New Zealand Consumer Medicine Information Ocuzo

Active ingredient: chloramphenicol

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

Where to find information in this leaflet:

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

Ocuzo contains the active ingredient chloramphenicol.

Ocuzo is a topical antibiotic, which works by stopping the growth of the bacteria causing your infection.

Ocuzo is used to treat bacterial conjunctivitis. Bacterial conjunctivitis is a highly contagious bacterial infection involving the mucous membrane of the surface of the eye. The common symptoms are the presence of a sticky yellow-white discharge with mucous and pus, a gritty sensation in the eye, irritation and redness of the eye and watery eyes. The infection usually starts in one eye and then spreads to the other.

2. What should I know before I use Ocuzo?

Warnings

Do not use Ocuzo:

- 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.
- if you are allergic to any other similar medicines.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.

- after the expiry date printed on the pack.
- if the pack or if the packaging is torn or shows signs of tampering.

Do not use Ocuzo if you wear contact lenses except on medical advice.

Do not give Ocuzo to children under 2 years of age, unless on medical advice.

Check with your doctor, optometrist or pharmacist if:

- you have allergies to any other medicines, foods, preservatives or dyes
- 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 stop the healing of the wound
- you wear contact lenses; contact lenses should not be worn during the course of Ocuzo treatment.
 If you wear hard or soft 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 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 looks cloudy)
- there is copious yellow-green purulent discharge that accumulates after begin 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 had surgery (including dental surgery) using a general anaesthetic
- you feel unwell
- you have any other condition.

If you have not told your doctor, optometrist or pharmacist about any of the above, tell him/her before you start using Ocuzo.

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. Are there any side effects?</u>

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.

Your doctor, optometrist or pharmacist will advise you of the risks and benefits of using Ocuzo in pregnancy or while breastfeeding.

Ocuzo contains boron, which has been shown to reduce fertility and affect embryo development in animals.

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

These medicines may be affected by Ocuzo or may affect how well it works. You may need different amounts of your medicines, or you may need to use different medicines.

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

4. How do I use Ocuzo?

How much 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.
- Place one or two drops in the affected eye(s) every two to six hours for two to three days. The interval between doses may then be increased.
- The dose of Ocuzo may be different for different people. Your doctor or pharmacist will tell you the right amount to use.

When to use Ocuzo

- Use Ocuzo eye drops at about the same time each day. Using it at the same time each day will help you remember when to use it.
- It does not matter if you use this medicine before or after food.

How to use Ocuzo

- Wash your hands.
- Tilt your head back and pull the lower lid away from you eye to make a space.
- Drop the medicine into this space.
- Let go of your eyelid and gently close your eyes. Try not to blink.
- Keep your eyes closed for one or two minutes to allow the medicine to come into contact with the infection.

 Apply gentle pressure to the inner corner of the eye (the tear duct) for approximately one minute immediately after placing the drops in the eye. This will reduce the amount of medicine absorbed into the blood stream or other parts of the body.

To keep the medicine as germ free as possible, do not touch the tip of the bottle to any surface, including the eye.

How long to use Ocuzo

- Normally treatment is continued for at least two days 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.

If you use too much Ocuzo

If you think that you have used too much Ocuzo, or if you think an infant, young child or another adult may have accidentally swallowed Ocuzo eye drops, you/they may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26) (Australia) or the National Poisons Centre (by calling 0800 POISON or 0800 764 766) (New Zealand), 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.

5. What should I know while using Ocuzo?

Things you should do

- Use Ocuzo eye drops exactly as your doctor, optometrist or pharmacist has prescribed.
- If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor, optometrist or pharmacist.
- Stop using Ocuzo and tell your doctor, optometrist or pharmacist if irritation occurs or if you experience an allergic reaction.

Remind any doctor, dentist, optometrist or pharmacist you visit that you are using Ocuzo. If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Ocuzo eye drops.

Things you should not do

- Do not use Ocuzo for longer than your doctor, optometrist or pharmacist has prescribed.
- Do not use Ocuzo eye drops to treat any other complaints unless your doctor, optometrist or pharmacist tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop using your medicine or lower the dosage without checking with your doctor, optometrist or pharmacist.

• If you do not complete the full course prescribed by your doctor, optometrist or pharmacist, the infection may not be completely cured. The bacteria may grow again and your symptoms may return.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Ocuzo affects you.

Ocuzo generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Ocuzo may cause blurred vision in some people. If you are affected, do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

- Keep your eye drops in the bottle until it is time to use it. If you take the eye drops out of the bottle they may not keep well.
- Keep unopened bottles in the refrigerator, where the temperature stays between 2 – 8 °C. After opening, keep Ocuzo eye drops at or below 25 °C and protect from light.

Follow the instructions in the carton on how to take care of your medicine properly.

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.

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

Ocuzo eye drops should be discarded within 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?

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
Allergy-related: • Temporary itching • Burning/stinging eyes	Speak to your doctor, optometrist or pharmacist if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
 Allergic reaction: Fever Skin 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 Itching or general swelling 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
Eye-related:	
 Eye soreness, redness or swelling that was not present before treatment or that worsens after treatment 	
Other:	
 Unusual tiredness Weakness Bleeding or bruising more easily than normal 	

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 <u>www.tga.gov.au/reporting-problems</u> (for Australia) and <u>https://nzphvc.otago.ac.nz/reporting/</u> (for New Zealand). 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 Ocuzo contains

Active ingredient (main ingredient)	Chloramphenicol
Other ingredients (inactive ingredients)	Boric acid Borax
	Water or injections Sodium hydroxide and/or Hydrochloric acid

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

What Ocuzo looks like

Ocuzo eye drops are presented in an 11 mL plastic dropper bottle with a tamper-evident seal (AUST R 340136).

Who distributes Ocuzo

Ocuzo eye drops are supplied by:

AUSTRALIA: AFT Pharmaceuticals Pty Ltd 113 Wicks Road North Ryde, NSW 2113

Freephone (AU):1800 AFTPHARM (1800 238 74276)Email:customer.service@aftpharm.com

NEW ZEALAND:

AFT Pharmaceuticals Ltd Level 1, 129 Hurstmere Road Takapuna Auckland, 0622

Phone: 0800 423 823 Email: <u>customer.service@aftpharm.com</u>

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