PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a doctor's prescription only

NAFLOXIN

Eye and Ear Drops

Active ingredient:

Ciprofloxacin Hydrochloride Monohydrate 3.5 mg/ml (equivalent to Ciprofloxacin 3mg/ml)

For the inactive ingredients - see section 6 "Additional information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about this medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat your illness. 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 inflammation caused by bacteria susceptible to ciprofloxacin in adults and children over one year of age.

Therapeutic group: Antibacterial agent of the fluoroquinolone antibiotic class.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:

- You have known sensitivity to any of the medicine ingredients or to any of the quinolone antibiotics group.

! Special warnings regarding the use of the medicine

- Prolonged use may cause development of resistant strains, including fungal infection.
- If you are sensitive to any type of food or medicine, inform the doctor before commencing treatment with this medicine.
- Discontinue treatment and refer to the doctor immediately 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 serious allergic reaction - you may need emergency treatment.
- If you experience pain, swelling or you develop an inflammation while or shortly after taking Nafloxin – stop treatment and refer to the doctor.
- Elderly people treated with steroids are at higher risk of developing tendon problems during treatment with Nafloxin. In the event of additional infections development – discontinue treatment and refer to the doctor immediately.
- Use in infants under one year of age is only upon the doctor's instructions.

! If you are using, or have recently used, other medicines, including non-prescription medications and nutritional supplements, tell the doctor or pharmacist.

In particular, inform the doctor or the pharmacist if you are using:

- 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 instillations. If you are also using eye ointments, apply them last.

! Pregnancy and breastfeeding

If you are pregnant, planning to become pregnant or are breastfeeding, consult a doctor before you use Nafloxin.

! Children

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

! Driving and using machines

Nafloxin has no known effect on ability to drive or operate machines. If blurred vision occurs after using the preparation in the eyes, exercise caution when driving a car, operating machinery and the like.

! Important information regarding some of the medicine ingredients

For use in the eyes - this preparation contains the preservative benzalkonium chloride, that may cause eye irritation or can discolour soft contact lenses.

Do not use this medicine when you are wearing contact lenses (hard or soft). Remove the lenses prior to using the medicine, you may wear them again at least 15 minutes after instilling the medicine into the eye.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. You should check with the doctor or the pharmacist if you are unsure.

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

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

Attention: Do not swallow! 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 drops bottle may not be full; this is to allow a better control of the drip rate.

How to use the drops: First, wash your hands, tilt your head back. Pull down your lower eyelid with the aid of the forefinger, to form a "pocket". Instill the medicine into the "pocket" formed. Close your eyes gently. Do not blink. Keep your eyes closed for 1 to 2 minutes. Immediately after instilling the drops into the eye, press with your middle finger on the inner corner of the eye. Continue pressing for 1 to 2 minutes after applying to the eye. This action helps prevent side effects. After using the medicine, wash your hands thoroughly to clean them of any remnants of the medicine. In order to prevent spread of 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 touch any surface (including the ear). The drops bottle may not be full; this is to allow a better control of the drip rate.

How to use the drops: Lie on your back or tilt your head, so that the ear to be treated faces upward. Straighten the ear canal: For adults: gently pull the earlobe upwards and backwards; For children: gently pull downwards and backwards. Instill the medicine into the ear canal. Maintain a position where the ear is facing upward for 5 minutes, so that the medicine will be able to penetrate to the bottom of the ear canal (for children and other patients unable to remain still for 5 minutes, try to have them maintain a position where the treated ear is facing upward for at least 1 or 2 minutes). Do not wash the dropper after use. Wipe the edge of the dropper with a clean tissue and keep the bottle tightly closed.

If you took an overdose

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

If you forget to take the medicine

If you forgot to take this medicine at the scheduled time take it immediately when you remember; but never take a double dose.

Persist with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with this medicine without consulting the doctor or the pharmacist.

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

If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Nafloxin 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.

Discontinue use and refer to a doctor immediately if the following effects develop:

Rash or any other hypersensitivity reaction (including urticaria, itching, breathing problems).

Contact the physician immediately if the following effect develops:

Appearance of white particles in the eyes.

Common side effects (affects 1-10 users out of 100):

White deposits on the eye surface (cornea), discomfort (itching or burning) and gritty feeling in the eye after instillation, irritation and redness in the eye, bad taste in the mouth.

Uncommon side effects (affects 1-10 users out of 1,000):

Damage to or staining of the cornea, sensitivity to light, blurred vision, ocular or eyelid edema, pain, dry eyes, ocular pruritus, strange sensation in the eye, eye discharge, eyelid crusting, eyelids scales, reduced visual acuity, watery eyes, red eyes, ocular allergy, nausea, headache.

Rare side effects (affects 1-10 users out of 10,000):

Ocular damage, keratitis, double vision, decreased eye sensation, tired eyes, sty, hypersensitivity reaction, dizziness, ear pain, inflammation and discharge from the nose, diarrhea, abdominal pain, dermatitis, tendons problems, intolerance to the medicine, abnormal laboratory test results.

Additional side effects observed when used in the ears:

Local pain in the ears, ear pruritus, fungal ear infection, headache.

If a side effect occurs, if any side effect gets worse, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health (MoH) by clicking on the "Report on side effects due to medication therapy" link on the MoH home page www.health.gov.il which refers to the online form for side effects reporting, or by entering the link: https://sideeffects.health.gov.il/

Side effects can be also reported by email: safety@trima.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a close place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from 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.
- Stop using the bottle 28 days after first opening.
- **Storage conditions:** Store at a temperature below 25˚C. Do not refrigerate. Protect from light.
- Close tightly to prevent penetration of air and moisture.

6. FURTHER INFORMATION

- **In addition to the active ingredient, the medicine also contains:** mannitol, sodium acetate, acetic acid, benzalkonium chloride, disodium edetate, sodium hydroxide, water for injection.
- **What does the medicine look like and what are the contents of the package?**
- Nafloxin is packed in a plastic bottle placed in a carton pack. Each Nafloxin bottle contains 5 ml solution.
- **Registration holder:** Trima, Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000 Israel.
- **Manufacturer:** Cooper S.A., Pharmaceutical industry, 64 Aristovoulou., Petralona, Athenes-Greece.
- Revised in April 2021 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 155.32.34358.00

0421C

Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

TRIMA

C/3000/752 P00001475 PIL-0420-07