

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(MEDICAL PRODUCTS) – 1986**

The medicine is dispensed with a doctor's prescription only

Ciplox

Eye and Ear Drops (solution)

Active ingredient:

Ciprofloxacin (as hydrochloride) 0.3% W/W
Each 1 ml drops solution contains 3 mg ciprofloxacin (as hydrochloride).

For the list of inactive ingredients and allergens in the medicine - see section 2 subsection - "Important information about some of the ingredients of the medicine" and section 6 - "Additional information".

Read this leaflet carefully in its entirety before using this medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Ciplox, antibiotic eye and ear drops, is intended for adults and pediatric patients above the age of 1 year, to treat:

- Corneal ulcers and conjunctivitis caused by Gram-positive and Gram-negative microorganisms susceptible to ciprofloxacin.
- Localized or diffused otitis externa, accompanied by a strong inflammatory reaction with strains susceptible to ciprofloxacin, and for the acute flare-up of a chronic otitis media.
- Additional ear infections caused by strains susceptible to ciprofloxacin. Ciplox can be used under the supervision of an otorhinolaryngologist.

Therapeutic group:

Antibacterial fluoroquinolone antibiotic.

2. BEFORE USING THE MEDICINE:

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see section 6, "additional information").
- You are hypersensitive (allergic) to antibiotics of the quinolone group, including Ciprofloxacin.

Special warnings regarding the use of this medicine:

Before treatment with Ciplox, tell the doctor if:

- you use Ciplox as eye and ear drops only.
- you develop a rash after using Ciplox, refer to the doctor.
- you notice the first signs of a skin rash or any other hypersensitivity reaction, including hives, itching or breathing problems, **stop treatment and refer to a doctor immediately**. If a serious allergic reaction occurs, you may need emergency treatment.
- you experience pain, swelling or inflammation of the tendons during the use of this medicine or shortly thereafter, **stop treatment and refer to a doctor**.
- you are elderly or taking medicines from the corticosteroids group used to treat conditions such as pain and inflammation, asthma or skin problems, you are at increased risk of experiencing tendon problems during treatment with Ciplox. If you have an inflammation or inflammatory condition, **stop treatment and consult the doctor immediately** (also see section 4 - "Side effects").
- you may develop increased sensitivity to other infections while using this medicine, especially after prolonged use. If the symptoms worsen or suddenly recur, **consult the doctor**.
- you notice a skin reaction, **refer to a doctor**. Skin sensitivity to light has been observed with antibiotics. Similar reactions are uncommon with ciprofloxacin.
- you have a corneal ulcer and use Ciplox often, you may notice white deposit in the eyes (medicine deposit). This will pass with continued use of Ciplox. This deposit does not preclude continued use of Ciplox and will not adversely affect the further course of the recovery process.
- **Do not use contact lenses** (hard or soft) during the course of treatment with Ciplox.
- you use additional medicines, please also read the "Drug interactions" section.

Use in the ears

Use of Ciplox in the ears requires close medical monitoring.

Children and adolescents

Only use Ciplox in children over 1 year of age.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

If you are using additional ophthalmic products, you should apply them at least 5 minutes apart from each other. If you are also using an eye ointment, it should be the last product used.

Use of the medicine and food

There is no effect.

Pregnancy, breastfeeding and fertility

Do not use Ciplox during pregnancy or when breastfeeding, unless the doctor thinks that it is necessary.

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult the doctor or pharmacist before using this medicine.

Driving and operating machinery

If your vision is blurred for some time after using Ciplox as eye drops, do not drive or operate machinery until your vision is clear again.

Children should be cautioned against riding bicycles or playing near roads and similar areas. Use of Ciplox as ear drops does not affect the ability to drive or operate machinery.

Important information about some of the ingredients of the medicine

This medicine contains 0.3 mg benzalkonium chloride per 5 ml, which is a concentration equivalent to 0.06 mg/ml. Benzalkonium chloride may be absorbed by soft

contact lenses and may change the color of the contact lenses. Avoid contact of the medicine with soft contact lenses. If, despite this, you have been allowed to use contact lenses, remove them before using the eye drops and wait at least 15 minutes before reinserting them in your eyes. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or corneal disorders (the clear layer at the front of the eye). Contact the doctor if you experience an unusual eye sensation, stinging or pain in the eye after using this medicine.

When using the medicine in the ear, the preservative in the medicine (benzalkonium chloride) may cause irritation and skin reactions.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of this medicine.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:

Use in the eye (adults and children over one year of age only):

• Corneal ulcers:

Use Ciplox at the following intervals, even during nighttime hours:

- **Day 1:** 2 drops in the affected eye, every 15 minutes for the first 6 hours and then 2 drops, every 30 minutes, for the rest of the day.
- **Day 2:** 2 drops, every hour.
- **Day 3 to Day 14:** 2 drops, every 4 hours.

• Superficial bacterial infections of the eye and eyelids:

Use Ciplox at the following intervals, during waking hours only:

- **Days 1 and 2:** 1 or 2 drops in the affected eye, every two hours.
- **Day 3 and on:** 1 or 2 drops, every 4 hours.

Use in the ear (in adults and children over one year of age only):

3 to 4 drops in the affected ear, 2 to 4 times a day or more frequently, in accordance with the doctor's instructions.

Consult the doctor if your symptoms worsen or suddenly recur.

Instructions for use

A) Use in the eye:



1. Wash your hands.

2. Twist off the bottle cap. If the child-resistant snap collar is loose after removal of the cap, remove it before using the product.

3. To avoid contamination of the drops, **be sure that the dropper at the tip of the bottle does not come into contact with anything else**.

4. Pull the lower eyelid of the treated eye downward (Picture 1).

5. Tilt your head back and bring the dropper at the tip of the bottle close to the eye, without touching it.

6. Gently press on the base of the bottle (Picture 2) until 1 or 2 drops drip into the space between your eye and lower lid.

7. **Close the eye and press with the finger on the corner of the eye near the nose for 2 minutes (Picture 3).**

This will limit the amount of medicine that reaches your blood.

8. Repeat steps 4 to 7 in the second eye, as needed. Tightly close the bottle cap.

If a drop misses your eye, try again.

B) Use in the ear:

1. Make sure the solution is at room temperature or, preferably, at body temperature. This makes instillation of the drops into the ear more pleasant.

2. Wash your hands.

3. Twist off the bottle cap. If the child-resistant snap collar is loose after removal of the cap, remove it before using the product.

4. To avoid contamination of the drops, **be sure that the dropper at the tip of the bottle does not come into contact with anything else**.

5. Clean the outer ear canal of the affected ear.

6. Lie down on your side with the ear being treated facing upwards.

7. Instill one or two drops into the ear.

8. Remain lying on your side for 5 to 10 minutes.

9. Repeat steps 5 to 8 in the second ear, as needed. Tightly close the cap of the bottle.

If a drop misses your ear, try again.

Instead of instilling the drops, a wick or pack soaked with the solution can be inserted into the ear. Leave the wick in place for 1 to 2 days. Soak the wick twice a day in the solution until it is saturated.

Do not exceed the recommended dose.

Wait at least 5 minutes between the administration of this medicine and the administration of other eye drops.

Attention: Do not inject or swallow! For external use only.

Method of administration

For use in the eyes or ears only.

Duration of treatment

The doctor will tell you how long to use Ciplox. **Do not stop treatment too early.**

The ear treatment generally takes 5 to 10 days. In some cases, the treatment duration may be extended. Refer to the doctor for further information.

Do not use Ciplox for more than 21 days, unless instructed to do so by the doctor.

If you used too much Ciplox

• If you used a larger amount of Ciplox than required in the eye or ear, rinse the area with lukewarm water. Do not instill additional drops until it is time for the next dose.

• If an adult or child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. However, no serious complications are expected.

If you forgot to use Ciplox

Take the forgotten dose as soon as possible. **However, do not take a double dose to compensate for a forgotten dose.**

If you remember close to the time the next dose should be taken, skip the forgotten dose and

continue with the regular dosing intervals.

Adhere to the treatment regimen as recommended by the doctor.

If you stop using Ciplox

Do not stop treatment too early, even if the symptoms have passed. If you stop using this medicine before the designated time, your symptoms may recur.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them. If you have further questions regarding the use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Ciplox may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

The side effects reported with Ciplox have been categorized according to the frequency with which they occur:

• **"Very common"** occur in more than 1 in 10 users;
• **"Common"** occur in 1 to 10 in 100 users;
• **"Uncommon"** occur in 1 to 10 in 1,000 users;
• **"Rare"** occur in 1 to 10 in 10,000 users;
• **"Very rare"** occur in fewer than one in 10,000 users;
and in the case of **"unknown frequency"**, the prevalence cannot be determined from the available data.

The following side effects have been reported with other antibiotics of the same family (quinolones), but may also occur with Ciplox.

Stop treatment and immediately consult a doctor in the following cases:

- You notice the first signs of a skin rash or any other sign of a hypersensitivity reaction, such as hives, itching or breathing problems. If a serious hypersensitivity reaction occurs, emergency treatment is required immediately.
- You feel pain, swelling or inflammation of the tendons while using this medicine or shortly thereafter. If you are elderly or take anti-inflammatory medicines similar to cortisone, you are at increased risk of developing tendon problems.

The following side effects have been reported with Ciplox:

A) After use in the eye:

• Eye problems:

- **Common:** White deposits on the surface of the eye (cornea), discomfort in the eye, eye redness.
- **Uncommon:** Damage or staining of the cornea, photosensitivity, reduced or blurred vision, ocular or eyelid edema, eye pain, dry eyes, itching in the eyes, increased tearing, discharge from the eye, crust on the eyelids, scales on the eyelids, redness of the eyelids.
- **Rare:** damage to the eye, inflammation in the eye, double vision, reduced sensitivity of the eyes, tired eyes, stye, eye irritation.

• Effects in other parts of the body:

- **Common:** bad taste in the mouth.
- **Uncommon:** headache, nausea.
- **Rare:** hypersensitivity, dizziness, ear pain, inflammation of the nasal mucosa (rhinitis), increased secretion from the sinuses of the nose, diarrhea, abdominal pain, skin inflammation.
- **Unknown frequency:** tendon disorder.

B) After use in the ear:

• Ear problems:

- **Uncommon:** ear pain, congestion in the ear, discharge from the ear, itchy ear.
- **Unknown frequency:** ringing in the ear (tinnitus).

• Reactions in other parts of your body:

- **Uncommon:** headache, skin inflammation, fever.

No serious side effects have been reported in children under 12 years of age.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report side effects due to medication treatment" found on the Ministry of Health website (www.health.gov.il) that directs to an online form for reporting side effects, or by clicking the link: <https://sideeffects.health.gov.il>.

5. HOW TO STORE THE MEDICINE?

• Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

• Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.

• The medicine may be used for up to **28 days** after the bottle is first opened, and not later than the expiry date of the medicine stated on the package.

• **Storage conditions:** Store below 25°C in its tightly closed bottle. Do not freeze.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:

Mannitol, disodium edetate, sodium acetate trihydrate, benzalkonium chloride, acetic acid solution (1mol/L), Water for injections.

What does the medicine look like and what are the contents of the package?

Ciplox is a clear solution provided in a plastic 5 ml bottle.

Marketing authorization Holder and Importer and its address:

Raz Pharmaceuticals LTD.,
31 GESHER HAETZ ST., INDUSTRIAL PARK
EMEK HEFER, 3877701, ISRAEL.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

177-11-37316-99.

Revised in April 2025 according to MOH guidelines.

RAZP0389-01