

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

The medicine is dispensed with
a doctor's prescription only

Ciloxan

Ocular and Otic Solution

Active ingredient: Ciprofloxacin Base (as HCl) 3 mg/ml

Read this 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 the treatment of 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?

Therapeutic activity:

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 antibiotics of the fluoroquinolone family.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you have a known sensitivity to any of the ingredients of the medicine or to other antibiotics of the quinolone group.

Special warnings regarding use of this medicine:

Do not use the medicine without consulting the doctor before starting treatment:

- If you are pregnant or breastfeeding.
- Prolonged treatment may cause development of resistant strains, including fungal infection.
- If you are sensitive to any type of food or medicine, inform the doctor before taking the medicine.
- Stop treatment and immediately contact your doctor if one or more of the following side effects occur: first signs of a skin rash or any other allergic reaction, including urticaria, itching, breathing problems. In case of a severe allergic reaction - you may need emergency medical care.
- If you experience pain, swelling or you developed an inflammation while taking **Ciloxan**, or shortly after taking it – Stop treatment and contact your doctor.
- Elderly people treated with steroids are at higher risk of developing tendon problems when using **Ciloxan**. If additional infections develop, stop treatment and immediately contact your doctor.
- Use in infants under one year of age is only upon the doctor's instructions.

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

In particular inform the doctor or the pharmacist if you are taking:

- Cyclosporine (to prevent transplant rejection).
- Theophylline (to treat asthma).
- Warfarin (to prevent blood clotting).
- Ciprofloxacin administered systemically.

If you are using additional eye drops, wait at least 15 minutes between applications.

Pregnancy and breastfeeding

If you are pregnant, or about to get pregnant, or if you are breastfeeding, consult the doctor before commencing treatment with **Ciloxan**.

Children

This medicine is not usually intended for infants under one year of age.

Driving and use of machines

Ciloxan has no known effect on the ability to drive or operate machines. If blurred vision occurs after using the ophthalmic preparation, be cautious when driving a car, operating machinery and the like.

Important information regarding some of the ingredients of the medicine

For use in the eyes - this preparation contains the preservative benzalkonium chloride, which can cause irritation of the eyes or discoloration of soft contact lenses. Do not use this preparation when you are wearing soft contact lenses.

Remove the lenses before using the preparation; they can be reinserted no less than 15 minutes after instilling the medicine into the eye.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only. Do not exceed the recommended dose.

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

Wait at least 15 minutes between the application of this medicine and other eye drops.

Attention: This medicine is intended for external use only.

Directions for use:

For the eyes -

In order to prevent contamination, do not allow the tip of the bottle to touch any surface (including the eye itself). Keep the bottle closed tightly. The bottle of drops may not be full; this is to allow for better control of the drip rate.

How to use the drops: First, wash your hands. Tilt your head back. Using your index finger, pull the lower eyelid downward, to create a "pocket". Drip the medicine into the "pocket" that is formed. Close your eyes gently. Do not blink.

Leave your eyes closed for 1 to 2 minutes. Immediately after instilling the drops into the eye, put pressure on the inner corner of the eye using your middle finger. Continue applying pressure for 1 to 2 minutes after instilling the drops into the eye. This action helps to avoid absorption of the medicine into the body and thus helps prevent side effects. After using the medicine, wash your hands thoroughly in order to wash off remnants of the medicine. In order to avoid transmitting the infection, do not use the same bottle of medicine for more than one person.

For the ears -

In order to prevent contamination of the drops, do not allow the tip of the bottle to come into contact with any surface (including the ear). The bottle of drops may not be full; this is to allow for better control of the drip rate.

How to use the drops: Lie on your back or tilt your head so that the ear needing treatment is facing upward. Straighten the ear canal: For adults: Gently pull the ear lobe upward and back. For children: gently pull downward and back.

Instill the medicine into the ear canal. Maintain the position in which the ear is turned upwards for approximately five minutes so that the medicine can reach the bottom of the ear canal (for children and other patients who are unable to lie still for five minutes, try to maintain a position in which the treated ear is facing upward for at least 1 or 2 minutes). Do not rinse the dropper after use. Wipe the tip of the dropper with a clean tissue and keep the bottle tightly closed.

If you forgot to take this medicine at the designated time, take a dose as soon as you remember; but never take two doses together.

If you took an overdose or if a child accidentally swallowed the medicine, refer to a doctor or proceed to a hospital emergency room immediately and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

Adhere to the treatment regimen recommended by the doctor.

Even if there is an improvement in your health, do not discontinue treatment with the medicine without consulting the doctor or pharmacist.

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.

Side effects requiring special attention:

Rash or any other hypersensitivity effect (including urticaria, itching, breathing problems): stop treatment and refer to the doctor immediately.

Side effects occurring **frequently**: White deposits on the surface of the eye (cornea), discomfort (pruritus or burning) and sensation of a foreign object in the eye after application, irritation and redness in the eye, bad taste in the mouth.

Side effects occurring **infrequently**: Damage to, or staining of, the cornea, photosensitivity, blurred vision, ocular or eyelid edema, pain, dry eyes, ocular pruritus, strange sensation in the eye, discharge from the eye, crust and scales on the eyelids, redness of the eyelids, reduced visual acuity, tearing eyes, redness of the eyes, ocular allergy, nausea, headache.

Side effects occurring **rarely**: ocular damage, keratitis, double vision, reduced sensitivity of the eyes, tired eyes. Hypersensitivity reaction, dizziness, ear pain, stye, inflammation and discharge from the nose, diarrhea, abdominal pain, skin inflammation, intolerance to the medicine, abnormal laboratory test results.

If any of the side effects worsen, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Reporting side effects

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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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 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:** In a cool and dark place. Store below 25°C.

- Close tightly to prevent infiltration of air and moisture.

6 FURTHER INFORMATION

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

Benzalkonium Chloride, Sodium Acetate Trihydrate, Mannitol, Acetic Acid (6N), Disodium Edetate, Hydrochloric Acid, 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.

Manufacturer: Alcon-Couvreur N.V., Puurs, Belgium.

Registration Holder: Novartis Israel Ltd., 36 Shacham St. Petach-Tiqva

The format of this leaflet was determined by the Ministry of Health, and its content was checked and approved by it in August 2013

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