

CILOQUIN* 0.3% Ear Drops

ciprofloxacin hydrochloride

Consumer Medicine Information

What is in this Leaflet

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

All medicines have benefits and risks. Your doctor has weighed the risks of you using CILOQUIN against the expected benefits of using this medicine.

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 CILOQUIN Ear Drops is used for

CILOQUIN 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.

CILOQUIN contains the active ingredient ciprofloxacin hydrochloride. Ciprofloxacin hydrochloride is an antibiotic that belongs to a group of medicines called fluoroquinolones. This antibiotic works by killing the bacteria that are causing your infection.

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

Before prescribing CILOQUIN*, the doctor will have examined your

ear(s) and decided that CILOQUIN is the right medicine.

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

Your doctor may have prescribed CILOQUIN for another reason.

There is no evidence that CILOQUIN is addictive.

Before you use CILOQUIN Ear Drops

When you must not use it

Do not use CILOQUIN if you have an allergy to:

- ciprofloxacin, other fluoroquinolone antibiotics or any of the ingredients in CILOQUIN listed under Product Description at the end of this leaflet
- any other similar medicines.

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.

Ask your doctor or pharmacist to be sure you do not have any of these conditions.

Do not use CILOQUIN if:

- the seal around the cap 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 use CILOQUIN* 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 CILOQUIN, 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 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 CILOQUIN.

Using other medicines

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

Some medicines and CILOQUIN may interfere with each other. These include:

- medicines to thin your blood (e.g. warfarin)
- medicines to prevent tissue or transplant rejection (e.g. cyclosporin)
- theophylline for asthma or breathing problems

- caffeine for the treatment of migraines.

These medicines may be affected by CILOQUIN*, 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 this medicine.

How to use CILOQUIN Ear Drops

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

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

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

How much to use

Use CILOQUIN only when prescribed by your doctor.

The usual dose for adults is five drops of CILOQUIN 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 CILOQUIN* exactly as your doctor or pharmacist has told you. If you use it less often than you should, it may not work as well and the ear problem may not improve. Using it more often than you should may not improve the ear

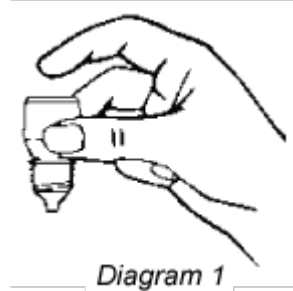
problem any faster and may cause increased side effects.

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 CILOQUIN, 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:

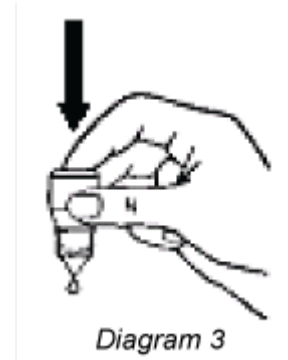
1. Wash your hands thoroughly with soap and water.
2. Shake the bottle.
3. Remove the cap from the bottle.
4. Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).



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 (see Diagram 2).



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 (see Diagram 3).



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 CILOQUIN*, 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

Keep using CILOQUIN* for the full time of treatment, even if you begin to feel better after a few days.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

Do not use CILOQUIN longer than your doctor tells you.

If you use it longer than your doctor or pharmacist tells you, the chance of side effects may increase.

If you are unsure about when or how to stop using CILOQUIN 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 CILOQUIN* 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 CILOQUIN, or used too many drops, immediately telephone your doctor or the Poisons Information Centre.

In Australia call 13 1126; in New Zealand call 0800 POISON or 0800 764 766 for advice or go to Accident & Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using CILOQUIN Ear Drops

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.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking CILOQUIN.

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

Tell your doctor if, for any reason, you have not used CILOQUIN exactly as prescribed.

Otherwise your doctor may think that it was not effective and change the treatment unnecessarily.

If you become pregnant while using CILOQUIN, tell your doctor.

Things you must not do

Do not use CILOQUIN to treat any other complaints unless your doctor tells you to.

Do not give CILOQUIN* to anyone else, even if they have the same condition as you.

Do not stop using CILOQUIN or lower the dosage because you are feeling better, unless advised by your doctor.

If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return.

Things to be careful of

Be careful driving or operating machinery until you know how CILOQUIN 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 CILOQUIN.

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 CILOQUIN*
- ear stinging or discomfort following use of CILOQUIN
- 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 CILOQUIN and tell your doctor immediately or go to Accident & Emergency at your nearest hospital:

- skin rash
- swelling of the face, hands or feet (peripheral oedema)
- wheezing, difficulty in breathing (bronchospasm, exacerbation of asthma, respiratory failure, pulmonary distress)
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettlerash (urticaria)

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 elderly or if you are taking inflammation-inhibiting products similar to cortisone, you have a higher risk of getting tendon problems during treatment with CILOQUIN* 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 CILOQUIN Ear Drops

Storage

Store CILOQUIN in a cool dry place where the temperature stays below 25°C.

Do not refrigerate or freeze. Cold ear drops may hurt your ear(s) or cause temporary dizziness.

CILOQUIN should be protected from light (store the bottle in the carton).

Do not store CILOQUIN* or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

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

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

Keep it where children can not reach it.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

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

Disposal

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

CILOQUIN 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 CILOQUIN® 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

CILOQUIN comes in a 1 mL, 2.5 mL or a 5 mL oval dropper bottle (DROP-TAINER*) with screw cap. The safety seal must be removed before use.

Ingredients

Active ingredients

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

Other ingredients:

It also contains:

- benzalkonium chloride (0.06 mg/mL) as preservative
- sodium acetate
- acetic acid
- mannitol
- disodium edentate
- hydrochloric acid and /or sodium hydroxide (to adjust pH)
- purified water

Supplier

CILOQUIN* is supplied in Australia by:

Alcon Laboratories (Australia) Pty Ltd
54 Waterloo Road
Macquarie Park NSW 2113

This leaflet was revised in September 2016.

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* a trademark of Novartis