Size: 125 x 500 mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

Consilient Health

Ciprofloxacin/Dexamethasone

3 mg/ml /1 mg/ml ear drops, suspension

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ciprofloxacin/Dexamethasone is and what it is used for
2. What you need to know before you use Ciprofloxacin/Dexamethasone
3. How to use Ciprofloxacin/Dexamethasone
4. Possible side effects
5. How to store Ciprofloxacin/Dexamethasone
6. Contents of the pack and other information

1. WHAT CIPROFLOXACIN/ DEXAMETHASONE IS AND WHAT IT IS USED FOR

Ciprofloxacin/Dexamethasone is a suspension for auricular use (in the ear). It contains:

- ciprofloxacin, an antibiotic belonging to the group fluoroquinolones. Ciprofloxacin works by killing bacteria that cause infections
- and dexamethasone, a corticosteroid or anti-inflammatory agent that will help to relieve inflammation and redness.

Ciprofloxacin/Dexamethasone is an ear drop. This medicine is used to treat acute middle ear infection (otitis media) in patients with draining ear tubes (tympanostomy tubes or "Grommets") or to treat an outer ear infection (acute otitis externa). It has been shown to be safe and effective in paediatric patients 6 months of age and older for the treatment of middle ear infections (AOMT) and 1 year of age and older for the treatment of outer ear infections (AOE).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE CIPROFLOXACIN/ DEXAMETHASONE

Do not use Ciprofloxacin/ Dexamethasone:

- If you are **allergic** to ciprofloxacin, dexamethasone or any of the other ingredients of this medicine (listed in section 6).
- If you are **allergic** to medicines called quinolone antibiotics, as this medicine may cause the same allergy.
- If you have an ear infection caused by a **virus** or **fungus.**

Warnings and precautions

Talk to your doctor or pharmacist before using Ciprofloxacin/ Dexamethasone.

- This preparation should only be applied to the ear. It is not for use in the eye and should not be swallowed, injected or inhaled.
- Once treatment has begun, if you notice the first signs of a skin rash or any other allergic symptoms (e.g. urticaria (hives), sudden swelling of face, throat or eyelids, breathing problems), you must stop treatment immediately and you should consult with your doctor. Serious allergic reactions may need immediate emergency treatment.
- Tell the doctor if the symptoms do not improve within one week of starting treatment, get worse or suddenly return. As with all antibiotics, sometimes additional infections may occur caused by organisms which are not affected by ciprofloxacin. In case of such infection appropriate treatment should be started by your doctor.
- If you feel pain, swelling or inflammation of the tendons while, or soon after taking this medicine, stop treatment and contact your doctor. Pay special attention if you are over 65 years old or being treated with corticosteroids.
- Contact your doctor if you experience blurred vision or other visual disturbances.
- **Use in children:** There is insufficient clinical experience available on the use of Ciprofloxacin/Dexamethasone in children below 6 months in the treatment of middle ear infections and in children younger than 1 year in the treatment of outer ear infections, so talk to your doctor before giving this medicine to your very young child if your child has these ages.

If any of these apply ask your doctor for advice.

Other medicines and Ciprofloxacin/ Dexamethasone

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

There are no known effects of Ciprofloxacin/Dexamethasone on the ability to drive or use machines.

Ciprofloxacin/Dexamethasone contains benzalkonium chloride.

This medicine contains 0.004 mg benzalkonium chloride in each drop which is equivalent to 0.1 mg per millilitre suspension.
Benzalkonium chloride may irritate the skin.

3. HOW TO USE CIPROFLOXACIN/ DEXAMETHASONE

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose for **adults and children** is **4 drops** in the ear canal, **twice a day** – morning and evening – **for 7 days**. This medicine is intended to be administered into the ear (auricular use) only.

Remove the loose collar from the cap when the bottle is first opened.

Your doctor will tell you how long your treatment with this medicine will last. To make sure that the infection does not return, **do not stop treatment early,** even if your ear(s) feel better.

Only use this medicine in both ears if your doctor told you to do so.

Instructions for Use

It is best if another person can put the drops in for you. Children should never be allowed to put the drops in themselves.

1. **Wash hands**
   The person giving Ciprofloxacin/ Dexamethasone should wash his/ her hands with soap and water.
2. **Warm & shake the bottle**
   The person giving Ciprofloxacin/ Dexamethasone should hold the bottle in their hand(s) for several minutes to warm the ear drops (picture 1) to avoid the dizziness that may result from the instillation of a cold solution into the ear canal, then shake the bottle well before use.



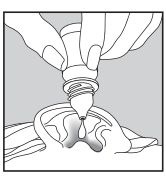
Picture 1

3. **Give drops**
   The patient should lie with the infected ear upward (picture 2).



Picture 2

Put **4 drops** of Ciprofloxacin/ Dexamethasone into the infected ear (picture 3). **Do not touch** the fingers or the ear or any other surfaces **with the tip of the bottle** as it could infect the drops.



Picture 3

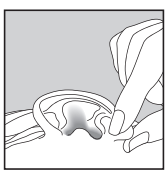
After putting in the drops follow the instructions below **for the patient's specific ear infection.**

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4. **For patients with middle ear infection with draining ear tubes (tympanostomy tubes or "Grommets"):**
While the patient lies on his/her side, the person giving Ciprofloxacin/Dexamethasone should gently press the flap of skin at the entrance to the ear canal (picture 4) 5 times in a pumping motion. This will allow the drops to pass through the tube in the eardrum and into the middle ear.


Picture 4

5. **For patients with outer ear infection.**
While the patient lies on his/her side, the person giving Ciprofloxacin/Dexamethasone should gently pull the outer ear lobe upward and backward (picture 5). This will allow the ear drops to flow down into the ear canal.


Picture 5

6. **Stay on side**
The patient should remain on his / her side around 5 minutes to facilitate penetration of the drops into the ear. When you raise your head up again, some drops can run out. You can dry them with a non-sterile absorbent paper.

   It is of the utmost importance to follow this instruction to achieve good efficacy of the drug in your ear. When you instil ear drops, keeping your head vertical or moving your head too rapidly constitute factors for losing a part of the drug because drops are going to run down onto your face and do not go into the depths of the auditory canal.

   Keep the bottle tightly closed when not in use.

   Keep the bottle until the completion of the treatment. Do not keep it for subsequent use.

   When applying the medicine, be careful that the dropper does not come into contact with your ear or your fingers so as to avoid contamination.

   Repeat Steps 2-5 for the other ear if both ears are infected.

If you use more medicine than you should, please tell your doctor or pharmacist.

If you forget to use this medicine do not worry, just continue with your next dose. **Do not use a double dose to make up for a forgotten dose.**

If you stop using Ciprofloxacin/ Dexamethasone
Do not stop using this medicine without
telling your doctor or pharmacist. If your ear(s) **do not feel better** after 1 week of treatment **go back to your doctor.**
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ciprofloxacin/ Dexamethasone can cause side effects, although not everybody gets them.

If you experience a severe allergic reaction and any of the following, stop taking this medicine and tell your doctor immediately:
swelling of hands, feet, ankles, face, lips, mouth or throat, difficulty in swallowing or breathing, rash or hives, sores, ulcers.

Common: May affect up to 1 in 10 people
- *Effects in the ear:* ear pain.

Uncommon: May affect up to 1 in 100 people
- *Effects in the ear:* ear discomfort, blockage of tube draining the ear, tingling, ear congestion, itchy ear, fungal infection of outer ear, ear discharge, scaling in ear.
- *General side effects:* Candida infection, irritability, crying, flushing of skin, vomiting, bad taste, tiredness.

Rare side effects: May affect up to 1 in 1000 people
- *Effects in the ear:* reduced hearing, ringing in the ears, medication residue.
- *General side effects:* dizziness, headache, redness in ear.

The following side effects have been seen with Ciprofloxacin/ Dexamethasone.
Frequency cannot be estimated from the available data:
- *Effects in the eye:* blurred vision
- *Effects in the ear:* ear inflammation
- *General side effects:* allergy

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CIPROFLOXACIN/ DEXAMETHASONE

Keep this medicine out of the sight and reach of children.

Do not use **this medicine** after the expiry date which is stated on the bottle and the carton. The expiry date refers to the last day of that month.

Do not freeze.

Keep the bottle in the outer carton in order to protect from light.

Discard the bottle 4 weeks after first opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ciprofloxacin/Dexamethasone contains
The active substances are ciprofloxacin and dexamethasone.

Each 1 ml of suspension contains 3 mg ciprofloxacin as hydrochloride and 1 mg dexamethasone.

The other ingredients are benzalkonium chloride, hydroxyethyl cellulose, sodium acetate trihydrate, acetic acid, sodium chloride, disodium edetate, tyloxapol, boric acid, hydrochloride acid/sodium hydroxide (for pH-adjustment), purified water.

What Ciprofloxacin/ Dexamethasone looks like and contents of the pack
Ciprofloxacin/Dexamethasone is a white to off-white uniform suspension supplied in a pack containing a 5-ml bottle (LDPE) with a white (PP) closure.

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Advice/medical education
Antibiotics are used to cure bacterial infections. They are ineffective against viral infections. If your doctor has prescribed antibiotics, you need them precisely for your current illness. Despite antibiotics, some resistant bacteria may survive or grow; therefore, some antibiotic treatment may not be effective. Misuse of antibiotics may increase resistance. You may even help bacteria become resistant and therefore delay your cure or decrease antibiotic efficacy if you do not respect appropriate:
- dosages,
- schedules,
- duration of treatment.

Consequently, to preserve the efficacy of this drug:
1. Use antibiotics only when prescribed.
2. Strictly follow the prescription.
3. Do not re-use an antibiotic without medical prescription, even if you want to treat a similar illness.
4. Never give your antibiotic to another person; maybe it is not adapted to his/her illness.
5. After completion of treatment, return all unused drugs to your chemist's shop to ensure they will be disposed of correctly.

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