

# CHLORAMPHENICOL 1% W/W EYE OINTMENT PIL

V I C T O R D E S I G N	
MANUFACTURER	ParaPharm Development Limited,
PRODUCT	CHLORAMPHENICOL 1% W/W EYE OINTMENT PIL
PL NUMBER	14308/0018
A/W VERSION	Third Draft
DIMENSIONS	120 x 300 mm (profile supplied by client)
INKS USED	Pantone Black
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Patient information leaflet

## CHLORAMPHENICOL 1% W/W EYE OINTMENT chloramphenicol

TransDermal

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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, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. 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. 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 Eye Ointment contains the active substance chloramphenicol, which is an antibiotic.

Chloramphenicol Eye Ointment is used to treat acute bacterial conjunctivitis, which is an infection of the outer surface of eye that causes redness, discomfort and discharge from the affected eye. Your doctor can provide further advice about these symptoms. Chloramphenicol Eye Ointment is indicated in both adults and children.

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

Do not use Chloramphenicol Eye Ointment if you:

- are sensitive/allergic to chloramphenicol or any of the other ingredients of this medicine (listed in section 6)
- wear any type of contact lenses.

### Warning and precautions

Talk to your doctor before using this medicine if you:

- have problems with your blood (in particular very low numbers of blood cells) after taking chloramphenicol
- you, or anyone in your family, have had blood or bone marrow problems
- have had eye surgery within the last 6 months
- have an eye injury
- have glaucoma
- have dry eye syndrome
- have recently had an eye infection

- have disturbed vision
- are sensitive to light
- have severe pain inside the eye
- have cloudy eye
- have eye inflammation accompanied by a rash on the scalp or face
- have, or think you have a suspected foreign body in the eye.

**Other medicines and Chloramphenicol Eye Ointment**  
Please tell your doctor or pharmacist if you are applying any other type of eye drops or eye ointment before you start to use this medicine. Your medicine may affect their action and could alter their effect.

Please tell your doctor or pharmacist if you are taking or using, have recently taken or used any other medicines, including any other type of eye ointment or eye drops. This also includes medicines obtained without any prescription.

### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Chloramphenicol Eye Ointment should not be used by pregnant women or women who are breast-feeding unless necessary.

### Driving and using machines

Do not drive or operate machines if you have blurred vision after using Chloramphenicol Eye Ointment. You should wait until this clears before driving or using machines.

### 3. How to use Chloramphenicol Eye Ointment

Always use Chloramphenicol Eye Ointment exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose:

#### Use in adults and children under 18 years of age

A small amount (about 1 cm) of ointment to be applied into the affected eye (every three hours or more frequently if required), as directed by your doctor.

#### Use in newborn infants

Your child's doctor may prescribe a lower dose to reduce the risk of side effects. The maximum duration of treatment is 10-14 days.

Chloramphenicol may not work against certain types of infections. If your symptoms are not getting better you should tell your doctor immediately.

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.

The contents are sterile until the seal is broken. Do not use if the seal is broken before first opening. Always wash your hands before applying the eye ointment.

Apply your eye ointment in the following way:

1. Remove the cap
2. Take special care that the nozzle of the tube does not touch your eye, the skin around your eye or your fingers
3. You may use a mirror to help you see what you are doing
4. Place the nozzle of the tube close to your eye and gently pull the lower eyelid downwards and look up
5. Squeeze the tube gently and apply about 1 cm of ointment to the space between the lower eyelid and the eye
6. Close your eye for a moment
7. Where both eyes are to be treated repeat step from 3 to 6
8. Replace the cap securely after use.

### If you use more Chloramphenicol Eye Ointment than you should

If you accidentally use too much Chloramphenicol Eye Ointment or swallow your ointment, contact your doctor or go to the nearest hospital casualty department immediately. Always take the remaining ointment in the tube with the label, to enable the doctor or the hospital to identify the medicine.

### If you forget to use Chloramphenicol Eye Ointment

If you forget to take a dose, apply it as soon as possible, but if it is almost time for the next dose then miss the skipped dose and return to your normal dosing schedule.

### 4. Possible side effects

Like all medicines, Chloramphenicol Eye Ointment can cause side effects, although not everybody gets them.

Most of these side effects affect only the eye and may not last very long.

#### Serious side effects

If you notice any of the following side effects, you must stop using the ointment and contact your doctor or the nearest hospital emergency department immediately:

- Very severe side effects:
- swelling of your face and neck
  - difficulty in breathing
  - a drop in blood pressure and unconsciousness
  - high temperature
  - rashes that may be red and raised and may blister.

Less severe side effects:

- allergic reactions that affect only the eyes and can cause redness and itching, with swelling of the eyelids.

#### Other local side effects:

- burning or stinging in and around the eye.

If you have any severe or persistent side effect you should stop using the ointment and contact your doctor immediately.

When chloramphenicol is given by mouth or by injection, it may cause drops of the numbers of all types of blood cells leading to anemia, infections and easy bruising and bleeding. Very occasionally, these effects cannot be reversed and have been fatal. Although only very small amounts of chloramphenicol is absorbed from the eye ointment into your bloodstream, there have been reports of these severe effects even with eye ointment.

Tell your doctor immediately if you:

- notice that you are feeling generally weak and tired, or
- get another infection or
- notice easy bleeding or bruising during or shortly after using the ointment.

### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store Chloramphenicol Eye Ointment

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

Do not store the tube at a temperature above 25°C. Protect from light.

### Do not use this medicine for longer than 28 days after first opening the tube.

Do not use Chloramphenicol Eye Ointment after the expiry date which is stated on the tube and on the carton the tube is packed in.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

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

#### What Chloramphenicol Eye Ointment contains

- The active ingredient is chloramphenicol. The ointment contains 1% chloramphenicol which is equivalent to 10 mg of chloramphenicol per gram of ointment.
- The other ingredients are liquid paraffin and white soft paraffin as excipients.

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

Each tube of Chloramphenicol Eye Ointment contains 4 grams of ointment.

#### Marketing Authorisation Holder

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PL 14308/0018

#### Manufacturer

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Carton Profile  
Profile 1

Carton Colours CMYK  
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