



MercuryPharma

PATIENT INFORMATION LEAFLET

Chloramphenicol 1% w/w Ophthalmic Ointment

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 Ophthalmic Ointment throughout the rest of this leaflet.

In this leaflet:

1. What Chloramphenicol Ophthalmic Ointment is and what it is used for
2. Before you use Chloramphenicol Ophthalmic Ointment
3. How to use Chloramphenicol Ophthalmic Ointment
4. Possible side effects
5. How to store Chloramphenicol Ophthalmic Ointment
6. Further information

1. WHAT CHLORAMPHENICOL OPHTHALMIC OINTMENT IS AND WHAT IT IS USED FOR

Chloramphenicol belongs to a group of medicines called antibiotics. Chloramphenicol Ophthalmic Ointment is 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 OPHTHALMIC OINTMENT

Do not wear contact lenses during this treatment, wear spectacles. You can wear contact lenses 24 hours after you have finished this treatment.

DO NOT use Chloramphenicol Ophthalmic Ointment 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 anaemia (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 ointment and speak to your doctor.

If you use Chloramphenicol Ophthalmic Ointment for a long time, your doctor may do some blood tests to check for any problems.

Take special care with Chloramphenicol ophthalmic ointment and check 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 eye
- You have an eye infection that keeps coming back
- You have glaucoma (raised pressure in the eye)
- You have dry eyes
- 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 ointment 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 ointment should not be used in pregnancy unless your doctor feels that it is clearly needed, as the effects are unknown. The ointment 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 ointment blurs your vision, do not drive or operate machines until you can clearly see again.

3. HOW TO USE CHLORAMPHENICOL OPHTHALMIC OINTMENT

Always use Chloramphenicol Ophthalmic Ointment 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 a small amount of the ointment to be applied to the affected eye every 3 hours or more frequently if required.

It is quite possible to use the ointment on your own, but you may find it easier to ask someone else to put the ointment in your eye. Let them stand behind you while you sit in a chair.

Directions for use:

1. Wash and dry your hands
2. Open the tube. Be careful not to touch or breathe on the tip of the tube
3. Tilt your head backwards while seated or lying down on your back
4. Look straight upwards and gently pull the lower lid downwards to uncover the lower part of your eye ball. This exposes the inner surface of the lower eyelid and is a good place to apply the ointment.
5. Squeeze the tube and apply about 1cm of the ointment to the inner surface of the lower eyelid. Make sure the tip of the tube does not touch the eye or skin around the eye and your fingers
6. Repeat steps 4 to 5 for the second eye if it is infected
7. Replace the cap securely after use. Make sure your fingers do not touch the tip of the tube.

After starting to take your Chloramphenicol Ophthalmic Ointment:

- 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 Ophthalmic Ointment 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.

The ointment must NOT be taken by mouth. If you accidentally swallow any of the ointment, you should contact your doctor or pharmacist at once.

What to do if you overdose: If you accidentally apply too much ointment, you should wash your eye with plenty of water. If any painful symptoms continue after this, you should tell your doctor immediately.

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.

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 Ophthalmic Ointment.

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 or 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 gets serious
- You notice any side effects not listed in this leaflet
- You notice that your eyes burn or sting for a short while after using the ointment. 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.

5. HOW TO STORE CHLORAMPHENICOL OPHTHALMIC OINTMENT

Keep Chloramphenicol Ophthalmic Ointment out of the sight and reach of children.

Do not store above 25°C.

Do not use Chloramphenicol Ophthalmic Ointment after the expiry/use by date on the tube or carton (the expiry date refers to the last day of that month). Discard the ointment 28 days after opening. Ask your Pharmacist how to dispose of them.

6. FURTHER INFORMATION

What Chloramphenicol Ophthalmic Ointment contain:

The active substance is chloramphenicol. Each 1 gram of ointment contains 10 milligrams of Chloramphenicol.

The other ingredients are liquid paraffin, polyethylene in paraffin liquid.

What Chloramphenicol Ophthalmic Ointment looks like and contents of the pack:

Chloramphenicol Ophthalmic Ointment is supplied in a 4 gram laminate tube with nozzle.

Marketing Authorisation Holder:

Mercury Pharmaceuticals Ltd.,

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Manufacturer:

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