

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

The medicine is dispensed with a doctor's prescription only.

Tobrex® Ophthalmic Ointment

Composition:

Each 1 gram contains:

Tobramycin 3 mg

For inactive and allergenic ingredients, see 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 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?

Therapeutic action: An antibiotic preparation for the treatment of eye inflammations caused by bacteria sensitive to tobramycin.

Therapeutic group: Aminoglycoside antibiotics.

2. BEFORE USING THE MEDICINE:

Do not use the medicine if:

- You are sensitive (allergic) to tobramycin or to any of the additional ingredients contained in the medicine (see section 6). Symptoms of allergy generally include: shortness of breath, wheezing or breathing difficulties, swelling of the face, lips, tongue or other parts of the body, rash, itching, hives.
- You have a known sensitivity to aminoglycoside antibiotics.

Special warnings regarding use of the medicine:

Before beginning treatment with Tobrex Ophthalmic Ointment, tell the doctor if:

- You have had an allergy to other medicines, food, preservatives or dyes.
- You have or have ever had a neuromuscular disorder, such as myasthenia gravis, Parkinson's disease. Consult your doctor. Antibiotics of this kind may worsen muscle weakness.
- You are pregnant or are planning a pregnancy. The doctor will discuss with you the risks and benefits of using Tobrex Ophthalmic Ointment during pregnancy.
- You are breastfeeding or plan to breastfeed. The doctor will discuss with you the risks and benefits of using Tobrex Ophthalmic Ointment when breastfeeding.
- Prolonged use of antibiotics may cause an infection. In case an infection develops, inform the doctor so you can start the appropriate treatment.

Children and adolescents:

The safety and effectiveness of Tobrex Ophthalmic Ointment in children under the age of 12 months have not been established.

Drug interactions:

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

Especially if you are taking:

- Other ophthalmic preparations.
- Beta-lactam-type antibiotics intended to treat infections of the eye, ear or skin.
- Medicines that can cause hearing loss, medicines that may damage the nervous system.
- Other aminoglycoside antibiotics that are similar to tobramycin.

These medicines may affect how Tobrex Ophthalmic Ointment works or Tobrex Ophthalmic Ointment may affect them. You may need different amounts of the medicines or you may need to take different medicines.

Pregnancy, breastfeeding and fertility:

Tell the doctor if you are pregnant or plan to become pregnant.

The doctor will discuss the risks and benefits of using Tobrex Ophthalmic Ointment during pregnancy.

Tobrex Ophthalmic Ointment should only be used during pregnancy if the benefit to the mother justifies the risk to the unborn baby. Otherwise, Tobrex Ophthalmic Ointment is not recommended during pregnancy.

Tell the doctor if you are breastfeeding or planning to breastfeed.

The doctor will discuss the risks and benefits of using Tobrex Ophthalmic Ointment when breastfeeding.

Tobrex Ophthalmic Ointment should only be used during breastfeeding if the benefit to the mother justifies the risk to the baby.

No studies have been conducted to assess the effect of use of Tobrex Ophthalmic Ointment on human fertility.

Driving and using machinery:

Exercise caution when driving a car and operating machinery until you know the effect Tobrex Ophthalmic Ointment has on your eyesight. As with other ophthalmic medicines, blurred vision or other vision disturbances may affect your ability to drive and operate machinery. If you have blurred vision after using Tobrex Ophthalmic Ointment, wait until your vision is clear before driving or operating machinery.

Important information if you wear contact lenses:

Do not use Tobrex Ophthalmic Ointment when wearing contact lenses. The ointment base present in Tobrex Ophthalmic Ointment may be very difficult to clean off the contact lenses. You can put the contact lenses back into your eyes 15 minutes after using Tobrex Ophthalmic Ointment.

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 recommended dosage is generally: 1-1.5 cm of ointment, 2-3 times a day.

Dosage for children: as per the doctor's instructions.

Do not exceed the recommended dose.

Do not swallow. The ointment is intended for external use, in the eyes only.

Use Tobrex Ophthalmic Ointment at set times every day, unless you have been instructed otherwise by the doctor. This will also help you remember when to use the medicine.

Instructions for use:

It is important to use Tobrex Ophthalmic Ointment exactly as instructed by the doctor. If used less frequently than the doctor's instructions, your eye inflammation may not improve.

More frequent use will not make the eye inflammation resolve faster and may even cause onset of side effects.

If you are wearing soft contact lenses, remove them before using Tobrex Ophthalmic Ointment.

Follow these instructions when using Tobrex Ophthalmic Ointment:

- Wash your hands thoroughly with soap and water.
- Remove the cap from the ointment tube. Using your forefinger, carefully pull down your lower eyelid to form a "pocket". See Diagram 1.
- Using your other hand, carefully press the ointment tube to release a small amount of ointment (approximately 1-1.5 cm is usually sufficient, unless you have been instructed otherwise by the doctor or pharmacist) into the pocket. See Diagram 2.
- To be sure that the ointment stays in the eye, slowly close your eye and do not blink. Keep your eye closed for 1-2 minutes. See Diagrams 3 and 4.
- If necessary, repeat steps 1-4 for the other eye as well.
- Replace the cap on the tube and close tightly.
- Wash your hands again with soap and water to remove any residue.



You may feel a burning sensation in the eye shortly after using the ointment. If this sensation persists or causes considerable discomfort, refer to the doctor.

In order to prevent spreading of infection, do not use the same tube of medicine for more than one person.

To avoid contamination of the ointment, do not allow the tip of the tube to come into contact with any surface (including the eye itself). After use, wipe the tip of the ointment tube with a clean tissue, and then close the tube tightly.

After using Tobrex Ophthalmic Ointment, wait at least 5 minutes before using eye drops or another eye ointment. Wait 15 minutes before putting in contact lenses.

If you accidentally took a higher dosage, rinse the eye with lukewarm water. If a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

Use this medicine at set intervals, as determined by the attending doctor.

If you forgot to take the medicine at the required time, do not take a double dose. Skip the forgotten dose and take the next dose at the scheduled time, and consult the doctor.

Adhere to the treatment regimen as recommended by your doctor. Even if there is an improvement in your health, do not stop using Tobrex Ophthalmic Ointment without consulting the doctor. **If you stop using Tobrex Ophthalmic Ointment** prematurely, against the doctor's instructions, the infection will not fully disappear and the symptoms may return.

If your doctor switches your Tobrex Ophthalmic Ointment treatment with another treatment, carefully follow the doctor's instructions regarding when to stop Tobrex Ophthalmic Ointment and when to start the new medicine.

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 Tobrex Ophthalmic Ointment may cause side effects in some users. Do not be alarmed by reading the list of the side effects. You may not suffer from any of them.

Eye-related side effects:

Common side effects (effects occurring in 1-10 in 100 users): eye discomfort, eye redness.

Uncommon side effects (effects occurring in 1-10 in 1,000 users): inflammation of the cornea, corneal scratch, conjunctival disorder, poor vision, blurred vision, eyelid redness, conjunctival edema, eyelid swelling, eyelid disorder, eye pain, dry eye, eye discharge, itchiness in the eye, sensation of a foreign object in the eye, increased tear production.

Side effects of unknown frequency (effects whose frequency has not yet been established): eye allergy, eye irritation, itchy eyelid,

Side effects related to other body parts:

Uncommon side effects (effects occurring in 1-10 in 1,000 users): allergy, headache, hives, skin inflammation, eyelash or eyebrow loss, vitiligo (leukoderma), itching, dry skin.

Side effects of unknown frequency (effects whose frequency has not yet been established): anaphylactic reaction, Steven's-Johnson syndrome, erythema multiforme, rash.

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 outer package. The expiry date refers to the last day of that month.

Storage conditions:

Do not store above 25°C.

After first opening, can be used for 4 weeks.

6. FURTHER INFORMATION:

In addition to the active ingredient, the medicine also contains: Mineral Oil (Liquid Paraffin), Chlorobutanol Anhydrous, White Soft Paraffin.

What the medicine looks like and the content of the package: Tobrex Ophthalmic Ointment is supplied in an aluminum tube and contains 3.5 grams ointment.

Manufacturer: Alcon Couvreur, Belgium.

RIJKSWEG 14, 2870 PUURS, BELGIUM.

Registration Holder: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 047 16 22795

This leaflet was checked and approved by the Ministry of Health in June 2015 and was updated in accordance with the Ministry of Health guidelines in April 2020.