

# Ciproxin®HC

## Ear Drops

Ciprofloxacin and Hydrocortisone

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### 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.

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## 1. Why am I using Ciproxin HC Ear Drops?

Ciproxin HC Ear Drops contains the active ingredients ciprofloxacin hydrochloride and hydrocortisone. Ciproxin HC Ear Drops are used to treat acute bacterial otitis externa (acute infection of the outer ear caused by bacteria) in adults and children aged 2 years and older.

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

## 2. What should I know before I use Ciproxin HC Ear Drops?

Do not use if you have ever had an allergic reaction to Ciproxin HC Ear Drops or any of the ingredients listed at the end of the CMI.

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**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 Ciproxin HC Ear Drops?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with Ciproxin HC 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 Ciproxin HC Ear Drops?**

- Put three drops in the affected ear(s) twice daily for seven days.
- Follow the instructions provided by your doctor and use Ciproxin HC Ear Drops carefully.

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

### **5. What should I know while using Ciproxin HC Ear Drops?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or</li></ul>
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	<p>pharmacist or specialist you visit that you are using Ciproxin HC Ear Drops.</p> <ul style="list-style-type: none"> <li>• Tell your doctor immediately if you develop any signs of an allergic reaction.</li> <li>• Avoid direct exposure to sunlight during treatment with Ciproxin HC Ear Drops.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop using this medicine suddenly.</li> <li>• Do not use it in children less than 2 years of age.</li> </ul>

	<ul style="list-style-type: none"> <li>• Do not give Ciproxin HC Ear Drops to anyone else, even if they seem to have the same condition as you.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how Ciproxin HC Ear Drops affect you.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store below 25°C. Do not refrigerate or freeze.</li> <li>• Do not leave the top off the bottle for any length</li> </ul>

	of time. Put the top back on the bottle immediately after use to avoid any contamination.
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For more information, see Section [5. What should I know while using Ciproxin HC Ear Drops?](#) in the full CMI.

## 6. Are there any side effects?

Common side effects include ear pain, itching in ear, uncomfortable feeling in ear, fever, dizziness, buzzing, hissing, whistling, ringing or other persistent noise in the ear, headache.

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.

# Ciproxin®HC

Ear Drops

**Active ingredient(s):** *ciprofloxacin hydrochloride and hydrocortisone*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Ciproxin HC 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 Ciproxin HC Ear Drops.**

**Where to find information in this leaflet:**

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

## **1. Why am I using Ciproxin HC Ear Drops?**

**Ciproxin HC Ear Drops contain the active ingredients ciprofloxacin hydrochloride and hydrocortisone.** Ciprofloxacin hydrochloride belongs to class of medicines called fluoroquinolone which are used to treat different types of infections caused by bacteria. Hydrocortisone is a steroid which helps to reduce swelling, pain and redness.

**Ciproxin HC Ear Drops are used to treat acute bacterial otitis externa in adults and children aged 2 years and older. It is the acute infection of the outer ear caused by bacteria. Symptoms include ear pain and swelling. Ciproxin HC Ear Drops help to kill the bacteria that causes infection and decrease the symptoms of otitis externa. Ciproxin HC Ear Drops do not work against infections caused by viruses or fungus.**

## **2. What should I know before I use Ciproxin HC Ear Drops?**

### **Warnings**

#### **Do not use Ciproxin HC Ear Drops:**

- If you are allergic to ciprofloxacin hydrochloride and hydrocortisone, 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 have any ear problems such as ear drum rupture (symptoms such as ear pain, dizziness, hearing loss).
- If you have been treated for a condition called Necrotising malignant otitis externa (severe ear infection).
- If you suffer from any viral or fungal ear infection.

### **Check with your doctor if you:**

- have any other medical conditions such as diabetes
- take any medicines for any other condition
- are allergic to natural rubber (latex) since the dropper cap contains it.
- have any eye problems such as blurred vision.

**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.

Your doctor will advise you regarding the possible risks and benefits of using Ciproxin HC 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 Ciproxin HC 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 other ear drops, medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with Ciproxin HC Ear Drops and affect how it works.**

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

## **4. How do I use Ciproxin HC Ear Drops?**

### **How much to use**

#### **For children (age 2 and above) and adults:**

- Put three drops in the affected ear(s) twice daily for seven days.
- Follow the instructions provided when Ciproxin HC Ear Drops were prescribed, including the number of days it should be taken.
- **Ask your doctor or pharmacist if you do not understand your dose.**

### **When to use Ciproxin HC Ear Drops**

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

### **How to use Ciproxin HC Ear Drops**

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

#### **Below are steps to use Ciproxin HC Ear Drops:**

- Wash your hands thoroughly.
- To 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 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.
- Put Ciproxin HC Ear Drops in a 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 30-60 seconds. 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.

### **If you forget to use Ciproxin HC Ear Drops**

Ciproxin HC Ear Drops should be used regularly at the same time each day. If you miss your dose at the usual time, 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 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 Ciproxin HC Ear Drops**

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

**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 Ciproxin HC Ear Drops?**

### **Things you should do**

Avoid direct 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 allergic reaction.
- become pregnant or if you are breast feeding while using Ciproxin HC Ear Drops.
- have any ear problems e.g. ear drum rupture (having symptoms such as ear pain, dizziness, hearing loss).
- suffer from any eye problems such as blurred vision.
- are taking any other medicines for any other medical conditions.

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

### **Things you should not do**

- Do not stop using this medicine suddenly.
- Do not use it in children less than 2 years of age.

- Do not give Ciproxin HC Ear Drops to anyone else, even if they seem to have the same condition as you.
- Do not use it in your eyes. Ciproxin HC Ear Drops are only for ear use.
- Do not use Ciproxin HC 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 Ciproxin HC Ear Drops affect you.**

## **Looking after your medicine**

Follow the instructions in the carton on how to take care of your medicine properly.

Store below 25°C.

### **Do not refrigerate or freeze.**

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

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 any remaining Ciproxin HC Ear Drops solution after 14 days after opening it.

## 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
<b>General problems</b> <ul style="list-style-type: none"><li>• Rash</li><li>• Feeling of tingling or numbness</li><li>• Itching</li><li>• Hives</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Headache</li> <li>• Fever</li> <li>• Feeling sick</li> <li>• Dizziness</li> <li>• Blurred vision or other eye problems</li> <li>• Fungal nail infection</li> </ul> <p><b>Ear problems:</b></p> <ul style="list-style-type: none"> <li>• Ear pain</li> <li>• Uncomfortable feeling in ear</li> <li>• Sensation of fullness of the ear</li> <li>• Itching in ear</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Ear problems:</b></p> <ul style="list-style-type: none"> <li>• Partial loss of hearing</li> <li>• Buzzing, hissing, whistling, ringing or other persistent noise in the ear</li> <li>• Medication residue (white material</li> </ul>	<p><b>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.</b></p>

Serious side effects	What to do
<p>remaining in the ear while using Ciproxin HC Ear Drops without or with symptoms such as uncomfortable feeling in ear, hearing disorders, ear pain)</p> <ul style="list-style-type: none"> <li>• Infection of the outer ear (otitis externa) of the non-treated ear</li> <li>• Infection of the middle ear (symptoms: temporary hearing loss and pain, earache)</li> </ul>	

**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](http://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 Ciproxin HC Ear Drops contains**

<b>Active ingredients (main ingredients)</b>	Ciprofloxacin hydrochloride and Hydrocortisone.
<b>Other ingredients (inactive ingredients)</b>	polysorbate 20, sodium acetate, acetic acid-glacial, sodium chloride, hydrogenated soy phosphatidylcholine, polyvinyl alcohol, water-purified, soya bean products
<b>Potential allergens</b>	benzyl alcohol and, soya bean products

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What Ciproxin HC Ear Drops looks like**

Ciproxin HC Ear Drops are supplied as a non-sterile, slightly viscous white to off-white opaque suspension in a 10 mL bottle with a separately wrapped non-sterile dropper assembly.

## **Who distributes Ciproxin HC 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](http://www.novartis.com.au)

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