

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 your 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
6. Contents of pack and other information

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”).

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 (listed in Section 6).

Warnings and precautions

- Only use CILOXAN in your ears.
- 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 notice the first signs of a skin rash or any other allergic reaction, including hives, itching, breathing problems, stop treatment and immediately contact your doctor. If you have a serious allergic reaction then you may need emergency treatment.
- If you feel pain, swelling or inflammation 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.
- Avoid **excessive sunlight** while using CILOXAN.

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

Children

- Only use CILOXAN in children younger than 1 year if explicitly prescribed by your doctor

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 cyclosporin (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 taking 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 described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is

Adults: 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.

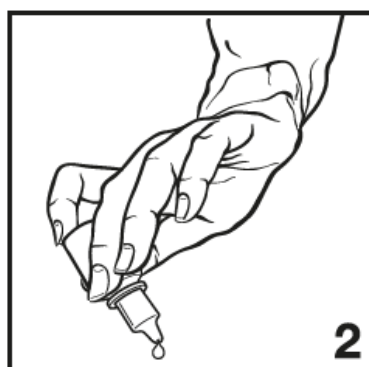
Only use CILOXAN in both ears if your doctor told you to.

Instructions for use

- Wash your hands.
- Hold the bottle in your hand(s) for several minutes to warm the ear drops to avoid the dizziness that may result from the instillation of a cold solution into the ear canal, then shake the bottle well before use.
- 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 side - The patient should remain on his/her side for at least 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 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 use more CILOXAN than you should**, rinse it all out with lukewarm water. Do not put in more drops until it is time for your next dose.
- **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 CILOXAN, ask your doctor or pharmacist.

4. Possible Side effects

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

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

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

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

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

Uncommon (may affect up to 1 in every 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 HPRÁ 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 refrigerate or freeze.

Do not use the drops after the expiry date (marked 'EXP') on the bottle and the carton. The expiry date refers to the last day of that month.

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 3 mg/ml.
- 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

Novartis Ireland Limited,
Vista Building,
Elm Park,
Merrion Road,
Ballsbridge,
Dublin 4,
Ireland

Manufacturer

Novartis Pharma GmbH
Roonstrasse 25,
90429 Nürnberg,
Germany

This leaflet was last revised in 11/2021.