Ciloxan®

Eye Drops 0.3%

Ciprofloxacin hydrochloride

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 or pharmacist.

1. Why am I using Ciloxan Eye Drops?

Ciloxan Eye Drops contain the active ingredient Ciprofloxacin hydrochloride. Ciloxan Eye Drops are used to treat certain types of eye infections such as bacterial keratitis (infected ulcer of cornea) and severe bacterial conjunctivitis (swelling of conjunctiva)

For more information, see Section <u>1. Why am I using</u> Ciloxan Eye Drops? in the full CMI.

2. What should I know before I use Ciloxan Eye Drops?

Do not use if you have ever had an allergic reaction to Ciloxan Eye Drops 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 <u>2. What should I know before I use Ciloxan Eye Drops?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ciloxan 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 Ciloxan Eye Drops?

- Your doctor will advise you regarding your dose.
- Use the Ciloxan Eye Drops as prescribed by your doctor.
- Consult your doctor or pharmacist if you do not understand your dose.

More instructions can be found in Section <u>4. How do I</u> <u>use Ciloxan Eye Drops?</u> in the full CMI.

5. What should I know while using Ciloxan Eye Drops?

Things you should do

 Remind any doctor, dentist, pharmacist or

	specialist you visit that you are using Ciloxan Eye Drops. Avoid excessive exposure to sunlight while on treatment with Ciloxan Eye Drops as it may cause moderate to severe phototoxicity (increased sensitivity of the skin to sun). Tell your doctor immediately if you become pregnant while using Ciloxan Eye Drops.
Things you should not do	 Do not stop using this medicine suddenly. Do not touch the dropper tip with your fingers or to your eye or any other surface. Do not wear contact lenses during treatment with Ciloxan Eye Drops.
Driving or using machines	 Ciloxan Eye Drops may cause temporary blurred vision or other eye problems. Be careful before you drive or use any

	machines or tools until you know how Ciloxan Eye Drops affect you.
Looking after your medicine	 Store below 25°C. Do not refrigerate or freeze.

For more information, see Section <u>5. What should I know while using Ciloxan Eye Drops?</u> in the full CMI.

6. Are there any side effects?

Common side effects include discomfort in eye(s), redness of the eye(s), itching, burning sensation in eye(s), feeling that something is in your eye(s), increased sensitivity to light (Photophobia)

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.

Ciloxan®

Eye Drops 0.3%

Active ingredient: Ciprofloxacin hydrochloride

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Ciloxan Eye Drops?

Ciloxan Eye Drops contain the active ingredient Ciprofloxacin hydrochloride. Ciloxan Eye Drops belongs to class of drugs called fluoroquinolone which are used to treat different types of infections caused by bacteria. Ciloxan Eye Drops are used to treat certain eye infections such as bacterial keratitis (infected ulcer of cornea, symptoms include eye pain, blurred vision, discharge from eye) and severe bacterial conjunctivitis (swelling of conjunctiva with symptoms such as eye irritation, discharge) in adults and children 12 months old and above. Ciloxan Eye Drops help to kill the bacteria that cause infection.

2. What should I know before I use Ciloxan Eye Drops?

Warnings

Do not use Ciloxan Eye Drops:

- If you are allergic to Ciprofloxacin hydrochloride, 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 other quinolone antibiotics e.g. nalidixic acid, Levaquin.
 - Symptoms of an allergic reaction may include:
 - shortness of breath, difficulty breathing,
 - swelling of the face, lips, tongue or other parts of the body rash, hives.
- If you suffer from any muscle problem or have any swelling to your tendons (strands of connective tissue between muscles and bones).

Check with your doctor if you:

 have any other medical conditions or take any medicines for any other condition.

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 if you are pregnant or intend to become pregnant.

As a precautionary measure, it is preferable to avoid Ciloxan Eye Drops during pregnancy. Your doctor will advise you regarding the possible risks and benefits of using Ciloxan Eye Drops during pregnancy.

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

Your doctor will advise you regarding the possible risks and benefits of using Ciloxan Eye Drops during breast feeding.

3. What if I am taking other medicines?

Tell your doctor 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 Ciloxan Eye Drops and affect how it works.

Tell your doctor if you take any of the following medicines:

- medicines that help to thin your blood e.g. warfarin
- medicines to prevent tissue rejection e.g. cyclosporin
- medicines such as theophylline which are used for asthma or other breathing problems
- caffeine for the treatment of migraines

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

4. How do I use Ciloxan Eye Drops?

How much to use

 Follow the instructions provided when Ciloxan Eye Drops were prescribed, including the number of days it should be taken.

Dose for bacterial conjunctivitis (corneal ulcers)

Day 1

 Put two drops into the affected eye(s) every 15 minutes for the first six hours and then two drops into the affected eye(s) every 30 minutes for the remainder of the 1st day.

Day 2

Put two drops in the affected eye(s) hourly.

Day 3 to 14

Put two drops in the affected eye(s) every four hours.

Dose for bacterial conjunctivitis

Day 1 & Day 2

 Put one drop into the conjunctival sac(s) every two hours while you are awake.

Day 3 to 7

- Put one drop every four hours while you are awake
- If you do not understand your dose consult your doctor or pharmacist.

When to use Ciloxan Eye Drops

 Ciloxan Eye Drops should be used as prescribed by your doctor.

How to use Ciloxan Eye Drops

- Sitting or lying down might make putting in your eye drops process simpler.
- Remove contact lenses if you are wearing them before putting in the eye drops.
- Shake the bottle well prior to use.

Follow the steps below to use Ciloxan Eye Drops:

Wash your hands thoroughly with soap and water.

- Before using a bottle for the first time, break the safety seal around the neck area and throw the loose plastic ring away.
- Remove the cap from the bottle.
- After the cap is removed, if a tamper evident snap collar is present and loose, remove before using the eye drops.
- Mix the contents of the bottle by inverting 5 to 10 times.
- Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).

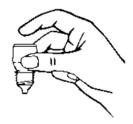


Diagram 1

- Tilt your head back, gently pull down the lower eyelid of your eye to form a pouch/pocket.
- Place the tip of the bottle close to your eye. Do not touch the tip to your eye as this may cause injury to the eye.
- Do not touch the dropper tip to eyelid or surrounding areas or any surface to avoid contamination of the dropper tip and solution.
- Release one drop into the pouch/pocket formed between your eye and eyelid by gently tapping or pressing the base of the bottle with your forefinger (see Diagrams 2 and 3).



Diagram 2



Diagram 3

- Gently close your eye. Do not blink or rub your eye.
- When your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to prevent the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body and may result in a decrease in side effects.
- This will also help to reduce the unpleasant taste sensation that some people experience when using these drops.
- If necessary, repeat the above steps for the other eye.
- You may feel a slight burning sensation in the eye shortly after using Ciloxan Eye Drops. If it persists, or is uncomfortable, contact your doctor or pharmacist.
- If you want to use any other eye drops, wait at least 5 minutes after putting Ciloxan Eye Drops in.

- It is normal for a small amount of eye drops to spill onto your cheek since your eyelids can only hold less than one drop at a time. Wipe away any spillage with a tissue.
- Replace the cap on the bottle, closing it tightly.
- Always keep the bottle tightly closed when not in use.
- Wash your hands again with soap and water to remove any residue.
- Discard the Ciloxan Eye Drops after 4 weeks after opening it.

If you forget to use Ciloxan Eye Drops

Ciloxan Eye Drops should be used as prescribed by your doctor. If you miss your dose at the usual time, put in the drops that you missed as soon as you remember and then go back to using them as recommended by your doctor.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Ciloxan Eye Drops

If you think that you have used too much Ciloxan Eye Drops, you may need urgent medical attention.

You should immediately:

phone the Poisons Information Centre

(by calling 13 11 26), 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.

If you accidentally put several Ciloxan Eye Drops in your eyes, immediately wash your eyes with warm tap water.

5. What should I know while using Ciloxan Eye Drops?

Things you should do

Use Ciloxan Eye Drops in adults and children 12 months old and above.

Avoid excessive exposure to sunlight as it may cause moderate to severe phototoxicity (increased sensitivity of the skin to sun having symptoms such as redness, itching, swelling).

Ciloxan Eye drops are for Eye use only.

Call your doctor straight away if you:

- develop any signs of allergic reaction.
- become pregnant or if you are breast feeding while using Ciloxan Eye Drops.

Avoid excessive exposure to sunlight as it may cause moderate to severe phototoxicity (increased sensitivity of the skin to sun having symptoms such as redness, itching, swelling).

Remind any doctor, dentist, pharmacist or specialist you visit that you are using Ciloxan Eye Drops.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not wear contact lenses during treatment with Ciloxan Eye Drops. Ciloxan Eye Drops contain benzalkonium chloride which may cause irritation and is known to discolour soft contact lenses.
- Do not give Ciloxan Eye Drops to anyone else, even if they seem to have the same condition as you.
- Do not use Ciloxan Eye Drops in newborn babies with conjunctivitis (eye infection caused by certain bacteria).

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Ciloxan Eye Drops affect you.

Ciloxan Eye Drops may cause temporary blurred vision or other eye problems.

If the blurred vision occurs after putting in Ciloxan Eye Drops, wait until the vision clears before driving or using machinery.

Looking after your medicine

- Store below 25°C.
- Do not refrigerate or freeze.
- Protect from the 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.

When to discard your medicine

Discard the Ciloxan Eye Drops container after 4 weeks after opening it.

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 or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Eye problems:	Speak to your doctor if
 Burning sensation in eye(s) Uncomfortable feeling in eye(s) A white precipitate in the eye(s) or crusting on the eyelid(s) Feeling that something is in your eye(s) Redness of the eye(s) Itching Eye pain Eye irritation 	you have any of these less serious side effects and they worry you.
General problems:	
 Increased drainage from the sinuses (symptoms like stuffy or runny nose, cough) Headache 	

Less serious side effects	What to do
Rhinitis (an inflammation of the inner lining of the nose with symptoms such as runny or blocked nose, sneezing, facial pressure or pain)	

Serious side effects

Serious side effects	What to do
 Allergic reaction with symptoms such as: Shortness of breath, difficulty breathing Swelling of the face, lips, tongue or other parts of the body Rash, hives Taste disturbance or loss of taste Corneal deposits (an eye condition that may cause decrease in vision) Increased sensitivity to light (Photophobia) 	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.

Serious side effects	What to do
Decrease in visionBlurred vision	
General problems:	
 Tendon (strands of connective tissue between muscles and bones) problems 	

Tell your doctor 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 or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Ciloxan Eye Drops contain

Active ingredient (main ingredient)	Ciprofloxacin hydrochloride
Other ingredients (inactive ingredients)	Sodium acetate, glacial acetic acid, mannitol, disodium edetate, hydrochloric acid and/ or sodium hydroxide (to adjust pH), purified water and benzalkonium chloride (0.06 mg/mL) as preservative.

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

What Ciloxan Eye Drops look like

Ciloxan Eye Drops is a sterile ophthalmic solution 5 mL supplied in a pack containing a plastic bottle.

Australian registration number: AUST R No. 42899

Who distributes Ciloxan Eye Drops

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone: 1800 671 203

Web Site: www.novartis.com.au

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