

## **PACKAGE LEAFLET**

### **Chloramphenicol 1.0% w/w Eye Ointment**

#### **Chloramphenicol**

**Read all of this leaflet carefully before you start 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 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **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 belongs to a group of medicines called antibiotics. An antibiotic is a medicine which is used for the treatment of a variety of infections caused by bacteria. Chloramphenicol Eye Ointment are used in both adults and children for the treatment of a wide range of eye infections caused by bacteria.

#### **2. What you need to know before you use Chloramphenicol Eye Ointment**

##### **Do not use the ointment if:**

- You are allergic to Chloramphenicol or any of the other ingredients of this medicine listed in section 6
- You or a member of your family has had problems with their blood or bone marrow. These problems can include a severe reduction in red blood cells or lower than normal blood count.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before using Chloramphenicol Eye Ointment 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

### **Other medicines and Chloramphenicol Eye Ointment**

Tell your doctor or pharmacist if you are using, have recently used or might use 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
- the dietary supplement chymotrypsin

### **Pregnancy and breast-feeding**

Chloramphenicol should not be used during pregnancy and breast-feeding unless considered essential by your doctor, as the effects are unknown.

If you are a 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.

### **Chloramphenicol Eye Ointment contains**

This ointment contains wool fat. This may cause a skin reaction around the eyes such as “contact dermatitis”.

### **Driving and using machines**

The ointment may cause blurred vision due to smearing or stinging.

- This will only happen for a short period after it is put in your eye.
- If this happens do not drive or use machinery until you can see clearly.

## **3. How to use Chloramphenicol Eye 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.

You should not wear contact lenses whilst you are using Chloramphenicol Eye Ointment.

If you usually wear contact lenses you should wait until you have completed your treatment before you can use your lenses again.

You should wait 24 hours after you use your last dose of Chloramphenicol Eye Ointment before starting to use your lenses again.

A small amount of ointment to be applied into the affected eye (every three hours or more frequently if required), as directed by your doctor.

### **Instructions for use**

1. Wash your hands well before use
2. Remove the outer cap. You may find it easier to apply your ointment in front of a mirror.
3. Tilt the head back and pull the lower lid of the eye out to form a pocket
4. Hold the tube between the thumb and middle finger of the other hand, turn the tube upside down near to the eye, try not to touch the eye with the nozzle
5. Place about half an inch of the ointment into the pocket formed between the lid and the eye
6. Blink the eye a few times
7. Repeat in the other eye if you have been told to use Chloramphenicol Eye Ointment in both eyes
8. Replace the outer cap on the tube, trying not to touch the applicator tip with anything, including the eye or the fingers
9. Wash your hands

### **How much to use**

Apply Chloramphenicol Eye Ointment every three hours or more frequently as advised by your doctor.

### **OR**

Chloramphenicol Eye Ointment can be applied at night with appropriate eye drops used during the day.

### **Use in children:**

Dosage adjustment may be necessary in new-born infants to reduce the risk of adverse effects. The maximum duration of treatment is 10-14 days.

Prolonged use of Chloramphenicol Eye Ointment is not advisable. You should not use this product for longer than 5 days at a time unless your doctor has told you otherwise.

If you use Chloramphenicol Eye Ointment for a long time, your doctor may want to take blood samples to make sure the chloramphenicol has not affected your blood in any way.

Seek further immediate medical advice any time if symptoms worsen.

Consult with your doctor if your eye infection does not start to improve within 48 hours.

### **If you use more chloramphenicol than you should**

Chloramphenicol Eye Ointment is for external use only. If you suspect someone has swallowed any Chloramphenicol, contact your doctor or go to the accident and emergency department of your local hospital at once. Always take the container with you, if possible, even if empty.

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 Chloramphenicol Eye Ointment**

Try not to miss doses. If you do miss a dose, do not worry, just carry on as normal. Do not use extra ointment to make up.

#### 4. Possible side effects

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

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 skin (the rash could be puffy (swollen) or blotchy, or look like little blisters.
- Disease of the blood with a reduced number of red or white blood cells or platelets. Symptoms include tiredness, headaches, fever, severe chills, bleeding or bruising more easily than normal, nosebleeds.
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing

Possible side effects include:

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

- burning sensation
- hives (urticaria)
- pain (stinging sensation)
- red raised or sac-like skin rashes
- high temperature (pyrexia)

#### 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

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Website: [www.hpra.ie](http://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 Chloramphenicol Eye Ointment

Keep out of the sight and reach of children.

Do not use Chloramphenicol Eye Ointment after the expiry date printed on the crimp seal of the tube. The expiry date refers to the last day of that month. Once the tube is open use within 28 days.

You are advised to dispose of the tube once you have finished your 5 day course of treatment.

This medicine needs to be stored below 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. The measures will help to protect the environment.

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

### **What Chloramphenicol Eye Ointment contains**

- The active substance is Chloramphenicol 1.0% w/w.
- The other ingredients are Liquid Paraffin, Wool Fat and Yellow Soft Paraffin.

### **What Chloramphenicol Eye Ointment looks like and contents of the pack**

Chloramphenicol Eye Ointment is supplied in plastic tubes, each tube containing 4 grams of sterile eye ointment.

### **Marketing Authorisation Holder**

Martindale Pharmaceuticals Ltd. Bampton Road,  
Romford, RM3 8UG, England

### **Manufacturer**

Farmigea S.p.A. Via G.B. 8 – 56121, Pisa, Italy

**If you would like any more information, or  
would like the leaflet in a different format,  
please contact Medical Information at the above  
address.**

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