

CIPROXIN[®] HC

Ear Drops

Ciprofloxacin and Hydrocortisone

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Please read this leaflet carefully before you use Ciproxin HC Ear Drops.

This leaflet answers some common questions about Ciproxin HC 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 Ciproxin HC against the risks this medicine could have for you.

The information in this leaflet applies to Ciproxin HC 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 Ciproxin HC is used for

Ciproxin HC is used to treat an infection of the outer ear caused by bacteria. This condition is known as bacterial otitis externa. It may cause itching or pain.

Ciproxin HC contains two active ingredients:

- Ciprofloxacin; a "fluoroquinolone" antibiotic which kills the bacteria causing the infection.
- Hydrocortisone; a corticosteroid that reduces the pain, redness and/or inflammation.

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

Before prescribing Ciproxin HC for you or your child, your doctor will have examined the ears and decided that Ciproxin HC is the right medicine.

Your doctor may have prescribed Ciproxin HC for another reason.

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

Ciproxin HC is only available on a doctor's prescription.

Use in children

Ciproxin HC is not recommended in children under the age of 2 years.

The safety and effectiveness of Ciproxin HC in children under 2 years has not been established.

Before you use Ciproxin HC

When you must not use it

Do not use Ciproxin HC if you or your child is allergic to:

- Ciprofloxacin
- Any other "quinolone" antibiotics e.g. nalidixic acid
- Hydrocortisone
- Benzyl alcohol used as a preservative
- Any of the other ingredients in Ciproxin HC 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 Ciproxin HC if you or your child:

- have a perforated ear drum
- are being treated for a condition called necrotising malignant otitis externa

This is a condition common to people who suffer from diabetes.

- have a viral or fungal infection of the external ear canal.

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

Do not use Ciproxin HC just before having a bath, shower or going swimming.

If you do, you may reduce the effectiveness of Ciproxin HC.

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.

Ciproxin HC has been developed for use in the ear only. This product is not suitable for use in the eye.

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 are allergic to latex.

The dropper cap contains natural rubber (latex) which may cause severe allergic reactions in some people.

Tell your doctor if you or your child have diabetes or any other medical condition.

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

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

Tell your doctor if you are breastfeeding.

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

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

Using other medicines

Tell your doctor or pharmacist if you are using or 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 Ciproxin HC may interact with each other.

Your doctor or pharmacist will be able to tell you what to do when using Ciproxin HC with other medicines.

How to use Ciproxin HC

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 (2 years and older) is 3 (three) drops in the affected ear(s) twice a day for 7 (seven) days.

The 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 Ciproxin HC 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.

Use Ciproxin HC at about the same time every day unless your doctor tells you otherwise.

To open a new bottle of Ciproxin HC, 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 tip of the dropper tip with your fingers, to the ear or any other surface. This will help prevent the ear drops becoming dirty or contaminated.

Follow these steps to use Ciproxin HC:

1. Wash your hands thoroughly.
2. Shake the bottle.
3. Squeeze the bulb on the dropper cap to draw up the liquid into the dropper.
4. Tilt your/your child's 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 1).



Diagram 1

5. Open the bottle and remove the dropper which has the liquid in it.
6. Put the tip of the dropper close to the ear and gently squeeze three drops into the ear (see Diagram 2).

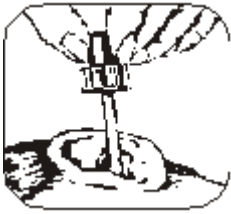


Diagram 2

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



Diagram 3

8. Repeat the above steps for the other ear if necessary.

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.

When to use it

Use Ciproxin HC 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 Ciproxin HC starts 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 Ciproxin HC 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 Ciproxin HC, you

should talk to your doctor or pharmacist.

Do not use Ciproxin HC longer than your doctor tells you.

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

If you forget to use it

If you forget to use Ciproxin HC you should put the drops that you missed in the ear(s) as soon as you remember and then go back to using them as recommended by your doctor. If it is almost time for the next dose, skip the dose that you missed and continue using them as recommended.

Never take a double dose to make up for the one that you missed.

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

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

If you use too much (overdose)

If you think that you, your child or someone else has swallowed any, or all, of the contents of Ciproxin HC, or used too many drops, immediately telephone your doctor or the Poisons Information Centre on 131126 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 using Ciproxin HC

Things you must do

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

Tell your doctor if, for any reason, you have not used Ciproxin HC 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 or your child are about to be started on any new medicine, remind your doctor or pharmacist that you are using Ciproxin HC.

Tell all the doctors, dentists and pharmacists who are treating you or your child that you are using Ciproxin HC.

Things you must not do

Do not use Ciproxin HC 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 Ciproxin HC or lower the dose without first asking your doctor.

Do not let children handle Ciproxin HC.

Things to be careful of

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

Be careful of sun exposure.

Ciproxin HC may cause some people to sunburn more readily.

Ask your doctor or pharmacist if you are concerned about the length of time that you or your child have been using Ciproxin HC.

Side effects

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

This medicine helps most people with an 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:

- Itchy ears
- Earache
- A sensation of fullness of ear
- Ear discomfort
- Redness of the ears.

Occasionally some people notice unwanted effects in the rest of their body as a result of using Ciproxin HC.

These effects may include:

- Decreased sense of touch, pain or light
- Decreased sense of hearing
- Fever
- Headaches
- Dizziness
- Blurred vision
- Nausea
- Numbness or tingling
- Itching and/or rash
- Sensitivity to sunlight
- Fungal nail infection
- Flaking of skin.

On very rare occasions, you or your child may find a little bit of white material remaining in the ear while using Ciproxin HC. The formation of this white material may or may not be associated with symptoms such as ear discomfort, hearing disorder or ear pain.

Tell your doctor immediately and stop using Ciproxin HC at the first sign of an allergy. Symptoms of an allergy include:

- 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.

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.

Do not feel alarmed by this list of possible side effects. You may not experience any of them.

After using Ciproxin HC

Storage

Keep Ciproxin HC 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.

Protect from light.

Do not store Ciproxin HC 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.

Keep it out of the sight and reach of children.

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

Disposal

Write the date on the bottle when you first open the ear drops and throw out any remaining solution after 14 days.

Ciproxin HC contains a preservative which helps prevent germs growing in the solution for the first 14 days after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an ear infection.

If your doctor tells you to stop using Ciproxin HC or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

Ciproxin HC Ear Drops is a non-sterile slightly viscous white to off-white suspension that comes in a 10 mL bottle with a separately wrapped non-sterile dropper cap in the carton.

Ingredients

Ciproxin HC contains the active ingredients ciprofloxacin hydrochloride equivalent to ciprofloxacin 2.0 mg in 1 mL and hydrocortisone 10 mg in 1 mL.

Ciproxin HC also contains:

- Benzyl alcohol as a preservative
- Polysorbate 20
- Sodium acetate
- Acetic acid (glacial)
- Sodium chloride
- Hydrogenated soy phosphatidylcholine
- Polyvinyl alcohol
- Water purified.

Supplier

This product is supplied in Australia by:

Novartis Pharmaceuticals Australia
Pty Limited
ABN 18 004 244 160
54 Waterloo Road
Macquarie Park NSW 2113
Telephone: 1800 671 203
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