



Package leaflet: Information for the patient
Chloromycetin® 1%w/w Ophthalmic Ointment
Chloramphenicol

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

The name of your medicine is Chloromycetin 1% w/w Ophthalmic Ointment; it will be called Chloromycetin Ointment for ease here after.

What is in this leaflet

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

1. WHAT CHLOROMYCETIN OINTMENT IS AND WHAT IT IS USED FOR

Chloramphenicol belongs to a group of medicines called antibiotics. Chloromycetin 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. WHAT YOU NEED TO KNOW BEFORE YOU USE CHLOROMYCETIN OINTMENT

Do not wear contact lenses during this treatment.

Do not use Chloromycetin Ointment

- if you are allergic to chloramphenicol or any of the other ingredients of this medicine (listed in section 6)
 - if you or someone in your family have 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.

Warnings and precautions

Talk to your doctor or pharmacist before using Chloromycetin Ointment.

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

Other medicines and Chloromycetin Ointment

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, 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, breast-feeding and fertility

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. 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 CHLOROMYCETIN OINTMENT

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not wear contact lenses during this treatment.

Use in adults, elderly, 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. Continue applying the medicine for 48 hours after the eye appears normal.

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.

Always use Chloromycetin 1%w/w Ophthalmic Ointment exactly as your doctor has told you. You should check with your doctor if you are not sure.

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



Version No: **100278/LF/118/04**
Product Name: **Chloromycetin 1%w/w Ophthalmic Ointment**
Pack Size: 4 g
Component: Leaflet
SKU: 100278
Market: Ireland
Production Site: Sanochemia
Revision No.: 1
Revision Date: 20/02/2015
Revised by: ADD

Dimension: 160 x 195 mm
Commodity No.: N/A
Pharma Code: N/A
Core Spec Ref: N/A
DCMF: N/A
Print Colours: Black

Non-Print Colours: **Cutter**

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Min. Font Size: 8 pt

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Signature

Name

Date

- 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
 - 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
 - Repeat steps 4 to 5 for the second eye if both eyes are to be treated
 - Replace the cap securely after use. Make sure your fingers do not touch the tip of the tube.
- 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.

After starting to use your Chloromycetin Ointment:

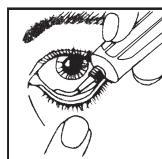
- Symptoms should start to improve after 24 hours. If symptoms do not improve in 48 hours, speak to your doctor
- Repeated use or long periods of treatment with this medicine can cause the infection to become resistant to treatment
- Seek immediate medical advice if symptoms worsen at any time
- If you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

If you use more Chloromycetin Ointment than you should

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.

If you forget to use Chloromycetin Ointment

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

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

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 this medicine. 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
- Any problem with your eyesight, especially if you have been using this medicine for a long time
- Fever.

Tell your doctor or pharmacist if:

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

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

Reporting of 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie

E-mail: medsafety@hpra.ie.

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

5. HOW TO STORE CHLOROMYCETIN OINTMENT

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

Do not use this medicine after the expiry date which is stated on the carton after **Use by:**. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any signs of discolouration or deterioration.

Do not store above 25°C.

Discard the ointment 28 days after first opening.

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 Chloromycetin Ointment contains

- The active substance is chloramphenicol. Each 1 gram of ointment contains 10 milligrams of chloramphenicol (1% w/w).
- The other ingredients (excipients) are liquid paraffin and Hydrophobic Base Gel (polyethylene in liquid paraffin).

What Chloromycetin Ointment looks like and contents of the pack

This medicine is supplied in a polyethylene tube laminated with aluminium and fitted with a white polyethylene nozzle and cap containing 4 grams of ointment.

Marketing Authorisation Holder: Mercury Pharmaceuticals Ltd., Capital House, 85 King William Street, London EC4N 7BL, UK

Manufacturer: Sanochemia Pharmazeutika AG, Landegger Strasse 7, 2491 Neufeld, Leitha, Austria

This leaflet was last revised in February 2015.

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100278/LF/118/04

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