CHOLFEN® EYE OINTMENT

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using CHOLFEN EYE OINTMENT?

CHOLFEN EYE OINTMENT contains the active ingredient chloramphenicol. CHOLFEN EYE OINTMENT is used to treat an eye infection called bacterial conjunctivitis, which is a bacterial infection involving the mucous membrane of the surface of the eye. For more information, see Section 1. Why am I using CHOLFEN EYE OINTMENT? in the full CMI.

2. What should I know before I use CHOLFEN EYE OINTMENT?

Do not use if you have ever had an allergic reaction to chloramphenicol or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use CHOLFEN EYE OINTMENT? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CHOLFEN EYE OINTMENT and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use CHOLFEN EYE OINTMENT?

- The dose of CHOLFEN EYE OINTMENT may be different for each person and their medical condition. Your doctor, optometrist or pharmacist will recommend the right dose for you.
- Usual recommended doses for adults and children (2 years and over):

Apply 1.5 cm of eye ointment every three hours for up to 5 days or as directed by your doctor, optometrist or pharmacist.

More instructions can be found in Section 4. How do I use CHOLFEN EYE OINTMENT? in the full CMI.

5. What should I know while using CHOLFEN EYE OINTMENT?

Things you should do	 Use CHOLFEN EYE OINTMENT as directed. Remind any doctor, dentist, optometrist or pharmacist you visit that you are using CHOLFEN EYE OINTMENT. Tell your doctor immediately if you become pregnant while you are using CHOLFEN EYE OINTMENT. 	
Things you should not do	 Do not use CHOLFEN EYE DROPS for a longer time than your doctor, optometrist or pharmacist has prescribed. Do not increase the dose or treat any other complaints without first checking with your doctor, optometrist or pharmacist. Do not use CHOLFEN EYE OINTMENT to without checking with your doctor, optometrist or pharmacist. 	
Driving or using machines	Do not drive or operate machinery until you know how CHOLFEN EYE OINTMENT affects you.	
Looking after your medicine	Store in a cool, dry place 25°C, protect from light. Discard after 4 weeks after opening.	

For more information, see Section 5. What should I know while using CHOLFEN EYE OINTMENT? in the full CMI.

6. Are there any side effects?

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

CHOLFEN® EYE OINTMENT

Active ingredient: chloramphenicol

Consumer Medicine Information (CMI)

This leaflet provides important information about using CHOLFEN EYE OINTMENT. You should also speak to your doctor or pharmacist or optometrist if you would like further information or if you have any concerns or questions about using CHOLFEN EYE OINTMENT.

Where to find information in this leaflet:

- 1. Why am I using CHOLFEN EYE OINTMENT?
- 2. What should I know before I use CHOLFEN EYE OINTMENT?
- 3. What if I am taking other medicines?
- 4. How do I use CHOLFEN EYE OINTMENT?
- 5. What should I know while using CHOLFEN EYE OINTMENT?
- 6. Are there any side effects?
- 7. Product details

Why am I using CHOLFEN EYE OINTMENT?

CHOLFEN EYE OINTMENT contains the active ingredient chloramphenicol, a synthetic antibiotic.

CHOLFEN EYE OINTMENT is used to treat an eye infection called bacterial conjunctivitis, which is a bacterial infection involving the mucous membrane of the surface of the eye.

The most common symptom is the presence of a sticky yellow-white discharge with mucus and pus (or glued eyes, especially in the morning on waking). Other symptoms include a gritty sensation in the eye, redness, irritation and watering of the eyes. The infection usually starts in one eye and then spreads to the other.

2. What should I know before I use CHOLFEN EYE OINTMENT?

Warnings

Do not use CHOLFEN EYE OINTMENT:

 if you are allergic to chloramphenicol, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction to CHOLFEN EYE OINTMENT may include irritation, pain and swelling in the eye. Skin rashes, blisters and fever may also occur.

- in children under 2 years of age unless your doctor or optometrist tells you.
- after the expiry date (EXP.) printed on the pack.
- if the packaging is torn, broken or shows signs of tampering.

Check with your doctor or pharmacist if:

- you or your family have blood disorders (e.g. anaemia) or problems with bone marrow.
- you have an injury to the cornea.

Eye preparations may inhibit the healing of the wound.

you wear contact lenses.

Contact lenses should not be worn during the course of CHOLFEN EYE OINTMENT treatment. If you wear *hard* or *disposable* contact lenses, you can start using them again after completing the course of treatment. If wearing *soft* contact lenses, you should wait 24 hours after completing a course of treatment before starting to use them again.

If you have bought this medicine without a prescription and without prior consultation from a doctor or optometrist, it is important to check the following list. Speak to your doctor or optometrist if any apply before you start to use CHOLFEN EYE OINTMENT:

- you are allergic to any other antibiotic eye ointments
- you are using other eye ointments
- you have pain within your eye (rather than just feeling sore or gritty)
- swelling around the eye
- blurred vision or sensitivity to light
- limited eye movement
- abnormal pupil (the black circle in the centre of the eye) your eye looks cloudy
- there is copious yellow-green purulent discharge that accumulates after being wiped away
- you have injured your eye or there is a foreign body in the eye
- you have been welding without eye protection immediately before your eye symptoms appeared
- you have glaucoma
- you have dry eye syndrome
- you have had similar symptoms in the past
- you have had eye surgery or laser treatment in the past six months
- you have recently travelled overseas
- you are allergic to any other medicines or any foods, dyes or preservatives
- you have surgery (including dental surgery) using a general anaesthetic
- you feel unwell
- you have any other medical conditions

If you have not told your doctor or optometrist about any of the above, tell them before you use CHOLFEN EYE OINTMENT.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. <u>Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

Your doctor, optometrist or pharmacist will advise you of the risks and benefits of taking CHOLFEN EYE OINTMENT in pregnancy and while breastfeeding.

3. What if I am taking other medicines?

Tell your doctor, optometrist or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with CHOLFEN EYE OINTMENT. These include other eye ointments.

These medicines may reduce or increase the effectiveness of CHOLFEN EYE OINTMENT, reduce its own effectiveness and/or react with CHOLFEN EYE OINTMENT resulting in untoward or sometimes dangerous side effects. Your doctor, optometrist or pharmacist has more information on medicines to be careful with or avoid while using this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CHOLFEN EYE OINTMENT.

4. How do I use CHOLFEN EYE OINTMENT?

How much and when to use

- Follow all directions given to you by your doctor, optometrist or pharmacist carefully. They may differ from the information contained in this leaflet.
- The dose of CHOLFEN EYE OINTMENT may be different for each person and their medical condition. Your doctor, optometrist or pharmacist will recommend the right dose for you.
- The usual recommended doses are:

CHOLFEN EYE OINTMENT: Adults and children 2 years and over: Apply 1.5 cm of ointment into the affected eye(s) every 3 hours. If ointment is used together with drops for day and night coverage, 1.5 cm should be applied before bedtime, while using the drops during the day. Continue treatment for at least 48 hours after the eye appears normal. Do not use for more than 5 days in total except on medical advice. For external use only.

- If the condition does not get better after 2 days, seek medical advice.
- Discard 4 weeks after opening.

How to apply CHOLFEN EYE OINTMENT

- Wash hands thoroughly before and after use
- On first use, squeeze the tube slowly at the base to expel any air
- tilt head back gently

- gently pull lower eyelid down
- squeeze 1.5 cm of eye ointment inside the lower eyelid, but do not let the tip of the tube touch the eye, eyelids or lashes
- release the eyelid slowly and close eyes gently for 1-2 minutes or blink a few times to help spread the ointment over the eye
- blot excessive ointment from around the eye with a tissue
- to minimise contamination, do not allow the tip to contact the surface of the eye
- vision may be temporarily blurred. Avoid activities that require good visual ability until vision clears.

How long to use it

CHOLFEN EYE OINTMENT should not be used for more than 5 days except on medical advice.

If you use too much CHOLFEN EYE OINTMENT

Accidental ingestion of the drug in adults is unlikely to cause any toxicity due to the low content of antibiotic, but consult your doctor or Poison Information Centre (see below).

If the eye ointment is accidentally ingested by infants or young children, immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26 in Australia) for advice, or go to Accident and Emergency at the nearest hospital. Do this even if there are no signs of discomfort or poisoning.

Urgent medical attention may be needed.

5. What should I know while using CHOLFEN EYE OINTMENT?

Things you should do

Use CHOLFEN EYE OINTMENT exactly as directed.

Tell all doctors, dentists, optometrists and pharmacists who are treating you that you are using CHOLFEN EYE OINTMENT.

Tell your doctor immediately if you become pregnant while you are using CHOLFEN EYE OINTMENT.

Always discuss with your doctor, optometrist or pharmacist any problems or difficulties during or after using this medicine.

Tell your doctor, optometrist or pharmacist if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise they may think that it was not effective and change your treatment unnecessarily.

Things you should not do

Do not use CHOLFEN EYE OINTMENT for a longer time than your doctor, optometrist or pharmacist has prescribed.

Do not increase the dose, without first checking with your doctor, optometrist or pharmacist.

Do not use this medicine to treat any other complaints without checking with your doctor, optometrist or pharmacist.

Do not give this medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Do not drive or operate machinery until you know how CHOLFEN EYE OINTMENT affects you.

CHOLFEN EYE OINTMENT may distort your vision temporarily. Make sure you know how you react to it before you drive a car, operate machinery or do anything else that could be dangerous.

Looking after your medicine

Store in a cool dry place, protected from light, where the temperature stays below 25°C.

Do not store CHOLFEN EYE OINTMENT in a bathroom or near a sink. Do not leave it in the car or on windowsills. Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

Discard 4 weeks after opening.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor, optometrist or pharmacist as soon as possible if you do not feel well while you are using CHOLFEN EYE OINTMENT.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, optometrist or pharmacist if you have any further questions.

Serious side effects		What to do
•	eye irritation or swelling that may include itching or burning skin rashes or blisters fever.	Speak to your doctor, optometrist or pharmacist immediately if you have any of these side effects.

Very serious side effects		What to do
•	allergic reactions including fever, rash, swelling of the face, lips, mouth or sore throat that may cause difficulty in swallowing or breathing.	Call your doctor straight away, or go straight to the Emergency
•	shortness of breath	Department at

Very serious side effects	What to do
swelling of the hands, feet or ankles.	your nearest hospital if you notice any of these serious side effects.

Tell your doctor, optometrist or pharmacist if you have any other problems while using CHOLFEN EYE OINTMENT even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What CHOLFEN EYE OINTMENT contains

Active ingredient	Chloramphenicol 10mg/g (1%)
(main ingredient)	
Other ingredients	Liquid paraffin
(inactive	White soft paraffin
ingredients)	Wool fat

CHOLFEN EYE OINTMENT is free from preservatives.

Do not take this medicine if you are allergic to any of these ingredients.

What CHOLFEN EYE OINTMENT looks like

CHOLFEN EYE OINTMENT is a pale yellow semisolid mass in a 5 g tube with an ophthalmic cap. (AUST R 380304).

Who distributes CHOLFEN EYE OINTMENT

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond 30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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