

Ciloxan®

0.3% Ear Drops

Ciprofloxacin hydrochloride

Consumer Medicine Information (CMI) summary

The [full CMI](#) 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 Ciloxan Ear Drops?

Ciloxan Ear Drops contain the active ingredient Ciprofloxacin hydrochloride. Ciloxan Ear Drops are used to treat chronic suppurative otitis media (CSOM) in adults and children 1 month old or above. It is a chronic infection of the middle ear.

For more information, see Section [1. Why am I using Ciloxan Ear Drops?](#) in the full CMI.

2. What should I know before I use Ciloxan Ear Drops?

Do not use if you have ever had an allergic reaction to Ciloxan Ear Drops 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 Ciloxan Ear Drops?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ciloxan Ear Drops 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 Ciloxan?

- Follow the instructions provided by your doctor and use Ciloxan Ear Drops carefully.
- Put five Ciloxan Ear Drops into the affected ear(s) twice daily for 9 days.

More instructions can be found in Section [4. How do I use Ciloxan Ear Drops?](#) in the full CMI.

5. What should I know while using Ciloxan Ear Drops?

Things you should do	• Remind any doctor, dentist, pharmacist or specialist you visit that you are using Ciloxan Ear Drops. • Tell your doctor immediately if you develop any signs of allergic reaction. • Avoid excessive exposure to sunlight during treatment with Ciloxan Ear Drops.
Things you should not do	• Do not stop using this medicine suddenly. • Do not touch the dropper tip with your fingers or to your ear or any other surface.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Ciloxan Ear Drops affect you.
Looking after your medicine	• Store below 25°C. • Do not refrigerate or freeze. • Do not leave the cap off the bottle for any length of time. Put the cap back on the bottle immediately after use.

For more information, see Section [5. What should I know while using Ciloxan Ear Drops?](#) in the full CMI.

6. Are there any side effects?

Common side effects include ear pain, vertigo, fever, ear itching, headache, buzzing, hissing, whistling, ringing or other persistent noise in the ear(s).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Ciloxan®

0.3% Ear Drops

Active ingredient: Ciprofloxacin hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ciloxan Ear Drops. **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 Ciloxan Ear Drops.**

Where to find information in this leaflet:

1. [Why am I using Ciloxan Ear Drops?](#)
2. [What should I know before I use Ciloxan Ear Drops?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Ciloxan Ear Drops?](#)
5. [What should I know while using Ciloxan Ear Drops?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Ciloxan Ear Drops?

Ciloxan Ear Drops contain the active ingredient Ciprofloxacin hydrochloride. Ciloxan Ear Drops belong to class of drugs called fluoroquinolone which are used to treat different types of infections caused by bacteria.

Ciloxan Ear Drops are used to treat chronic suppurative otitis media (CSOM) in adults and children 1 month old or above. It is a chronic infection of the middle ear. Symptoms include severe ear pain, discharge, hearing loss, fever. Ciloxan Ear Drops help to kill the bacteria that causes infection. It does not work against infections caused by viruses or fungus.

2. What should I know before I use Ciloxan Ear Drops?

Warnings

Do not use Ciloxan Ear Drops:

- If you are allergic to Ciprofloxacin hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- If you are allergic to other quinolone antibiotics e.g. nalidixic acid, Levaquin.

Symptoms of allergic reaction may include:

shortness of breath, difficulty breathing

swelling of the face, lips, tongue or other parts of the body, rash, hives

- If you suffer from any muscle problem or have any swelling to your tendons (strands of connective tissue between muscles and bones).

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- develop any skin reactions as Ciloxan Ear Drops contain benzalkonium chloride which may be an irritant.

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.

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

As a precautionary measure, it is preferable to avoid the use of Ciloxan Ear Drops during pregnancy. Your doctor will advise you regarding the possible risks and benefits of using Ciloxan Ear Drops 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 Ciloxan Ear Drops during breast feeding.

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 Ciloxan Ear Drops and affect how it works.

Tell your doctor if you take any of the following medicines:

- medicines that help to thin your blood e.g. warfarin
- medicines to prevent tissue rejection e.g. cyclosporin
- medicines such as theophylline which are used for asthma or other breathing problems
- caffeine for the treatment of migraines.

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

4. How do I use Ciloxan Ear Drops?

How much to use

For adults and children 1 month old or above:

- Put five Ciloxan Ear Drops into the affected ear(s) twice daily for 9 days.
- Follow the instructions provided when Ciloxan Ear Drops were prescribed, including the number of days it should be taken.
- **If you do not understand your dose consult your doctor or pharmacist.**

When to use Ciloxan Ear Drops

- Ciloxan Ear Drops should be used at about the same time every day unless your doctor tells you otherwise.

How to use Ciloxan Ear Drops

- Follow the instructions provided by your doctor and use Ciloxan Ear Drops carefully.

Below are steps to use Ciloxan Ear Drops:

- Wash your hands thoroughly.
- To open a new bottle of Ciloxan Ear Drops, remove the cap and replace it with the dropper cap supplied in the carton. Your pharmacist may have already done this for you.
- **Do not touch the dropper tip with your fingers or to your ear or any other surface. This will help prevent the ear drops getting contaminated.**
- Shake the bottle well prior to use.
- If the solution is cold, warm it by holding the bottle in your hand for one or two minutes before putting it in your ear.
- This will help to prevent dizziness which may be associated with putting a cold solution into the ear.
- Put Ciloxan Ear Drops in sitting or lying down position with the affected ear turned upwards (see Diagram 1).



Diagram 1

- Gently squeeze the bulb on the dropper cap to draw up the liquid into the dropper.
- Put the tip of the dropper close to the ear and gently squeeze three drops into the ear. (see Diagram 2)



Diagram 2

- Hold the head in the same position for about one min. This will help the drops to reach deeper into the ear. (see Diagram 3).



Diagram 3

- Repeat the above steps for the other ear if necessary.
- There might be a slightly unpleasant feeling since the drops flow all the way into the ear. If it persists, or is very uncomfortable, contact your doctor or pharmacist immediately.
- Place the cap on the bottle and close it tightly.
- Wash your hands again with soap and water to remove any residue.

If you forget to use Ciloxan Ear Drops

Ciloxan Ear Drops should be used as prescribed by your doctor. If you miss your dose at the usual time, use the drop(s) as soon as you remember, and then go back to use them as you would normally do.

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 use too much Ciloxan Ear Drops

If you think that you have used too much Ciloxan Ear Drops, you may need urgent medical attention.

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

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 Ciloxan Ear Drops?

Things you should do

Avoid excessive exposure to sunlight as it may cause moderate to severe phototoxicity (increased sensitivity of the skin to sun having symptoms such as redness, itching, swelling).

Call your doctor straight away if you:

- develop any signs of an allergic reaction.
- become pregnant or if you are breast feeding while using Ciloxan Ear Drops.
- are taking any other medicines for any other medical conditions.

Remind any doctor, dentist, pharmacist or specialist you visit that you are using Ciloxan Ear Drops.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not give Ciloxan Ear Drops to anyone else, even if they seem to have the same condition as you.
- Do not touch the dropper tip with your fingers or to your ear or any other surface.
- Do not use Ciloxan Ear Drops just before having a bath, shower or going swimming.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Ciloxan Ear Drops affect you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store below 25°C
- Do not refrigerate or freeze.
- 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 Ciloxan Ear Drops container 4 weeks after opening.

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
Ear Problems: • Ear itching • Mild local uncomfortable feeling in ear(s) Nervous system problems:	Speak to your doctor if you have any of these less serious side effects and

Less serious side effects	What to do
• Bitter taste in mouth (dysgeusia) • Transient dizziness • Vertigo • Headache General problems: • Fever	they worry you.

Serious side effects

Serious side effects	What to do
Ear problems: • Otomycosis, fungal infection of ear (symptoms such as itching, hearing loss, pain). • Uncomfortable feeling in ear(s), burning sensation or tingling in, on, or around the ear (stinging) • Buzzing, hissing, whistling, ringing or other persistent noise in the ear(s) • Ear pain • Allergic reaction with symptoms such as: - o shortness of breath, difficulty breathing - o swelling of the face, lips, tongue or other parts of the body - o rash, hives	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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 Ciloxan Ear Drops contain

Active ingredient (main ingredient)	Ciprofloxacin hydrochloride
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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.
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Do not take this medicine if you are allergic to any of these ingredients.

What Ciloxan Ear Drops looks like

Ciloxan Ear Drops are a sterile otic solution that comes in a 1 mL, 2.5 mL and 5 mL plastic bottle. The safety seal must be removed before use.

Who distributes Ciloxan Ear Drops

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone: 1800 671 203

Web Site: www.novartis.com.au

Australian Registration Number:

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