AURIXIN HC Ear Drops

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 AURIXIN HC?

AURIXIN HC contains the active ingredients ciprofloxacin hydrochloride and hydrocortisone. AURIXIN HC is used to treat an acute infection of the outer ear caused by bacteria in adults and children aged 2 years and older. This condition is known as acute bacterial otitis externa which may cause itching, pain and swelling of the outer ear. For more information, see Section 1. Why am I using AURIXIN HC? in the full CMI.

2. What should I know before I use AURIXIN HC?

Do not use if you have ever had an allergic reaction to ciprofloxacin hydrochloride, other quinolone antibiotics e.g. nalidixic acid, hydrocortisone, benzyl alcohol or any of the ingredients listed at the end of the CMI.

Do not use if you or your child have a perforated ear drum, diabetes, a condition known as necrotising malignant otitis externa or a viral of fungal infection of the external ear.

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 AURIXIN HC? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AURIXIN HC 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 AURIXIN HC?

- The usual dose in adults and children (2 years and older) is 3 drops in the affected ear(s) twice a day for 7 days.
- Apply the ear drops to yours or your child's ear by tilting the head to the side and gently squeezing 3 drops into the ear. Keep the head tilted in same position for 1 minute. Repeat if needed to the other ear.

More instructions can be found in Section 4. How do I use AURIXIN HC? in the full CMI.

5. What should I know while using AURIXIN HC?

Things you should do	• Tell your doctor if the symptoms of the infection do not improve within a few days, or if it becomes worse. • Tell your doctor immediately if you develop any signs of an allergic reaction • Remind any doctor, dentist or pharmacist you visit that you are using AURIXIN HC.
Things you should not do	• Do not give this medicine to anyone else, even if they have symptoms that seem similar to yours. • Do not stop using AURIXIN HC or lower the dose without first asking your doctor. • Be careful of sun exposure. AURIXIN HC may cause some people to sunburn more readily.
Driving or using machines	• Be careful driving or operating machinery until you know how AURIXIN HC affects your hearing.
Looking after your medicine	• Keep your AURIXIN HC with the cap on and in a cool, dry place where the temperature stays below 25°C and protected from light. Do not leave it in your bathroom or in the car on hot days. • Do not refrigerate or freeze your ear drops. • Do not carry your ear drops in the pockets of your clothes.

For more information, see Section 5. What should I know while using AURIXIN HC? in the full CMI.

6. Are there any side effects?

The common side effects include itchy ears, ear discomfort, redness of the ears, headache, fever, earache. If you notice signs of allergic reaction, contact your doctor or go to the Emergency Department of your nearest hospital immediately.

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.

Aurixin HC Ear Drops

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using AURIXIN HC. **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 AURIXIN HC.**

Where to find information in this leaflet:

1. Why am I using AURIXIN HC?
2. What should I know before I use AURIXIN HC?
3. What if I am taking other medicines?
4. How do I use AURIXIN HC?
5. What should I know while using AURIXIN HC?
6. Are there any side effects?
7. Product details

1. Why am I using AURIXIN HC?

AURIXIN HC Ear Drops is used to treat an acute infection of the outer ear caused by bacteria, in adults and children aged 2 years and older. This condition is known as acute bacterial otitis externa. It may cause itching, pain and swelling.

AURIXIN HC contains two active ingredients, ciprofloxacin hydrochloride and hydrocortisone. Ciprofloxacin hydrochloride is a fluoroquinolone antibiotic which kills the bacteria causing the infection. Hydrocortisone is a corticosteroid that reduces the pain, redness and/or inflammation.

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

Your doctor may have prescribed AURIXIN HC for another reason.

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

2. What should I know before I use AURIXIN HC?

Warnings

Do not use AURIXIN HC if:

- you or your child are allergic to ciprofloxacin hydrochloride and hydrocortisone, or any of the ingredients listed at the end of the leaflet.
- Always check the ingredients to make sure you or your child can use this medicine.
- You or your child have an allergy to other quinolone antibiotic e.g. nalidixic acid.

  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.
- If you or your child has any ear problem such as perforated ear drum (symptoms such as ear pain, dizziness, hearing loss).
- If you or your child are being treated for a condition called necrotising malignant otitis externa (severe ear infection).

  This is a condition common to people who suffer from diabetes.
- If you or your child have a viral or fungal infection of the external ear canal.

Use in children

AURIXIN HC is not recommended for children under 2 years of age, as its safety and effectiveness in children have not been established.

Check with your doctor, dentist or pharmacist if:

- you or your child have allergies to any other medicines, foods, preservatives or dyes.
- you or your child have diabetes or any other medical condition.
- you or your child take any medicines for any other condition.

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

Tell your doctor if you are pregnant or plan to become pregnant.
Your doctor will discuss the possible risks and benefits of using AURIXIN HC during pregnancy.

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

Your doctor will discuss the possible risks and benefits of using AURIXIN HC during breast feeding.

3. What if I am taking other medicines?

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

Some medicines may interfere with AURIXIN HC 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 AURIXIN HC.

4. How do I use AURIXIN HC?

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.

Follow the instructions provided when AURIXIN HC were prescribed, including the number of days it should be taken.

When to use AURIXIN HC

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

How to use AURIXIN HC

It is important to use AURIXIN HC exactly as your doctor or pharmacist has told you.

To open a new bottle of AURIXIN HC, remove the cap and use as instructed by your pharmacist.

Do not touch the tip of the nozzle with your fingers, to the ear or any other surface. This will help prevent the ear drops becoming contaminated.

Follow these steps to use AURIXIN HC:

1. Wash your hands thoroughly.
2. Shake the bottle and remove the cap.
3. 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

4. Put the tip of the nozzle close to the ear and gently squeeze three drops into the ear (see Diagram 2).



Diagram 2

5. 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

6. 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.

If you forget to use AURIXIN HC

If you forget to use AURIXIN HC, 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.

Do not double the dose (two doses at the same time) to make up for the forgotten dose.

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

If you use too much AURIXIN HC

If you or your child has swallowed any, or all, of the contents of AURIXIN HC, or used too many drops, you or your child may need 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 AURIXIN HC?

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

Things you should do

- Tell your doctor if the symptoms of the infection do not improve within a few days, or if it becomes worse.
- Avoid direct exposure to sunlight as it may cause moderate to severe phototoxicity (increase sensitivity of the skin to sun having symptoms such as redness, itching, swelling).

Call you doctor straight away if you:

- develop any signs of allergic reaction.
- become pregnant or if you are breast feeding while using AURIXIN HC.
- 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.

Remind any doctor, dentist, pharmacist or specialist you visit that you are using AURIXIN HC.

Things you should not do

- Do not use AURIXIN HC to treat other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have symptoms that seem like yours.
- Do not stop using AURIXIN HC or lower the dose without first asking your doctor.
- Do not use it in your eyes, AURIXIN HC has been developed for use in the ear only.
- Do not use AURIXIN HC just before you or your child have a bath, shower or go swimming. If you do, you may reduce the effectiveness of AURIXIN HC.

Driving or using machines

Be careful driving or operating machinery until you know how AURIXIN HC affects you and your child's hearing.

Looking after your medicine

- Store below 25°C.
- Do not refrigerate or freeze your ear drops. Cold ear drops may hurt you or your child's ear(s) or cause temporary dizziness.
- Do not carry your ear drops in the pockets of your clothes.
- Do not keep the cap off your bottle for any length of time, to avoid contamination of the ear drops.

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
- on a window sill or in the car on hot days.

Keep it where young children cannot reach it.

When to discard your medicine

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

AURIXIN 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.

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 or your child 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 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-related • Itchy ears • Earache • A sensation of fullness of ear • Ear discomfort • Redness of the ears. • Decreased sense of hearing **Skin-related** • Decreased sense of touch, pain or light • Itching and/or rash • Sensitivity to sunlight • Fungal nail infection • Flaking of skin. **General disorders/Other** • Fever • Headaches • Dizziness • Numbness or tingling **Eye-related** • Blurred vision **Gastrointestinal** • Nausea	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Signs of an allergy: • Swelling of the face, lips, tongue or other parts of the body • Wheezing, difficulty in breathing • Severe and sudden onset of pinkish, itchy swellings on the skin, also called hives **Ear-related** • Partial loss of hearing • Buzzing, hissing, whistling, ringing or other persistent noise in the ear • Medication residue (white material remaining in the ear while using AURIXIN HC without or with symptoms such as uncomfortable feeling in ear, hearing disorders, ear pain) • Infection of the outer ear of the non-treated ear • Infection of the middle ear (symptoms: temporary hearing loss and pain, earache)	**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

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

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

What AURIXIN HC contains

Active ingredient (main ingredient)	Ciprofloxacin hydrochloride and Hydrocortisone
Other ingredients (inactive ingredients)	• polysorbate 20, • benzyl alcohol, • sodium acetate, • acetic acid-glacial, • sodium chloride, • hydrogenated soy phosphatidylcholine, • polyvinyl alcohol, • sodium hydroxide, • hydrochloric acid, • water for injection.

Contains soya bean products.

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

What AURIXIN HC looks like

AURIXIN HC Ear Drops is a non-sterile, slightly viscous white to off-white suspension in a 10 mL bottle with a translucent nozzle and a white cap.

(Aust R 486405).

Who distributes AURIXIN HC

Nova Pharmaceuticals Australasia Pty Ltd
Suite 305, 10 Norbrik Drive
Bella Vista, NSW 2153
Toll free: 1800 002 171
www.novapharm.com.au

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