

CHOLFEN EYE DROPS

Chloramphenicol 0.5% w/v

Consumer Medicine Information

What is in this leaflet:

- This leaflet answers some common questions about Cholfen Eye Drops.
- It does not contain all of the available information.
- It does not take the place of talking to your doctor, pharmacist or optometrist.
- All medicines have risks and benefits. Your doctor, pharmacist or optometrist has weighed the risks of you taking Cholfen Eye Drops against the benefits they expect it will have for you.
- If you have any concerns about taking this medicine, ask your doctor, pharmacist or optometrist.
- Keep this leaflet with the medicine. You may need to read it again.

1. WHAT CHOLFEN EYE DROPS IS USED FOR

Cholfen Eye Drops contains chloramphenicol, a synthetic antibiotic, as the active ingredient.

Cholfen Eye Drops is available as eye drops, for external use only.

It 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.

Ask your doctor, pharmacist or optometrist if you have any questions about why Cholfen Eye Drops has been prescribed for you. They may have prescribed it for another purpose.

2. WHEN YOU MUST NOT USE IT

- Do not use Cholfen Eye Drops if you are allergic to chloramphenicol or any of the ingredients listed at the end of this leaflet.
- Some of the symptoms of an allergic reaction to Cholfen Eye Drops may include irritation, pain and swelling in the eye. Skin rashes, blisters and fever may also occur.
- Do not give Cholfen Eye Drops to children under 2 years of age unless your doctor or optometrist tells you.
- Do not use Cholfen Eye Drops after the expiry date (EXP.) printed on the pack.
- Do not use Cholfen Eye Drops if the packaging is torn, broken or shows signs of tampering.

3. BEFORE YOU START CHOLFEN EYE DROPS

Tell your doctor if the following conditions apply to you:

- 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.
- you are pregnant or plan to become pregnant. Your doctor, optometrist or pharmacist will advise you of the risks and benefits of taking Cholfen Eye Drops in pregnancy.
- you are breastfeeding or plan to breastfeed.

Your doctor, optometrist or pharmacist will advise you of the risks and benefits of taking Cholfen Eye Drops while breastfeeding.

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.

Taking other medicines

Tell your doctor, optometrist or pharmacist if you are using any other medicines, including medicines that you buy without a

prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with Cholfen Eye Drops. 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 TO USE IT

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 it

Cholfen Eye Drops should not be used for more than 5 days except on medical advice.

If you forget to use it

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 (overdose):

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, immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) 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. WHILE YOU ARE USING IT

Things you must 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 must not do

- 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.
- 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.

6. SIDE EFFECTS

Tell your doctor, optometrist or pharmacist as soon as possible if you do not feel well while you are using Cholfen Eye Drops.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor, optometrist or pharmacist if you have any questions.

Tell your doctor, optometrist or pharmacist immediately if you notice any of the following:

- eye irritation or swelling that may include itching or burning
- skin rashes or blisters
- fever.

If any of the following happen, tell your doctor immediately or go to

Accident and Emergency at your nearest hospital:

- allergic reactions including fever, rash, swelling of the face, lips, mouth or sore throat that may cause difficulty in swallowing or breathing, shortness of breath, swelling of the hands, feet or ankles.

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

Other side effects may also occur in some people.

7. AFTER USING IT

Storage

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

Do not store Cholfen Eye Drops 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 Cholfen Eye Drops out of the reach of children. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor, optometrist or pharmacist tells you to stop using Cholfen Eye Drops or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

8. PRODUCT DESCRIPTION

What it looks like

Cholfen Eye Drops are a sterile clear solution of Chloramphenicol. Available in 10 mL plastic container containing 5 mg of Chloramphenicol per mL of eye drops.

Ingredients

Active ingredient:

chloramphenicol 5 mg/mL (0.5%)

Other ingredients:

- boric acid
- borax
- hypromellose (Methocel E4M Premium)
- water for injection
- Phenylmercuric nitrate

SPONSOR

Alphapharm Pty Ltd

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Australian Registration Number
349371, Cholfen Eye Drops 10mL

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