

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Ciloxan

Eye and Ear Drops

Active ingredient: Ciprofloxacin (as hydrochloride) 3 mg/ml

Inactive and allergenic ingredients: see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the 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 your ailment. 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?

Antibiotic eye and ear drops for the treatment of inflammations caused by bacteria sensitive to ciprofloxacin in adults and children over one year of age.

Therapeutic group:

Antibacterial fluoroquinolone antibiotic.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine, detailed in section 6.
- you are sensitive (allergic) to antibiotics of the quinolone group, including Ciloxan.

Special warnings regarding use of the medicine:

- If 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.
- If you experience pain, swelling or inflammation of the tendons during use of the medicine or shortly thereafter, **stop treatment and refer to a doctor.**
- If you are elderly or are taking medicines called corticosteroids 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 Ciloxan. 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 get worse or suddenly recur, **consult the doctor.**
- If you notice a skin reaction, refer to a doctor. Skin sensitivity to light has been observed with antibiotics. Similar reactions are uncommon with ciprofloxacin.
- If you have a corneal ulcer and use Ciloxan often, you may notice white deposits in the eyes (medicine deposits). This will pass with continued use of Ciloxan. This deposit does not preclude prolonged use of Ciloxan 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 Ciloxan.
- Use Ciloxan as eye or ear drops only. If you use additional medicines, please also read the "Drug interactions" section.

Use in the ears

Use of Ciloxan in the ears requires close medical monitoring.

Children and adolescents

Only use Ciloxan 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 preparations, wait at least 5 minutes between each preparation. If you are also using an eye ointment, it should be the last preparation used.

Use of the medicine and food

There is no effect.

Pregnancy, breastfeeding and fertility

Do not use Ciloxan 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 Ciloxan as eye drops, do not drive or operate machinery until your vision is clear again.

Use of Ciloxan as ear drops does not affect the ability to drive and 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 putting them back in your eyes. Benzalkonium chloride may cause eye irritation, especially if you have dry eyes or corneal disease (the clear layer at the front of the eye). Contact the doctor if you experience an unusual 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 preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally:

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

- Corneal ulcers:

Use Ciloxan 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 Ciloxan 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 only over one year of age):

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 get worse 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, **do not let the tip of the bottle touch any surface (including the eye itself).** Keep the bottle tightly closed.
4. The bottle of drops may not be full; this is to allow better control of the drip rate.
5. How to use the drops: Tilt your head back. Using the index finger, pull the lower eyelid down to form a kind of "pocket" (Picture 1), and bring 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 your finger on the inner corner of the eye, near the nose, for 2 minutes** (Picture 3) after instilling into the eye. This step helps prevent the absorption of the medicine into the body and thus helps prevent side effects.
8. After using the medicine, wash your hands thoroughly to clean them of medicine residue.
9. To avoid spreading infection, do not use the same bottle of medicine for more than one person.
10. If necessary, repeat steps 5 to 8 in the other eye. Put the cap back on the bottle and close tightly in a twisting motion. 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, it should be removed before using the product.
4. To avoid contamination of the drops, **do not let the tip of the bottle touch any surface (including the ear).**
5. The bottle of drops may not be full; this is to allow better control of the drip rate.
6. Clean the outer ear canal of the affected ear.
7. Lie down on your side with the ear being treated facing upwards.
8. Straighten the ear canal: For adults: gently pull the earlobe upward and backward; For children: gently pull down and back. Instill the medicine into the ear canal.
9. Remain lying on your side for 5 to 10 minutes.
10. If necessary, repeat steps 6 to 9 in the other ear.
11. Do not rinse the dropper after use. Wipe the tip of the dropper with a clean tissue and keep the bottle tightly closed. 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 administration of this medicine and administration of other eye drops.

Attention: This medicine is intended for external use only.

Duration of treatment

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

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

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

If you used too much Ciloxan

- If you used a larger amount of Ciloxan 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 Ciloxan

Take the forgotten dose as soon as possible. **However, do not take a double dose to compensate for a forgotten dose.** Take the next dose at the usual time and consult a doctor.

Adhere to the treatment regimen as recommended by the doctor.

If you stop using Ciloxan

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 use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Ciloxan 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 Ciloxan have been categorized according to the frequency with which they occur: “**very common**” occur in more than 1 in 10 patients; “**common**” occur in 1 to 10 in 100 patients; “**uncommon**” occur in 1 to 10 in 1,000 patients; “**rare**” occur in 1 to 10 in 10,000 patients; “**very rare**” occur in fewer than one in 10,000 patients; 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 Ciloxan. **Stop treatment and immediately consult your 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 Ciloxan:

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.

● 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.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- 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) that appears on the package. The expiry date refers to the last day of that month.
- After first opening, can be used for 28 days.
- **Storage conditions:** Store below 25°C. Do not freeze. Do not refrigerate.

6. FURTHER INFORMATION

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

Mannitol, disodium edetate, acetic acid (6N), sodium acetate trihydrate, benzalkonium chloride, hydrochloric acid and/or sodium hydroxide, purified water.

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

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

Registration Holder and Importer and its address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in April 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 061 17 27635