



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
CIPROTAB-D EYE & EAR DROPS
 Ciprofloxacin 0.3% + Dexamethasone 0.1%

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

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

Ciprotab-D Eye & Ear drops contain ciprofloxacin, which is a fluoroquinolone antibacterial active against a broad spectrum of Gram-positive and Gram-negative ocular pathogens, and dexamethasone sodium phosphate, a corticosteroid that suppresses the inflammatory response to a variety of agents. It is indicated to use for post-operative inflammatory condition of eyes and Acute Otitis Media with tympanostomy tubes and Acute Otitis Externa.

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

Do not use Ciprotab-D Eye & Ear drops:

If you are allergic (hypersensitive) to ciprofloxacin and/or dexamethasone or any other quinolone antibiotic or to any of the other ingredients.

Tell 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 medicine, the medicines must be used at least 5 minutes apart. Eye ointments should be used last. Tell your doctor if you are using ritonavir or cobicistat as this may increase the amount of dexamethasone in the blood.

Take special care with Ciprotab-D Eye & Ear drops.

Only use Ciprotab-D eye & ear drops in your eye & ears.

Only use Ciprotab-D eye & ear drops in children younger than 1 year if recommended by your doctor.

Just like any antibiotic, use of Ciprotab-D 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-D. 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 & ear sight, 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-D 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-D Eye & Ear drops.

Driving and using machines


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

3. HOW TO USE CIPROTAB-D 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.

Title:	Insert Specification Sheet for Ciprotab-D Eye & ear Drops				
Paper type:	75gsm	Packaging tracking code:	PMN0617-0321-01	Font Colour:	Pantone 281 [Monocoloured]
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	Prepared By:	Approved by:	
Signature			
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Designation	MRA	HoM	HQRA



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If you take more Ciprotab-D Eye & Ear drops than you should
 A topical overdose of Ciprotab-D Eye & Ear drops may be flushed from the eye(s) & ear(s) with warm tap water.

If you forget to take Ciprotab-D Eye & Ear drops
 If you forget to take a dose, take it as soon as you remember. Then continue your treatments as before. Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

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

Common Side Effects (1 to 10 users in 100)

White deposits on the eye surface (cornea); Discomfort (stinging or burning, gritty feeling in the eye, irritation); Redness, watering of the eyes.

Uncommon (1 to 10 users in 1,000)

Damage to the eye surface (cornea); Sensitivity to light; Blurred vision; Swelling of the eye or eyelid, pain; Dry eye; Itchiness; Eye discharge; Eyelid crusting; Eyelids scales; Eyelid redness; Poor vision; Watery eyes; Red eyes.

Rare (1 to 10 users in 10,000)

Damage of the eye; Inflammation; Double vision; Decreased eye sensation; Tired eyes, sty.

Topical corticosteroids should not be used for longer than 1 week except under ophthalmic supervision.

If you notice white particles in your eyes, continue to use CIPROTAB-D Eye & Ear Drops but tell your doctor immediately.

You may also experience effects in other areas of your body such as the following:

Common: bad taste.

Uncommon: headache, nausea.

Rare: hypersensitivity, dizziness, ear pain, inflammation inside the nose, nasal sinus discharge, diarrhea, 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-D 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-D 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-D 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-D Eye & Ear drops contains

The active substance is ciprofloxacin and dexamethasone

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

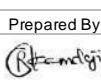

A clear colorless liquid supplied in a 5ml and 10ml plastic bottle with a screw cap placed in an outer carton with insert.

Supplier and Manufacturer

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