

Package leaflet: Information for the user

CHLORAMPHENICOL 1% w/w EYE OINTMENT

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

1. What Chloramphenicol Eye Ointment is and what it is used for
2. What you need to know before you use Chloramphenicol Eye Ointment
3. How to use Chloramphenicol Eye Ointment
4. Possible side effects
5. How to store Chloramphenicol Eye Ointment
6. Contents of the pack and other information

1. What Chloramphenicol Eye Ointment is and what it is used for

Chloramphenicol Eye Ointment is a topical ointment for administration to the eye only. It contains an antibiotic called chloramphenicol and 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 acute bacterial conjunctivitis 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 Ointment 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 Eye Ointment

Chloramphenicol Eye Ointment 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 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:

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

Other medicines and Chloramphenicol Eye Ointment

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 breastfeeding

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 eye ointment, 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.

3. How to use Chloramphenicol Eye Ointment

Applying the ointment

To be used in the eye(s) only

1. Check that the tube seal is not broken before first using the eye ointment.
2. Wash and dry your hands
3. Remove the cap. Take special care that the nozzle of the tube does not touch your eye, the skin around your eye or your fingers.
4. Use a mirror; this will help you see what you are doing
5. Place the nozzle of the tube close to your eye. Gently pull the lower eyelid downwards and look up.
6. Squeeze the tube gently and apply about 1cm of the ointment to the space between the lower eyelid and the eye.
7. Close your eye for a moment
8. When both eyes are to be treated, repeat steps 5-7.
9. Replace the cap securely after use.

Whilst applying the ointment, **do not**

- Breathe on or touch the nozzle of the tube
- Touch the eyes or eyelids with the nozzle of the bottle
- Share your eye ointment with anyone else

For external use only.

Dose

The dose is a small amount of ointment (approx 1cm) to be applied to the affected eye(s).

If you are using **drops during the day** and the **ointment at night**-apply the ointment at night, before going to bed.

If you are using **just the ointment**, apply **3 to 4 times a day**.

Length of treatment

The course of treatment is 5 days. **Keep using** the eye ointment 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 Ointment for **more than 5 days** without consulting your doctor. Dispose of any remaining eye Ointment appropriately after the 5 day course of treatment (see section 5).

If you forget to use your Ointment

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 ointment straight away. If it is nearly time for your next dose, just put in the next dose of ointment 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

Possible side effects include:

- **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**. Stop using the treatment and consult your doctor if you experience these effects.
- 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 ointment in. These should subside quickly.

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

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

5. How to store Chloramphenicol Eye Ointment

Replace the cap securely after use. Store below 25°C.

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

Do not use after the 'use by' date shown on the tube and end of the carton.

Discard any unused ointment after completing your 5 day course of treatment.

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 Eye Ointment contains

- The active substance is chloramphenicol. One (1) gram of ointment contains 10mg of chloramphenicol.
- The other ingredients are liquid paraffin and white Petroleum.

What Chloramphenicol Eye Ointment looks like and contents of the pack

Each pack contains one tube with 4g of ointment.

Marketing Authorisation Holder

Medicom Healthcare Ltd
Lynton House, 7-12 Tavistock Square,
Kings Cross, London,
WC1H 9LT, U.K.

Manufacturer

TUBILUX PHARMA S.P.A
via Costarica 20/22, 00071 Pomezia (RM),
ITALY

PL number: 18956/0009

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This leaflet was last revised in 11/2019

9-COLOP-8-GB-PV4

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Manufacturer

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07100 Annonay, France

PL number: 18956/0009

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