

CILOXAN™

0.3% Ear Drops

ciprofloxacin hydrochloride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Please read this leaflet carefully before you use Ciloxan Ear Drops.

This leaflet answers some common questions about Ciloxan Ear Drops. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

You can also download the most up to date leaflet from www.novartis.com.au.

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you using Ciloxan Ear Drops against the risks this medicine could have for you.

The information in this leaflet applies to Ciloxan only. This information does not apply to similar products, even if they contain the same ingredients.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Ciloxan is used for

Ciloxan is used to treat certain types of ear infections caused by bacteria. Your doctor will usually prescribe this medicine because you have a middle ear infection.

Ciloxan contains ciprofloxacin hydrochloride, an antibiotic that belongs to a group of medicines called fluoroquinolones. This antibiotic works by killing the bacteria that are causing your infection.

Ciloxan will not work against infections caused by viruses, such as colds or the flu, or infections caused by fungus.

Before prescribing Ciloxan, the doctor will have examined your ear(s) and decided that Ciloxan is the right medicine for you.

Your doctor may have prescribed Ciloxan for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Ciloxan Ear Drops are only available on a doctor's prescription.

Use in children

Do not use Ciloxan Ear Drops in children under 12 months of age.

The safety and effectiveness of Ciloxan Ear Drops in this age group has not been established.

Before you use Ciloxan

When you must not use it

Do not use Ciloxan Ear Drops if you have an allergy to:

- Ciprofloxacin
- Any other "quinolone" antibiotics e.g. nalidixic acid
- Any of the other ingredients in Ciloxan Ear Drops that 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 this medicine after the expiry date printed on the pack or bottle, or if the seal around the pack is broken or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

If this medicine has expired or is damaged, return to your pharmacist for disposal.

Do not use Ciloxan Ear Drops just before having a bath, shower or going swimming. If you do, you may reduce the effectiveness of this medicine.

If you are not sure whether you should start using Ciloxan, 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 have or have had any medical conditions.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the possible risks and benefits of using Ciloxan during pregnancy.

Tell your doctor if you are breastfeeding.

Your doctor will discuss the possible risks and benefits of using Ciloxan when you are breastfeeding.

If you have not told your doctor about any of the above, tell him/ her before you use Ciloxan.

Using or taking other medicines

Tell your doctor or pharmacist if you are using or taking any other medicines, including other ear drops or any other medicines that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and ciprofloxacin may interfere with each other.

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

- 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.

Your doctor and pharmacist will have more information on medicines to be careful with or avoid while using this medicine.

How to use Ciloxan

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 this medicine and when to start the new ear 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 in adults and children (one month and over) is five drops of Ciloxan in the affected ear(s), twice each day for nine days.

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 puts on the bottle or carton.

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

your doctor has advised, your medicine may not work as well and your ear infection may not improve. If you use the drops more often than your doctor has advised, your ear infection may not improve any faster and this may lead to increased side effects.

Before opening the bottle for the first time, make sure the safety seal joining the cap to the bottle is not broken. If it is, do not use the bottle and return it to your pharmacist.

To open a new bottle of Ciloxan, break the safety seal by removing the cap from the bottle. Remove the lower portion of the safety seal and discard.

Follow these steps to use the ear drops:

1. Wash your hands thoroughly with soap and water.
2. Shake the bottle.
3. Remove the cap from the bottle.
4. Hold the bottle upside down in one hand between your thumb and middle finger.
5. Tilt your head to one side so that the affected ear is facing up. This may be easier in the sitting or lying down position.
6. Place the dropper tip close to, but not touching, your ear and gently tap or press the base of the bottle with your forefinger to release drops.

7. Hold the head in the same position for about one minute. This will help the drops to reach deeper into the ear.
8. Repeat the above steps for the other ear if necessary.
9. Place the cap on the bottle and close it tightly.
10. Wash your hands again with soap and water to remove any residue.

There might be a slightly unpleasant feeling as the drops flow all the way into the ear. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

Be careful not to touch the dropper tip against your fingers or the ear, or anything else.

This will help prevent the ear drops becoming dirty or contaminated.

When to use it

Use Ciloxan, at about the same time every day unless your doctor tells you otherwise.

Using your ear drops at the same time each day will have the best effect on your ear infection. It will also help you remember when to use it.

How long to use it

Continue using your medicine for as long as your doctor tells you.

As Ciloxan Ear Drops start to kill the bacteria that are causing the infection in your ear(s) you will start to feel better.

However, it is very important that you continue to use Ciloxan Ear Drops for the full treatment period advised by your doctor to ensure that the infection does not return.

If you are unsure about when to stop using Ciloxan Ear Drops you should talk to your doctor or pharmacist.

If you forget to use it

If it is almost time for your next drop(s), skip the drop(s) you missed and use your next drop(s) when you are meant to.

Otherwise, use the drop(s) as soon as you remember, and then go back to using them as you would normally.

Do not use a double dose to make up for the drop(s) that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you accidentally put too many Ciloxan drops in your ear(s) immediately rinse your ear(s) with warm water.

If you think that you or someone else has swallowed any, or all, of the contents of Ciloxan, or used too many drops, immediately telephone your doctor or the Poisons Information Centre on 13 1126 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

Things you must do

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

Tell your doctor if, for any reason, you have not used Ciloxan Ear Drops exactly as prescribed. Otherwise your doctor may think that the ear drops were not effective and change the treatment unnecessarily.

If you become pregnant while you are using this medicine, tell your doctor immediately,

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are using Ciloxan Ear Drops.

Tell all the doctors, dentists and pharmacists who are treating you that you are using Ciloxan.

Things you must not do

Do not use Ciloxan Ear Drops to treat other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they appear to have the same condition as you.

Do not stop using Ciloxan Ear Drops or lower the dose without first asking your doctor.

Do not let children handle Ciloxan Ear Drops.

Things to be careful of

Be careful driving or operating machinery until you know how Ciloxan affects you and your hearing.

This medicine may cause dizziness or light-headedness in some people. Make sure you know how you react to the ear drops before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If you drink alcohol, dizziness or light-headedness may be worse.

Be careful of sun exposure.

These medicines cause some people to sunburn more readily.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Ciloxan.

This medicine helps most people with middle ear infection, but it may have unwanted side effects in a few people. 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.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- bad taste in the mouth following the use of Ciloxan
- ear stinging or discomfort following use of Ciloxan
- headache
- ear pain
- vertigo and transient dizziness
- ear itching (pruritus)
- inflammation, itching and scaling of the outer ear (fungus infection of the ear; otomycosis)
- fever
- weeping ear
- ear congestion.

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

If any of the following happen, stop using Ciloxan and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- skin rash
- swelling of the face, hands or feet
- wheezing, difficulty in breathing
- 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 hospitalisation. These side effects are very rare.

If you are over 65 years of age and taking inflammatory inhibiting medicines similar to cortisone, you have a higher risk of getting tendon problems during treatment with Ciloxan Ear Drops. If this occurs, stop treatment and immediately consult your doctor.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Ciloxan

Storage

Keep Ciloxan Ear Drops in a cool dry place, where the temperature stays below 25C. Do not refrigerate or freeze.

Cold ear drops may hurt your ear(s) or cause temporary dizziness.

Protect from light.

Do not store Ciloxan Ear Drops or any other medicine in the car, the bathroom or any other warm, damp place.

Heat and dampness can destroy some medicines.

Do not carry the ear drops in the pockets of your clothes.

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

Do not use the ear drops if the solution is discoloured brown.

Keep it out of the sight and reach of children.

Disposal

Write the date on the bottle when you first open the ear drops and throw out any remaining solution after four weeks.

Ciloxan contains 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 ear infection. A new bottle should be opened.

If your doctor tells you to stop using Ciloxan or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Ciloxan Ear Drops are a sterile liquid that comes in a 1 mL, 2.5 mL or a 5 mL oval dropper bottle (DROP-TAINER™) with a screw cap. The safety seal must be removed before use.

Ingredients

The active ingredient in Ciloxan Ear Drops is ciprofloxacin (base) 3mg in 1 mL.

Ciloxan Ear Drops also contain:

- Benzalkonium chloride (0.06mg/mL) as a preservative)
- Sodium acetate
- Acetic acid
- Mannitol
- Disodium edetate

- Purified water
- Hydrochloric acid and/or sodium hydroxide to adjust pH.

Supplier

This product is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

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