

PATIENT INFORMATION LEAFLET Chloramphenicol 0.5% w/v Eye Drops

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- · Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours. This medicine is for you.
- · Tell your doctor if:
- Any of the side effects gets serious
- You notice any side effects not listed in this leaflet.

The product is known by the name above but will be referred to as Chloramphenicol Eye Drops throughout the rest of this leaflet.

In this leaflet:

- 1. What Chloramphenicol Eye Drops are and what they are used for
- 2. Before you use Chloramphenicol Eye Drops
- 3. How to use Chloramphenicol Eye Drops
- Possible side effects
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- 6. Further information

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

Chloramphenicol belongs to a group of medicines called antibiotics. Chloramphenicol Eye Drops are used for the treatment of bacterial conjunctivitis (infection 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. Before you use Chloramphenicol Eye Drops

Do not wear contact lenses during treatment. Wait until 24 hours after the end of the treatment before you wear your contact lenses. You can wear glasses during treatment.

DO NOT use Chloramphenicol Eye Drops if the answer to the following questions is yes:

- Have you ever had an allergic reaction to chloramphenicol or to any of the other ingredients listed in this leaflet?
- Have 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). Signs of this include tiredness, unusual bruising or increase in the number of infections that you get.

Take Special Care:

If any new infection appears during treatment, you should stop taking 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.

Take special care with Chloramphenicol Eye Drops and talk with your doctor or pharmacist before taking your medicine if:

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

Using other medicines:

Please tell your doctor or pharmacist if you are taking or having recently taken any other medicines, including medicines obtained without a prescription. They may be affected by Chloramphenicol or affect how well the drops works.

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:

The drops should not be used in pregnancy unless your doctor feels that it is clearly needed, as the effects are unknown. The drops should not be used whilst breast feeding. Tell your doctor if you are planning to become pregnant, or are breastfeeding so that a different medicine can be considered.

Driving and using machines:

If the drops blurs your vision, do not drive or operate machines until you can clearly see again.

Important information about some of the ingredients of Chloramphenicol Eve Drops:

This medicine also contains phenylmercuric nitrate as a preservative and it is possible that you may experience an allergic reaction. Tell your doctor if you have any known allergies.

3. How to use Chloramphenicol Eve Drops

Always use Chloramphenicol Eye Drops exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Adults, children and infants: The recommended dosage is two drops to be applied to the affected eye every 3 hours or more frequently if required. Continue treatment at least 48 hours after the eye appears normal.

Directions for use:

- 1. Wash and dry your hands
- 2. Open the bottle. Be careful not to touch or breathe on the tip of the bottle
- 3. Tilt your head backwards while seated or lying down on your back
- Look straight upwards and gently pull the lower lid downwards
- Place the tip of the bottle close to your eye. Make sure the tip of the bottle does not touch the eye or skin around the eye and your fingers.
- 6. Squeeze the bottle gently, allow two drops to fall between the bottom evelid and eve
- 7. Repeat steps 4 to 6 for the second eve if it is infected
- 8. Replace the cap securely after use. Make sure your fingers do not touch the tip of the bottle.

What to do if you miss a dose: If you forget to apply a dose, apply it as soon as you remember unless it is time for your next dose. Do not apply two doses at the same time.

What to do if you overdose: if you accidently 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.

After starting to take your Chloramphenicol Eve Drops:

- Symptoms should start to improve after 24 hours. If symptoms do not improve in 48 hours, speak to your doctor
- · Repeated use or long periods of treatment with Chloramphenicol Eye Drops can cause the infection to become resistant to treatment.
- Seek immediate medical advice if symptoms worsen at any time
- If you have a severe infection, you may also be given antibiotics to take by mouth.

4. Possible side effects

Along with the relief of symptoms a medicine may produce side effects. Most people taking this medicine find it causes no problems. A few people can be allergic to Chloramphenicol Eye Drops.

 You may notice that your eyes burn or sting for a short while after using the drops. If prolonged irritation, swelling, watery eyes or sensitivity to light occurs, then the exposed eye should be washed with water for 15 minutes. If the symptoms continue after this, an eye examination may be required

Stop taking 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, rash with swelling of the 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.

Tell your doctor or pharmacist if:

- Any of the effects aets serious
- You notice any side effects not listed in this leaflet.

5. How to store Chloramphenicol Eye Drops

Keep Chloramphenicol Eye Drops out of the sight and reach of children.

Store in a refrigerator between 2°C and 8°C. Protect from light by storing in the original packaging.

Do not use Chloramphenicol Eye Drops after the expiry/use by date on the bottle or carton. Discard the drops 28 days after opening. Ask your Pharmacist how to dispose of them.

6. Further information

What Chloramphenicol Eye Drops contain:

The active substance is chloramphenicol.

The other active ingredients are borax, boric acid, phenylmercuric nitrate, water for injection.

What Chloramphenicol Eve Drops looks like and contents of the pack:

Chloramphenicol Eye Drops are supplied in a flexible bottle with a plastic plug and cap assembly. Each 1ml of eye drops contains 5 milligrams of Chloramphenicol. Bottle sizes are 5ml and 10ml.

Marketing Authorisation Holder:

Mercury Pharmaceuticals Ltd.,

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Manufacture

Lomapharm, Rudolf Lohmann GmbH KG, Langes Feld 5, D-31860 Emmerthal, Germany.

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