

CILOXAN[®] Eye Drops 0.3%

ciprofloxacin hydrochloride

CONSUMER MEDICINE INFORMATION

What Is In This Leaflet

Read this leaflet carefully before you start to use CILOXAN[®] Eye Drops.

This leaflet has been written to answer some common questions about CILOXAN[®] Eye Drops. It does not contain all of the available information and does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. In deciding to prescribe CILOXAN[®] Eye Drops for you, your doctor has weighed the potential risks and the expected benefits of using this medicine.

The information in this leaflet applies to CILOXAN[®] Eye Drops only. This information does not apply to similar products, even if they contain the same ingredients.

If you have any concerns about using CILOXAN[®] Eye Drops ask your doctor or pharmacist.

Keep this leaflet with your medicine.
You may need to read it again.

What CILOXAN[®] Eye Drops Is Used For

CILOXAN[®] Eye Drops contain the active ingredient ciprofloxacin hydrochloride. Ciprofloxacin hydrochloride is a “fluoroquinolone” antibiotic.

CILOXAN[®] Eye Drops are used to treat certain types of eye infections caused by bacteria. Your doctor will usually prescribe CILOXAN[®] Eye Drops because you have either:

- an ulcer on the surface of your eye (corneal ulcer),
- or
- a type of eye infection called bacterial conjunctivitis.

Before You Use CILOXAN[®] Eye Drops

When you must not use it

Do not use Ciloxan[®] Eye Drops if:

- You are allergic to ciprofloxacin, any other “quinolone” antibiotics (e.g. nalidixic acid) or to any of the other ingredients in Ciloxan[®] Eye

Drops (these are listed under “Product Description”);

Some of the 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.

Do not use Ciloxan[®] Eye Drops if:

- the safety seal around the closure and neck area is broken
- the bottle/packaging shows signs of tampering
- the expiry date on the bottle/carton has passed.

If you use this medicine after the expiry date has passed, it may not work.

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses. The preservative in CILOXAN[®] Eye Drops (benzalkonium chloride) may be deposited in soft contact lenses. CILOXAN[®] Eye Drops may cause irritation or discolour soft contact lenses. Contact lens wear is not recommended during treatment of an eye infection and therefore not recommended during treatment with CILOXAN[®] Eye Drops .

Do not use CILOXAN[®] Eye Drops in children under 12 months of age.

If you are not sure whether you should start using Ciloxan[®] Eye Drops, talk to your doctor.

Before you start to use it

Tell your doctor if you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you use Ciloxan[®] Eye Drops.

Using other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including other eye drops or ointments, and any other medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Ciloxan[®] Eye Drops may interfere with each other or add to the effects of Ciloxan[®] Eye Drops. These include:

- medicines to thin your blood (e.g. warfarin)
- medicines to prevent tissue rejection (e.g. cyclosporin)
- theophylline for asthma or breathing problems
- caffeine for the treatment of migraines.

These medicines may be affected by Ciloxan[®] Eye Drops, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using Ciloxan[®] Eye Drops.

How to use CILOXAN[®] Eye Drops

Carefully follow all directions given to you by your doctor and pharmacist. They may differ from the information contained in this leaflet.

If you are being changed from one medicine to another, follow your doctor's instructions carefully as to when to stop the medicine and when to start the new eye drops.

If you do not understand the instructions on the carton / bottle, ask your doctor or pharmacist for help.

How much to use The usual dose of CILOXAN[®] Eye Drops depends on the *type* and *severity* of eye infection that is being treated.

The usual dose for corneal ulcers is:

- Day 1: 2 drops in the affected eye(s) every 15 minutes for the first 6 hours.
2 drops in the affected eye(s) every 30 minutes for the remainder of the first day.
- Day 2: 2 drops in the affected eye(s) every 60 minutes.
- Days 3-14: 2 drops in the affected eye(s) every 4 hours.

Your doctor may continue your treatment with CILOXAN[®] Eye Drops until the surface of your eye (cornea) is completely healed.

The usual dose for bacterial conjunctivitis is:

- Days 1 & 2: 1 drop in the affected eye(s) every 2 hours while you are awake.
- Days 3-7: 1 drop in the affected eye(s) every 4 hours while you are awake.

Your doctor will tell you how many drops you need to use each day. These dosing instructions will be printed on the label your pharmacist adds.

How to use it

It is important to use Ciloxan[®] exactly as your doctor or pharmacist has told you. If you use the drops less often than prescribed, they may not work as well and the eye problem may not improve. Using the drops more often than prescribed may not improve the eye problem any faster and may cause increased side effects.

If you are wearing soft contact lenses, remove them before putting the drops in your eye.

Follow these steps to use the Eye Drops:

1. Wash your hands thoroughly with soap and water.
2. Immediately before using a bottle for the first time, break the safety seal around the neck area and throw the loose plastic ring away.
3. Shake the bottle.
4. Remove the cap from the bottle.
5. Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).



Diagram 1

6. While tilting your head back, gently pull down the lower eyelid of your eye to form a pouch/pocket.
7. Place the tip of the bottle close to your eye. Do not let it touch your eye.
8. 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

9. Close your eye. Do not blink or rub your eye.
10. While 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 stop 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 reduce the unpleasant taste sensation that some people experience when using these drops.
11. If necessary, repeat the above steps for the other eye.

12. Your eyelids can only hold less than one drop at a time, so it is normal for a small amount of the eye drop to spill onto your cheek. You should wipe away any spillage with a tissue.
13. Replace the cap on the bottle, closing it tightly.
14. 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 CILOXAN[®] Eye Drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

Be careful not to touch the dropper tip against your eye, eyelid or anything else. This will help to prevent your eye drops becoming dirty or contaminated.

If you have trouble knowing whether you have placed your drops correctly, you may want to store them in the fridge. Some people find it easier to feel the drops in the eye if they are cold.

After using CILOXAN[®] Eye Drops wait at least 5 minutes before putting any other eye drops in your eye(s).

When to use it

Use CILOXAN[®] Eye Drops every day, at about the same times each day unless your doctor tells you otherwise. Using your eye drops at the same times each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops.

How long to use it

As CILOXAN[®] Eye Drops start to kill the bacteria that are causing the infection your eye(s) will feel better. It is very important, however, that you continue to use CILOXAN[®] Eye Drops for the full treatment period as directed by your doctor to ensure that the infection does not return.

If you are unsure about when to stop using CILOXAN[®] Eye Drops you should talk to your doctor or pharmacist.

If you forget to use it

If you forget to use CILOXAN[®] Eye Drops you should put the drops that you missed in 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 that you have missed and continue to take them as recommended.

Do not use double the amount to make up for the dose that you missed. Using multiple doses may cause unwanted side effects.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

If you are having trouble remembering to use the medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you accidentally put several drops in your eye(s) immediately rinse your eye(s) with warm water.

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of CILOXAN[®] Eye Drops, immediately telephone your doctor or Poisons Information Centre.

If Australia call 13 11 26; in New Zealand call 0800 POISON or 0800 764 766 for advice, or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While You Are Using CILOXAN[®] Eye Drops

Things you must do

- **Tell your doctor if, for any reason, you have not used CILOXAN[®] Eye Drops exactly as prescribed. Otherwise your doctor may think that the eye drops were not effective and change the treatment unnecessarily.**
- Tell your doctor if you become pregnant while you are using CILOXAN[®] Eye Drops.
- Tell your doctor and pharmacist that you are using CILOXAN[®] Eye Drops before you start taking any other medicines.

Things you must not do

- **Do not use CILOXAN[®] Eye Drops to treat other complaints unless your doctor tells you to.**
- Do not let children handle CILOXAN[®] Eye Drops.
- Do not stop using CILOXAN[®] Eye Drops without first asking your doctor.
- Do not give this medicine to anyone else, even if they appear to have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how CILOXAN[®] Eye Drops affects you and your vision. As with any eye medicine, temporary blurred vision or other visual disturbances may affect the ability to drive or use machinery in some people. If blurred vision occurs when you use your drops, wait until your vision is clear before driving or operating machinery.

Side Effects

All medicines can 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.

Tell your doctor as soon as possible if you do not feel well while you are using CILOXAN[®] Eye Drops.

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

Most side effects from CILOXAN[®] Eye Drops occur in, or around, the eye. These include:

- Redness, itching, irritation, pain, swelling or discomfort in or around the eye(s) and/or eyelids;
- A white precipitate in the eye(s) or crusting on the eyelid(s);
- Excess tear production or discharge from the eye(s);
- Dry eye(s);
- Staining, swelling or irregular appearance of the front of the eye(s) (cornea);
- Flaking skin of the eyelids
- A numb sensation in or around the eye(s);
- Tired eyes
- Allergic reactions;
- A feeling that something is in your eye(s);
- Decreased or blurred vision; Double vision
- Sensitivity to light.

These are the most common side effects of your medicine. They are usually mild and short lived.

Occasionally some people notice unwanted effects in the rest of their body as a result of using CILOXAN[®] Eye Drops. These effects may include:

- Bad taste in the mouth following the use of CILOXAN[®] Eye Drops;
- Nausea;
- Diarrhoea or abdominal pain
- Headache;
- Dizziness
- Ear pain
- Increased drainage from the sinuses.
- Skin inflammation

If you are elderly or if you are taking inflammation-inhibiting products similar to cortisone, you have a higher risk of getting tendon problems during treatment with CILOXAN[®] Eye Drops. If this occurs, stop treatment and immediately consult your doctor.

If any of the following happen, stop using the CILOXAN[®] Eye Drops and tell your doctor immediately or go to Accident & Emergency at your nearest hospital:

- skin rash
- swelling of face, hands or feet
- wheezing, difficulty in breathing
- shortness of breath (dyspnoea, heart failure)
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash.

These hypersensitivity reactions can be very serious side effects. You may need urgent medical attention or hospitalization. These side effects are very rare.

Let your doctor know if you notice any unwanted effects while using CILOXAN[®] Eye Drops, even if they do not appear in the lists above.

After Using CILOXAN[®] Eye Drops

Storage

Store CILOXAN[®] Eye Drops in a cool dry place, where the temperature stays below 25°C. It is not necessary to store the Eye Drops in the refrigerator, but it is acceptable if you prefer to instil cold drops. Do not freeze.

Do not store CILOXAN[®] Eye Drops or any other medicine in the car, in the bathroom or in other warm, damp places. Heat and dampness can destroy some medicines.

Do not leave the top off the bottle for any length of time, to avoid contaminating the eye drops.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Write the date on the bottle when you open the eye drops and throw out any remaining solution after four weeks. Eye drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should then be used.

If your doctor tells you to stop using CILOXAN[®] Eye Drops or they have passed their expiry date, ask your pharmacist what to do with the remaining solution.

Product Description

What it looks like

CILOXAN[®] Eye Drops is a sterile liquid supplied in a pack containing one 5mL dropper bottle (DROP-TAINER[®]) with screw cap.

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

Ingredients

Active ingredients(s):

- Ciprofloxacin hydrochloride (equiv. to 3mg/mL ciprofloxacin)

Inactive ingredients:

- Benzalkonium chloride (0.06mg/mL; preservative)
- Sodium acetate
- Acetic acid
- Mannitol
- Disodium edetate
- Purified water

Supplied By

In Australia this product is supplied by:

Alcon Laboratories (Australia) Pty Ltd
25 Frenchs Forest Road East
FRENCHS FOREST NSW 2086

In New Zealand this product is distributed by:

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c/o Pharmaco NZ Limited
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