

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.medsafe.govt.nz.

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.

What CIPROXIN is used for

Ciproxin HC Ear Drops contains two active ingredients; ciprofloxacin and hydrocortisone.

Ciprofloxacin is a “fluoroquinolone” antibiotic which kills the bacteria causing the infection.

Hydrocortisone is a corticosteroid that reduces the pain, redness and inflammation.

Ciproxin HC Ear Drops are used to treat a condition called bacterial otitis externa, which is an infection of the outer ear caused by bacteria which may cause itching or pain.

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

Your doctor may have prescribed it for another reason.

Ciproxin HC Ear Drops are not addictive.

This medicine is only available with a doctor’s prescription.

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

Use in Children

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

The safety and effectiveness in this age group have not been established.

Before you use CIPROXIN

When you must not use it

Ciproxin HC Ear Drops should not be used if you or your child have an allergy to:

- Ciprofloxacin
- Hydrocortisone
- Any of the ingredients listed at the end of the leaflet under “Product description”
- Any other quinolone antibiotic
- Any other corticosteroid.

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 Ear Drops if you or your child has any of the following conditions:

- necrotising malignant otitis externa, a condition common to people who suffer from diabetes
- a viral or fungal infection of the external ear canal
- diabetes
- otitis media, an infection of the middle ear.

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

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

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

Do not use Ciproxin HC Ear Drops:

- after the expiry date printed on the pack
- if the packaging is torn
- if the bottle shows signs of tampering.

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

Ciproxin HC Ear Drops 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 allergies to any other medicines or any substances such as foods, preservatives or dyes or latex.

The Ciproxin HC Ear Drops dropper cap contains latex which may cause allergic reactions in some people.

Tell your doctor if you or your child have or have had any medical conditions, especially the following:

- a perforated ear drum
- any other medical conditions.

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

Your doctor will discuss the risks and benefits of using Ciproxin HC Ear Drops when pregnant.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Your doctor will discuss the risks and benefits of using Ciproxin HC Ear Drops when breast-feeding.

If you have not told your doctor about any of the above, tell them before using Ciproxin HC Ear Drops.

Using other medicines

Tell your doctor or pharmacist if you or your child are taking any other medicines, including medicines that you buy at a pharmacy or health food shop without a doctor's prescription.

This is particularly important if you or your child are currently

using any other type of ear drops.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when using Ciproxin HC Ear Drops with other medicines.

How to use CIPROXIN

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box ask your doctor or pharmacist for help.

How much to use

The usual dose of Ciproxin HC Ear Drops in adults and children 2 years and older is three drops in the affected ear(s) twice each day for 7 days. The dosing instructions will be printed on the label your pharmacist put on the bottle or carton.

How to use it

Open a new bottle of Ciproxin HC 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 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 Ear Drops:

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 or 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).

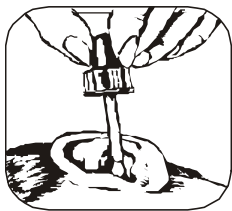


Diagram 2

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.

How long to use it

As Ciproxin HC Ear Drops starts to kill the bacteria that are causing the infection, the ear(s) will start to feel better.

It is very important that you continue to use Ciproxin HC Ear Drops for the full treatment period as directed by your doctor to ensure that the infection does not return.

Do not use Ciproxin HC Ear Drops longer than your doctor tells you. If you use Ciproxin HC Ear Drops 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 Ciproxin HC Ear Drops you should talk to your doctor or pharmacist.

If you forget to use it

If you forget to use Ciproxin HC Ear Drops, 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 use 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 (overdosage)

If you think that you, your child or someone else has swallowed Ciproxin HC Ear Drops immediately telephone your doctor or the National Poisons Centre on 0800 POISON or 0800 764 766 for advice, or go to Accident and Emergency at the nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While using CIPROXIN

Things you must do

It is important to use Ciproxin HC Ear Drops 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 Ear Drops every day, at about the same times each day, unless your doctor tells you otherwise.

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

Tell your doctor if, for any reason, you have not used Ciproxin HC Ear Drops exactly as prescribed.

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

Tell your doctor if your symptoms persist, worsen or recur.

Tell all doctors and pharmacists who are treating you or your child that are using Ciproxin HC Ear Drops.

If you become pregnant while using Ciproxin HC Ear Drops tell your doctor immediately.

Things you must not do

Do not stop using Ciproxin HC Ear Drops without first asking your doctor.

Do not use Ciproxin HC Ear Drops to treat other complaints unless your doctor or pharmacist tells you to.

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

Do let children handle Ciproxin HC Ear Drops. If a child accidentally swallows any of the drops read the instructions under *“If you use too much (overdose)”*.

Side effects

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

Ciproxin HC Ear Drops is generally well tolerated and helps most people with an infection of the outer ear but it may have unwanted effects in a few people.

All medicines can have side effects. Sometimes they are serious, however most of the time they are not. You may need to medical treatment if you get some of the side effects.

Do not feel alarmed the 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 pain
- 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 Ear Drops. These effects may include:

- Reduced sense of touch
- Decreased sense of hearing
- Fever
- Headaches
- Dizziness
- Nausea
- Numbness or tingling
- Blurred vision
- Itching and/or rash
- Fungal infections of the skin
- 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 Ear Drops. 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 Ear Drops at the first sign of an allergy.

Symptoms of an allergic reaction 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.

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

Let your doctor know if you observe any unwanted effects while using Ciproxin HC Ear Drops, even if they do not appear in the list above.

After using CIPROXIN

Storage

Store Ciproxin HC Ear Drops in a cool, dry place where the temperature stays below 25°C.

Do not refrigerate Ciproxin HC Ear Drops.

Ciproxin HC Ear Drops should be protected from light. Store the bottle in the carton.

Do not leave Ciproxin HC Ear Drops in the car, in the bathroom or in other warm, damp places.

Heat and humidity can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the

ground is a good place to store medicines.

Disposal

Discard each bottle of Ciproxin HC Ear Drops 14 days after it has been opened.

Write the date the bottle was opened on the label to remind you when to discard the bottle.

If your doctor tells you to stop using Ciproxin HC Ear Drops 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 are a slightly viscous white to off-white suspension that comes in a 10 mL glass bottle with a dropper cap supplied in the carton.

Ingredients

Ciproxin HC Ear Drops contain ciprofloxacin 0.2% and hydrocortisone 1 % as the active ingredient.

Ciproxin HC Ear Drops also contain:

Benzyl alcohol as a preservative

Polysorbate 20

Sodium acetate

Glacial acetic acid

Phospholipon 90 H

Sodium chloride

Polyvinyl alcohol

Purified water.

Supplier

Ciproxin HC Ear Drops are supplied in New Zealand by:

Novartis New Zealand Limited

PO Box 99102

Newmarket

Auckland 1149

New Zealand.

Free Phone: 0800 354 335

Date of Preparation

This leaflet was revised in July 2020

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