



CIPROTAB[®]

CIPROFLOXACIN USP 0.3% W/V

EYE & EAR DROPS



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again before, during or after use of this medicine.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

1. What Ciprotab Eye & Ear drops is and what it is used for.
2. What you need to know before you use Ciprotab Eye & Ear drops.
3. How to use Ciprotab Eye & Ear drops.
4. Possible side effects.
5. How to store Ciprotab Eye & Ear drops.
6. Contents of the pack and other information.

1. WHAT CIPROTAB EYE & EAR DROPS IS AND WHAT IT IS USED FOR

Ciprotab eye & ear drops belongs to a group of medicines known as Fluoroquinolone antibiotics. It is used for the treatment of corneal ulcers and some other bacterial infections of the eye & ear(s) in adults and children 12 months of age or older. Ciprotab eye & ear drops contain the equivalent of 3 mg/mL Ciprofloxacin base. It works by killing the bacteria that cause infection.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE CIPROTAB EYE & EAR DROPS SOLUTION

Do not use Ciprotab Eye & Ear drops: If you are allergic (hypersensitive) to ciprofloxacin or any other quinolone antibiotic or to any of the other ingredient. Ask your doctor for advice before using Ciprotab Eye & ear drops.

Take special care with Ciprotab Eye & Ear drops.

- Only use Ciprotab eye & ear drops in your eye & ears.
- Only use Ciprotab eye & ear drops in children younger than 1 year if recommended by your doctor.
- Just like any antibiotic, use of Ciprotab eye & ear drops for a long time may lead to other infections. If your symptoms get worse or suddenly return, tell your doctor. You may become more susceptible to other infections with the use of this medicine, especially after prolonged use.
- If you notice the first signs of a skin rash or any other allergic reaction, including hives, itching, breathing problems, stop treatment and immediately contact your doctor. If you have a serious allergic reaction, then you may need emergency treatment.
- If you feel pain, swelling or inflammation while or shortly after taking this medicine, stop treatment and contact your doctor.
- If you are elderly or if you are taking medicines called 'corticosteroids' used to treat conditions such as pain and inflammation, asthma or skin problems, then you have a higher risk of getting tendon problems during treatment with Ciprotab. If you experience any inflammation or inflammatory conditions, stop treatment, and immediately consult your doctor.

Look out for important symptoms.

- Rash, itching, hives, tingling.
- Change in eye & earsight, eye & ear pain or very bad irritation
- Eye & ear or eye & earlid swelling.
- Crusting or deposition of white crystals in the eye & ear
- Difficulty breathing or swallowing
- Hoarseness

Taking other medicines with Ciprotab Eye & Ear drops

- Inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- If you are using more than one type of eye & ear medicine, the medicines must be used at least 5 minutes apart. Eye & ear ointments should be used last

Pregnancy and Breastfeeding

If you are pregnant or might get pregnant, or if you are breastfeeding a baby, talk to your doctor before you use Ciprotab Eye & Ear drops.

Driving and using machines

If your sight is temporarily blurred or affected in any way following use of Ciprotab Eye & Ear drops, you should not drive or operate machinery until your vision is clear again.

3. HOW TO USE CIPROTAB EYE & EAR DROPS

- Adults and Children (age ≥ 1 year)
- The usual dose is one or two drops in the affected eye(s) & ear(s) four times a day.
- In severe infections, the dosage for the first 2 days may be one or two drops every 2 hours during waking hours.

A maximum duration of therapy of 21 days is recommended.

- If the product is contraindicated in a particular age group, this should be stated under this section.

If you take more Ciprotab Eye & Ear drops than you should

A topical overdose of Ciprotab eye & ear drops may be flushed from the eye & ear(s) with warm tap water.

If you forget to take Ciprotab Eye & Ear drops

If you forget to take a dose, take it as soon as you remember. Then continue your treatment as before. Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ciprotab Eye & Ear drops can cause side effects, but not everybody gets them.

Common Side Effects

- **Common** (1 to 10 users in 100): White deposits on the eye & ear surface (cornea), discomfort (stinging or burning, gritty feeling in the eye & ear, irritation), redness.
- **Uncommon** (1 to 10 users in 1,000): Damage to the eye & ear surface (cornea), sensitivity to light, blurred vision, swelling of the eye & ear or eye & earlid, pain, dry eye & ear, itchiness, eye & ear discharge, eye & earlid crusting, eye & earlids scales, eye & earlid redness, poor vision, watery eye & ears, red eye & ears
- **Rare** (1 to 10 users in 10,000): Damage of the eye & ear, inflammation, double vision, decreased eye & ear sensation, tired eye & ears, stye. If you notice white particles in your eye & ears, continue to use Ciprotab eye & ear drops but inform your doctor immediately.

You may also experience effects in other areas of your body including:

- a. Common:** Bad taste.
- b. Uncommon:** Headache, nausea.
- c. Rare:** Hypersensitivity, dizziness, ear pain, inflammation inside the nose, nasal sinus discharge, diarrhoea, abdominal pain, skin inflammation, tendon disorder.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE CIPROTAB EYE & EAR DROPS

Keep all medicines out of the reach of children. Store below 30°C, in a dry place.

Do not refrigerate or freeze.

Do not use Ciprotab Eye & Ear drops after the expiry date '**Exp. Date**' which is stated on the label. The expiry date refers to the last day of that month.

Do not use Ciprotab Eye & Ear drops if you notice leaking or visible particles in the product or if the solution is unclear or discoloured.

Medicines should not be disposed off via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Stop using the bottle 28 days after first opening.

6. INFORMATION

What Ciprotab Eye & Ear drops contains

The active substance is Ciprofloxacin.

What Ciprotab Eye & Ear drops solution looks like and contents of the pack

A clear colorless liquid supplied in a pack containing 10ml plastic bottle with a screw cap placed in an outer carton with insert.

Supplier and Manufacturer

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