos around lights)
- you have **pain** within the eye
- your eye(s) are more **sensitive to light** than usual
- your **pupil(s)** looks **unusual**
- your **eye(s)** looks **cloudy**
- you have **pain or swelling** around the eye or face
- your eye is **inflamed** and you have a rash on the scalp or face
- you have had an **eye infection** in the recent past
- you have **glaucoma** (a raised pressure in the eye) or **dry eye** syndrome
- your eye has suffered a blow or other **injury**

- you have (or think you have) a **foreign body** in your eye, which has not been removed
- you are using other **eye drops or eye ointment**
- you have had **eye surgery or laser treatment** in the last 6 months
- 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 replaced for 24 hours after completing the treatment
- you or someone in your family suffer from problems with your blood (aplastic anaemia) or bone marrow problems
- you suffer from any other **eye problems**
- you have ever had an allergic (hypersensitive) reaction to this or any other medicine
- you are pregnant, trying for a baby or are breast-feeding.

Other medicines and Chloramphenicol Antibiotic Eye Drops

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

If you are taking bone marrow depressant drugs (drugs 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

Chloramphenicol Antibiotic Eye Drops can cause temporary blurring of vision after you have used them. Wait until your vision is clear before driving or using machines. If in doubt, talk to your pharmacist or doctor.

Chloramphenicol contains phenylmercuric nitrate

Chloramphenicol Antibiotic Eye Drops contains phenylmercuric nitrate as a preservative which may cause allergic reactions.

3. How to use Chloramphenicol Antibiotic Eye Drops

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

Contact lens users

If you wear contact lenses they must be removed whilst you are using Chloramphenicol Antibiotic Eye Drops. You should wait 24 hours after you take your last dose of Chloramphenicol Antibiotic Eye Drops before starting to use your lenses again.

Instructions for use

- To be used in the eye(s) only
- First wash your hands
 - These drops are supplied as a sealed bottle with spiked cap. When using the bottle for the first time, screw the cap down tightly in order to pierce the tip of the bottle
 - After cap is removed, if the tamper evident snap collar is loose, please remove before using the



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- product. Take care not to touch the end of the nozzle
- 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
- 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 tip of the bottle
- touch the eyes or eyelids (or any other surface) with the tip of the bottle
- share your eye drops with anyone else.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use this medicine only in your eyes.

How much to use

Adults, the elderly and children over 2 years

The recommended dose is one drop into the affected eye(s) **every 2 hours for the first 48 hours. After this** you should reduce the dose to **one drop every 4 hours**. Use during waking hours only.

Do not use Chloramphenicol Antibiotic Eye Drops just before you go to sleep.

The course of treatment should be **5 days**. Do not use Chloramphenicol Eye Drops for longer than 5 days at a time. Do not stop just because you feel better, this could make your condition worse.

Seek further immediate medical advice any time if symptoms worsen.

Consult your doctor if your eye infection does not start to improve within 48 hours.

If you use more chloramphenicol than you should

Chloramphenicol Antibiotic Eye Drops is for external use only. If you have swallowed or you suspect someone else has swallowed any Chloramphenicol Antibiotic Eye Drops, contact your doctor or go to the accident and emergency department of your local hospital at once. Always take the container with you, if possible, even if empty.

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 Antibiotic Eye Drops

Try not to miss doses. If you do miss a dose do not worry, take your next dose at the normal time.

Never double up on a dose to make up for the one you have missed.

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

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 allergic reaction, with swelling or breathing problems stop using the drops immediately and 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 the preservative.
- The use of topical chloramphenicol may occasionally result in the overgrowth 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 a **typical band keratopathy** (appearance of calcium on the cornea). These may be due to the preservation 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 any of the side effects get serious or if you experience any side effect 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: 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 Antibiotic Eye Drops

Keep out of the sight and reach of children. Do not use Chloramphenicol Eye Drops after the expiry date printed on the bottle label. The expiry date refers to the last day of that month. Once the bottle is opened use within 4 weeks.

You are advised to dispose of the bottle once you have finished your 5 day course of treatment. This medicine needs to be **stored upright between 2-8°C (in a refrigerator)**. Protect from light. Do not allow it to freeze.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Chloramphenicol Antibiotic Eye Drops contains:

The active substance is chloramphenicol 0.5%w/v The other ingredients are borax, boric acid, phenylmercuric nitrate (as preservative) and purified water.

What Chloramphenicol Antibiotic Eye Drops looks like and contents of the pack

Chloramphenicol Antibiotic Eye Drops is a clear colourless solution supplied in plastic bottles. Each bottle contains 10ml of solution.

Marketing Authorisation Holder and Manufacturer:

Martindale Pharmaceuticals Ltd.
Bampton Road, Harold Hill
Romford
Essex
RM3 8UG
United Kingdom
Manufacturer:
Famar S.A.
63, Agiou Dimitriou Street
174 56 Alimos - Athens,
Greece

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at the above address.

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