

Package Leaflet: Information for the User

Ciloxan® 3 mg/ml ear drops, solution ciprofloxacin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ciloxan is and what it is used for
2. What you need to know before you use Ciloxan
3. How to use Ciloxan
4. Possible side effects
5. How to store Ciloxan
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1. What Ciloxan is and what it is used for

Ciloxan contains **ciprofloxacin**, a **quinolone antibiotic** that is effective against many of the types of germs that cause bacterial infection in your ear(s).

It is used to treat acute infections of the outer ear (otitis externa or “swimmer’s ear”) in adults and children aged 1 year and above.

2. What you need to know before you use Ciloxan

Do not use Ciloxan

- If you are **allergic** to ciprofloxacin or any other quinolones or to any of the other ingredients of this medicine (listed in Section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Ciloxan.

- Only use CILOXAN in your ears.
- If you notice the first signs of a skin rash or any other allergic reaction, including hives, itching or breathing problems, stop treatment and immediately contact your doctor. If you have a serious allergic reaction then you may need emergency treatment.
- Avoid **excessive sunlight** while using Ciloxan.
- As with any antibiotic, use of Ciloxan for a long time may lead to other infections. If your symptoms get worse or suddenly return, tell your doctor.
- If you feel pain, swelling or inflammation of the tendons while or shortly after taking this medicine, stop treatment and contact your doctor.
- If you are elderly or if you are taking medicines called ‘corticosteroids’ used to treat conditions such as pain and inflammation, asthma or skin problems then, you have a higher risk of getting tendon problems during treatment with Ciloxan. If you experience any inflammation or an inflammatory condition, stop treatment and immediately consult your

doctor.

Talk to your doctor or pharmacist before using Ciloxan if you are not sure.

Other Medicines and Ciloxan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

- Quinolone antibiotics, such as Ciloxan, can react with some other commonly used medicines, such as those containing warfarin (blood thinner), theophylline (used to treat asthma) and caffeine. It can also react with medicines containing ciclosporin (used to prevent transplant rejection).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

There are no known effects of Ciloxan on the ability to drive or use machines.

Ciloxan contains Benzalkonium chloride

This medicine contains 0.3 mg Benzalkonium chloride in each 5 ml which is equivalent to 0.06 mg/ml. Benzalkonium chloride may cause local irritation.

3. How to Use Ciloxan

Always use this medicine exactly as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Do not exceed the dose prescribed by your doctor.

The recommended dose for adults is 4 drops in the ear canal, twice a day - morning and evening.

Use in children

Children (over 1 year of age): 3 drops in the ear canal, twice a day - morning and evening.

Remove the loose collar from the cap when the bottle is first opened. Your doctor will tell you how long your treatment with Ciloxan will last. To make sure that the infection does not return, **do not stop treatment early**, even if your ear(s) feel better.

As with any antibiotic, **use of Ciloxan for a longer time than advised** may lead to other infections.

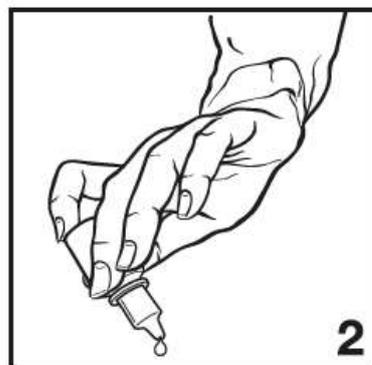
Only use Ciloxan in both ears if your doctor told you to.

Instructions for use

- Wash your hands.
- Warm the bottle just before use by holding it in the palm of your hand for a few minutes. This will prevent any unpleasant sensation associated with the cold solution coming into contact with the ear.
- Take the bottle and twist off the cap.
- Hold the bottle pointing down, between your thumb and middle finger.
- Lie down on your side with the infected ear facing up (Picture 1).
- Bring the bottle tip close to the ear canal.
- **Do not touch** the fingers or the ear or any other surfaces **with the tip of the bottle** as it could

infect the drops.

- Gently press on the base of the bottle to release one drop of Ciloxan at a time (Picture 2).
- Do not squeeze the bottle. A gentle press on the bottom is all that it needs.
- Stay on your side for around five minutes to help penetration of the drops into the ear.
- If both of your ears are infected, repeat the steps for the other ear.
- Put the bottle cap back on firmly immediately after use.



- **If a drop misses your ear, try again.**

If you use more Ciloxan than you should, do not put in any more drops until it is time for your next regular dose.

If you forget to use Ciloxan, do not worry, just use it as soon as you remember and then go back to your regular routine. Do not use a double dose to make up.

If you have accidentally swallowed Ciloxan, contact your doctor. However, no serious complications are expected.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

STOP using Ciloxan and seek medical help immediately if you experience any skin rash or any other allergic (hypersensitivity) reaction including:

- hives
- itching
- breathing problems.

You may experience some or all of the following effects in your ear(s):

Uncommon (may affect up to 1 in 100 people):

- weeping ear
- ear pain
- ear congestion
- itchy ear.
- ringing in the ear.

You may also experience effects in other areas of your body including:

Uncommon (may affect up to 1 in 100 people):

- headache
- skin inflammation
- fever.

When used in the ear, the ingredients rarely cause redness, rash and itching. However, when applied to the skin, Ciloxan may cause: rash, skin disease, peeling skin, serious inflammatory disease and skin eruptions, including wheals.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ciloxan

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and carton after 'EXP' The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

Stop using the bottle 4 weeks after first opening, to prevent infections.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ciloxan contains

- The active substance is ciprofloxacin. Each mL of solution contains 3 mg of ciprofloxacin (as hydrochloride).
- The other ingredients are benzalkonium chloride, acetic acid (E260), sodium acetate (trihydrate) (E262), mannitol (E421), disodium edetate, hydrochloric acid and/or sodium hydroxide (to adjust pH) and purified water.

What Ciloxan looks like and contents of the pack

Ciloxan is a clear, colourless to pale yellow liquid (a solution) supplied in a pack containing a 5 ml plastic bottle with a white screw cap.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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