CILOQUIN®

Eye Drops 0.3%

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 Ciloquin?

Ciloquin contains the active ingredient Ciprofloxacin hydrochloride. Ciloquin is used to treat bacterial keratitis (infection of cornea, infected corneal ulcers) and severe bacterial conjunctivitis (eye infection cause by a bacteria) in adults and children of 12 months of age or older.

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

2. What should I know before I use Ciloquin?

Do not use if you have ever had an allergic reaction to Ciloquin 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 Ciloquin? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ciloquin 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 Ciloquin?

- Your doctor will advise you regarding your dose.
- Use the Ciloquin 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 use Ciloquin?</u> in the full CMI.

5. What should I know while using Ciloquin?

Things you should do

• Remind any doctor, dentist or pharmacist

	you visit that you are using Ciloquin. Avoid excessive exposure to sunlight while on treatment with Ciloquin Eye Drops as it may cause increased sensitivity to sunlight for your skin or eyes. Tell your doctor immediately if you become pregnant while using Ciloquin Eye Drops.
Things you should not do	 Do not stop using this medicine suddenly. Do not use Ciloquin eye drops to treat other problems unless your doctor or pharmacist tells you to. Do not wear contact lenses while on treatment with Ciloquin Eye Drops.
Driving or using machines	 Ciloquin may cause blurred vision or other eye problems in some people after using the eye drops.

	 If the blurred vision occurs, wait until vision clears before driving or using machinery.
Looking after your medicine	 Store below 25°C. Do not refrigerate or freeze the eye drops.

For more information, see Section <u>5. What should I know while using Ciloquin?</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, pain in eye(s), swelling in eye(s), Allergic reactions (such as hives, shortness of breath itching or swelling on face, lips or other parts of body).

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.

Ciloquin®

Active ingredient(s): ciprofloxacin hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ciloquin. 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 Ciloquin.

Where to find information in this leaflet:

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

1. Why am I using Ciloquin?

Ciloquin contains the active ingredient Ciprofloxacin hydrochloride. Ciprofloxacin hydrochloride is a fluoroquinolone antibiotic which is used to treat different types of bacterial infections.

Ciloquin is used to treat bacterial keratitis (infection of cornea, infected corneal ulcers) and severe bacterial conjunctivitis (eye infection cause by a bacteria) in adults and children of 12 months of age or older. Ciloquin helps to destroy the bacteria that causes the eye infections.

2. What should I know before I use Ciloquin?

Warnings

Do not use Ciloquin if:

- you are allergic to Ciprofloxacin hydrochloride, or any of the ingredients listed at the end of this leaflet.
- you are allergic to other quinolones antibiotics (e.g. nalidixic acid)

Symptoms of allergic reactions may include:

- loss of consciousness
- tingling sensation
- cardiovascular collapse (having symptoms such as chest pain, dizziness, extreme tiredness or shortness of breath)
- swelling on face, lips or other parts of body
- hives
- itching
- shortness of breath

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

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have tendinitis (inflammation of tendon)

Avoid excessive exposure to sunlight while on treatment with Ciloquin Eye Drops as it may cause increased sensitivity to sunlight for your skin or eyes.

Do not wear contact lenses while on treatment with Ciloquin Eye Drops as it may cause eye irritation and may discolour soft contact lenses.

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 preventive measure, avoid the use of Ciloquin during pregnancy.

Your doctor will advise you regarding the possible risks and benefits of using Ciloquin 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 Ciloquin during breastfeeding.

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 Ciloquin and affect how it works.

Tell your doctor if you are taking any of the following medications:

- drugs that are used as blood thinners e.g. warfarin
- medicines used to prevent tissue rejection e.g. cyclosporin
- medicines that are used to treat asthma or breathing problems (e.g. theophylline)
- medicines used to treat migraines (e.g. caffeine)

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

4. How do I use Ciloquin?

How much to use

For corneal ulcers the recommended dose is:

Day 1:

- Put 2 drops into the affected eye (s) every 15 minutes for the first six hours.
- Put 2 drops into the affected eye(s) every 30 minutes for the remainder of the first day

Day 2:

Put 2 drops in the affected eye(s) each hour.

Day 3 to Day 14:

- Put 2 drops in the affected eye(s) every four hours.
- Your doctor may continue your treatment after 14 days if a favorable outcome is not achieved.
- Follow the instructions provided when Ciloquin was prescribed, including the number of days it should be taken.
- Your doctor will advise you regarding your dose.
- Consult your doctor if you do not understand your dose.

For bacterial conjunctivitis the recommended dose is:

Day 1 to Day 2:

 Put 1 drop into the conjunctival sac(s) every 2 hours while awake.

Day 3 to Day 7:

- Put 1 drop every 4 hours while awake.
- Your doctor will advise you regarding your dose.
- Consult your doctor if you do not understand your dose.

When to use Ciloquin

Ciloquin should be used as prescribed by your doctor.

How to use Ciloquin

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

Follow below steps to use Ciloquin 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.
- Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).

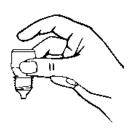


Diagram 1

- 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 any surface to avoid contamination.
- 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).

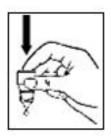


Diagram 2



Diagram 3

- 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.
- 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.
- It is normal for a small amount of the eye drop 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.
- You may feel a slight burning sensation in the eye shortly after using Ciloquin Eye Drops.
- Contact your doctor immediately if the burning persists for longer time.
- After using Ciloquin Eye Drops wait at least 5 minutes before instilling any other eye drops.
- Do not use the eye drops after 4 weeks after opening it.
- Discard any remaining solution after four weeks and open a new bottle every four weeks.

If you forget to use Ciloquin

Ciloquin should be used as prescribed by your doctor. If you miss your dose at the usual time, instill the drops that you missed as soon as you remember and then go back to the dosing 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 do not understand your dose, talk to your doctor or pharmacist.

If you use too much Ciloquin

If you think that you have used too much Ciloquin, you may need urgent medical attention.

If you accidently put too much of Ciloquin Eye Drops in your eye(s), immediately wash your eye(s) with warm tap water.

If you have accidently swallowed the contents of a bottle of Ciloquin 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.

5. What should I know while using Ciloquin?

Things you should do

Call your doctor straight away if you:

- notice any signs of allergic reactions such as shortness of breath, hives, itching or swelling on face, lips or other parts of body.
- become pregnant while using Ciloquin eye drops.

Keep the Ciloquin eye drops away from children.

Avoid excessive exposure to sunlight while on treatment with Ciloquin Eye Drops as it may cause increased sensitivity to sunlight for your skin or eyes.

Use the Ciloquin Eye Drops as prescribed by your doctor.

Remind any doctor, dentist or pharmacist you visit that you are using Ciloquin.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not give Ciloquin eye drops to anyone else, even if they seem to have the same condition as you.

 Do not use Ciloquin eye drops to treat other problems unless your doctor or pharmacist tells you to.

Driving or using machines

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

Ciloquin may cause blurred vision or other visual problems in some people after using the eye drops.

If the blurred vision occurs, wait until vision clears before driving or using machinery.

Looking after your medicine

- Store below 25°C.
- Do not refrigerate or freeze the eye drops.
- 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.

When to discard your medicine

Discard the 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: Burning sensation in eye(s) Eye(s) discomfort White crystalline precipitates (medication residue) or crusting on the eyelid(s) 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
 Foreign body sensation or feeling of something in the eye(s) 	
Redness of the eye(s)	
Itching	
Pain in eye(s)	
Swelling in eye(s)	
Discharge from eye(s)	
Dry eye(s)	
Vision decrease	
Blurred vision	
 Numbness in or around the eye(s) 	
General problems:	
Feeling sick	
Headache	
• Dizziness	

Serious side effects

Serious side effects	What to do
 General problems: Allergic reactions having symptoms such as hives, shortness of breath, itching or 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you

Serious side effects What to do swelling on face, lips or notice any of these other parts of the body. serious side effects. Cardiovascular collapse (having symptoms such as chest pain, dizziness, extreme tiredness or shortness of breath) Loss of consciousness Tingling Tendon disorder (Swelling of tendons, ruptures of the shoulder, hand, Achilles tendon) Increased drainage from the sinuses Skin rash Ear pain Eye problems: Eyelid(s) crusting and swelling (Blepharitis) Keratitis (a disease of the cornea) Uncomfortable sensitivity to light Corneal staining, swelling, Corneal deposits or irregular appearance of cornea

Serious side effects	What to do
 Excessive opening of blood vessels of eye causing reddening of white portion of the eye (sclera) (ocular hyperaemia) 	
Nervous system problems:	
 Taste problems or loss of taste 	

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 Ciloquin contains

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 Ciloquin looks like

Ciloquin Eye Drops is a sterile ophthalmic solution, multiple-dose product, supplied in a pack containing one 5mL dropper bottle with screw cap.

Tamper evidence is provided with a safety seal around the neck area of the bottle.

Australian registration number

AUST R No. 66567

Who distributes Ciloquin

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

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