CHOLFEN® EYE DROPS

Consumer Medicine Information (CMI) summary

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

1. Why am I using CHOLFEN EYE DROPS?

CHOLFEN EYE DROPS contains the active ingredient chloramphenicol. CHOLFEN EYE DROPS 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 <u>1. Why am I using</u> <u>CHOLFEN EYE DROPS?</u> in the full CMI.

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

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, optometrist or pharmacist 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 DROPS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CHOLFEN EYE DROPS 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 DROPS?

The dose of CHOLFEN EYE DROPS 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):

Instil 1 or 2 drops in the affected eye(s) every two to six hours for two to three days. The interval between applications may then be increased. Treatment should be continued for at least 48 hours after the eye appears normal. Do not use for more than 5 days in total except on medical advice.

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

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

Use CHOLFEN EYE Things you should do DROPS exactly as directed. Remind any doctor, dentist, optometrist or pharmacist you visit that you are using CHOLFEN EYE DROPS. Tell your doctor immediately if you become pregnant while you are using **CHOLFEN EYE** DROPS. Do not use CHOLFEN Things you should not EYE DROPS for a do 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 DROPS without checking with your doctor, optometrist or pharmacist.
Driving or using machines	 Do not drive or operate machinery until you know how CHOLFEN EYE DROPS affects you.
Looking after your medicine	 Store unopened bottles at between 2-8°C in a refrigerator. Do not freeze. Protect from light. After opening, store at room temperature (below 25°C). Discard 4 weeks after opening. Protect from light.

For more information, see Section <u>5. What should I know while using CHOLFEN EYE DROPS?</u> 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 <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

CHOLFEN® EYE DROPS

Active ingredient: chloramphenicol

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using CHOLFEN EYE DROPS?

CHOLFEN EYE DROPS contains the active ingredient chloramphenicol, a synthetic antibiotic. CHOLFEN EYE DROPS is available as eye drops, for external use only. CHOLFEN EYE DROPS 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 DROPS?

Warnings

Do not use CHOLFEN EYE DROPS 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.
- the packaging is torn, broken or shows signs of tampering.
- after the expiry date printed on the pack.

Do not give CHOLFEN EYE DROPS to children under 2 years of age unless your doctor or optometrist tells you.

Some of the symptoms of an allergic reaction to CHOLFEN EYE DROPS may include:

- Irritation, pain and swelling in the eye
- Skin rashes, blisters
- Fever.

Check with your doctor 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 DROPS 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.

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>. Are there any side effects?

Pregnancy and breastfeeding

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

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

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 DROPS:

- you are allergic to any other antibiotic eye drops or ointments
- you are using other eye drops or 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 DROPS.

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 DROPS and affect how it works. These include other eye drops and eye ointments.

These medicines may reduce or increase the effectiveness of CHOLFEN EYE DROPS, reduce its own effectiveness and/or react with CHOLFEN

EYE DROPS 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.

4. How do I use CHOLFEN EYE DROPS?

Follow all directions given to you by your doctor, optometrist or pharmacist carefully. They may differ from the information contained in this leaflet.

How much to use

- The dose of CHOLFEN EYE DROPS may be different for each person and their medical condition. Your doctor, optometrist or pharmacist will recommend the right dose for you.
- Do not use in children under 2 years of age except on doctor's advice.
- The usual recommended doses are:

CHOLFEN EYE DROPS:

For adults and children (2 years and over): Instill 1 or 2 drops in the affected eye(s) every two to six hours for 2 to 3 days. The interval between applications may then be increased. Treatment should be continued for at least 48 hours after the eye appears normal. Do not use for more than 5 days in total except on medical advice.

 If the condition worsens or does not get better after 2 days, seek immediate medical advice.

How to apply CHOLFEN EYE DROPS

- wash hands thoroughly before and after use
- open the eye, tilt head back and look upwards
- gently pull down the lower lid to form a pouch
- approach the eye from the side and hold the bottle dropper near the lid, but do not let the tip of the dropper touch the eye, eyelids or lashes
- apply one drop into the pouch
- close the eyes (do not rub them) and try not to blink for a short time
- apply gentle pressure for about one minute with a finger to the bridge of the nose to prevent the medicine being drained from the eye
- blot excess solution around the eye with a tissue
- if instilling more than one drop in an eye, separate each installation by several minutes to avoid washing drops out of the eye
- To minimise contamination, do not allow the dropper to contact the surface of the eye.

How long to use CHOLFEN EYE DROPS

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

If you forget to use CHOLFEN EYE DROPS

If it is almost time for your next dose, skip the dose you missed and use your next dose when next due.

Otherwise, use it as soon as you remember, and then go back to using it as you would normally.

If you are unsure about whether to use your next dose, speak to your doctor, optometrist or pharmacist.

Do not try to make up for missed doses by using more than one dose at a time. This may increase the chance of you getting an unwanted side effect.

If you use too much CHOLFEN EYE DROPS

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 drops are accidentally ingested by infants or young children, you should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should 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 DROPS?

Things you should do

- Use CHOLFEN EYE DROPS exactly as directed.
- Tell all doctors, dentists, optometrists and pharmacists who are treating you that you are using CHOLFEN EYE DROPS.
- Tell your doctor immediately if you become pregnant while you are using CHOLFEN EYE DROPS.
- 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 DROPS 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 DROPS affects you.

CHOLFEN EYE DROPS 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 unopened bottles in a refrigerator, where the temperature stays between 2-8°C. Do not freeze.
 Protect from light.
- After opening, store at room temperature (below 25°C). Discard 4 weeks after opening. Protect from light.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If your doctor, optometrist or pharmacist tells you to stop using CHOLFEN EYE DROPS 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?

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.

Less serious side effects

Less 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.

Serious side effects

Serious side effects	What to do
 Allergic reactions: fever rash swelling of the face, lips, mouth 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you

Serious side effects	What to do
 sore throat that may cause difficulty in swallowing or breathing shortness of breath swelling of the hands, feet or ankles. 	notice any of these serious side effects.

Tell your doctor, optometrist or pharmacist if you notice anything else that may be making you feel unwell.

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.

Always make sure you speak to your doctor, optometrist or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What CHOLFEN EYE DROPS contains

Active ingredient (main ingredient)	chloramphenicol 5 mg/mL (0.5%)
Other ingredients	borax
(inactive ingredients)	boric acid
	hypromellose
	phenylmercuric nitrate
	water for injections

CHOLFEN EYE DROPS contains the preservative phenylmercuric nitrate (0.002% w/v).

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

What CHOLFEN EYE DROPS looks like

CHOLFEN EYE DROPS is sterile clear to slightly hazy colourless, odourless, slightly viscous liquid. Available in 10 mL plastic container (AUST R 349371).

Who distributes CHOLFEN EYE DROPS

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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CHOLFEN® is a Viatris company trade mark

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