

**Package leaflet: Information for the user**  
**Chloromycetin® 0.5% w/v Redidrops Eye drops, Solution**  
**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, pharmacist or nurse.
- This medicine is prescribed for you only. Do not pass this medicine 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Chloromycetin® 0.5% w/v Redidrops Eye drops, Solution; it will be called Chloromycetin Redidrops for ease here after.

**What is in this leaflet**

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

**1. What Chloromycetin Redidrops are and what they are used for**

Chloramphenicol belongs to a group of medicines called antibiotics. Chloromycetin Redidrops is used for the treatment of bacterial conjunctivitis (infection of the eye) in adults and children. 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.

You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

**2. What you need to know before you use Chloromycetin Redidrops**

**Do Not use Chloromycetin Redidrops**

- If you are allergic to chloramphenicol or to 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, pharmacist or nurse before using Chloromycetin Redidrops 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
- your 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
- you regularly use contact lenses. Wait until 24 hours after the end of the treatment before you wear your contact lenses. You can wear glasses during treatment.

This medicine should not be given to a child younger than 2 years without medical advice, as it contains boron and may impair fertility in the future.

If any new infection appears during treatment, you should stop using the drops and speak to your doctor.

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

**Other medicines and Chloromycetin Redidrops**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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 to treat 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 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.

**Driving and using machines**

Chloromycetin Redidrops can cause blurred vision, do not drive or operate machines until you can clearly see again.

**Chloromycetin Redidrops 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 Chloromycetin Redidrops**

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

#### **Adults and children:**

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.

It is only necessary to use this medicine during the day when you are awake. You do not need to wake yourself up in the night to use it.

#### **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
4. Look straight upwards and gently pull the lower lid downwards
5. 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 eyelid and eye
7. Repeat steps 4 to 6 for the second eye if it is infected
8. Replace the cap securely after use. Make sure your fingers do not touch the tip of the bottle.

After starting to use your Chloromycetin Redidrops:

- 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 Chloromycetin Redidrops 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 Redidrops than you should**

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 Chloromycetin Redidrops**

If you forget to apply a dose, apply it as soon as you remember unless it is near the time for your next dose. Do not apply a double dose to make up for a forgotten dose.

#### **If you stop using Chloromycetin Redidrops**

If you stop treatment with Chloromycetin Redidrops before completing treatment your eye infection may not completely clear. Speak to your doctor or pharmacist before stopping Chloromycetin Redidrops.

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

#### **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 using this medicine find it causes no problems. A few people can be allergic to Chloromycetin Redidrops.

Stop using 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

Other side effects:

Not known (frequency cannot be estimated from the available data)

- You may notice that your eyes burn or sting for a short while after using the drops. If prolonged irritation, swelling or inflammation of the skin (dermatitis), 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.
- bone marrow depression (a condition where the marrow is unable to produce red blood cells)
- a reduced production and death of red blood cells (anaemia)
- Fever

#### **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](http://www.hpra.ie)  
E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

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

#### **5. How to store Chloromycetin Redidrops**

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

Store in a refrigerator between 2°C and 8°C. Keep the bottle in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the bottle or carton. The expiry date refers to the last day of that month. Discard the drops 28 days after opening. Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

#### **6. Contents of the pack and other information**

**What Chloramphenicol Redidrops contains**

- The active substance is chloramphenicol. Each 1ml of the drops contains 5 milligrams of chloramphenicol (0.5% w/v).
- The other ingredients are borax, boric acid, phenylmercuric nitrate, water for injections.

**What Chloramphenicol Redidrops looks like and contents of the pack**

Chloramphenicol Redidrops is a clear, colourless, sterile, aqueous solution. Chloramphenicol Redidrops is supplied in a flexible bottle with a plastic plug and cap assembly. Bottle size is 10ml.

**Marketing Authorisation Holder:** Amdipharm Limited, Temple Chambers, 3 Burlington Road, Dublin 4, Ireland.

**Manufacturer:** Lomapharm, GmbH, Langes Feld 5, D-31860 Emmerthal, Germany.

This leaflet was last revised in March 2022.

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