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

This medicine is dispensed with a doctor's prescription only

# TOBREX 2X

## Eye drops, 3 mg/ml

### Composition:

Active ingredients: Each mL contains tobramycin 3 mg.

For the list of inactive ingredients in the preparation, see section 6 - "Further Information".

**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 you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

This medicine is not intended for infants under 1 year of age.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

For the treatment of eye inflammations caused by bacteria susceptible to tobramycin.

#### Therapeutic group:

Antibiotic from the aminoglycoside group.

### 2. BEFORE USING THE MEDICINE

#### Do not use the medicine:

- If you have a known sensitivity to tobramycin or to antibiotics from the aminoglycoside group, or to any of the ingredients of the preparation (listed in section 6 - "Further Information").
- In children and infants under 1 year of age.

#### **Before treatment with Tobrex 2X, tell the doctor if:**

• You are suffering from liver or kidney diseases. Tell the doctor if you are taking other antibiotics, either orally or by injection.

• As with all antibiotics, prolonged use of **Tobrex 2X** may cause additional infections. Consult the doctor if you are suffering from worsening or sudden recurrence of symptoms.

#### **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 eye drops, wait 5-10 minutes after using **Tobrex 2X** before use. If you are also using an eye ointment - only use it after applying all the drops.

#### **Pregnancy and breastfeeding**

If you are pregnant, planning a pregnancy, or are breastfeeding, consult a doctor.

#### **Driving and use of machinery**

Use of Tobrex 2X may cause blurred vision. Do not drive or use machines until your vision is clear.

#### **Important information regarding some of the ingredients of the medicine**

**Tobrex 2X** eye drops contain the preservative benzododecium bromide, which may be absorbed by soft contact lenses. Do not use these drops when you are wearing soft contact lenses. Remove the lenses before using the drops and they can be reinserted after no less than 15 minutes have elapsed from instilling the medicine into the eye.

### 3. HOW SHOULD YOU USE THIS 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.

The usual dosage is generally: one drop in the treated eye, twice a day (morning and evening) for one week.

For severe infections, this dosage may be increased to one drop, four times a day on the first day and then one drop, twice daily, for six days.

#### **Do not exceed the recommended dose.**

Do not swallow. This medicine is intended for external use only.

#### Instructions for use:

- To avoid 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 better control of the drip rate.
- Do not squeeze the bottle; a gentle press on the base of the bottle is enough to release the drop.
- How to use the drops: First, wash your hands. Tilt your head back. With your index finger, pull the lower eyelid down, to create a "pocket" (Figure 1). Instill the medicine into the "pocket" that was formed (Figure 2). Close your eyes gently. Do not blink. Keep your eyes closed for 1 to 2 minutes.
- In addition to the instructions provided above - immediately after instilling the drops into the eye, press the inner corner of the eye with your middle finger. Continue applying pressure for 1 to 2 minutes after instilling into the eye.
- This action helps prevent the medicine from being absorbed into the body, and thereby helps prevent side effects.
- After using the medicine, wash your hands thoroughly to clean them from remnants of the medicine.
- To avoid spreading infection, do not use the same bottle of medicine for more than one person.

If you were unsuccessful in instilling into the eye - try again.

If you have to put a drop in the other eye, repeat the instructions above for the second eye as well.

If you are using more than one type of eye drops, wait at least 5-10 minutes between applying **Tobrex 2X** and other eye drops. Eye ointments should be used only after completion of application of eye drops.

If you wear soft contact lenses, do not use the drops while wearing the lenses. After using the drops, wait at least 15 minutes before putting the lenses in.

Wearing contact lenses during the course of treatment of an eye infection is not recommended, as their use may cause exacerbation of your condition.

**If you accidentally took a higher dosage,** wash the eye with lukewarm water.

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

**If you forgot to take the medicine at the required time,** do not take a double dose. Apply the medicine as soon as possible. However, if it is almost time for the next dose, skip the forgotten dose and return to the normal dosage regimen at the next dosing.

Adhere to the treatment regimen 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 pharmacist.

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 2X** 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.

#### **Common side effects - effects occurring in 1-10 in 100 users:**

- Eye redness, eye discomfort, allergy in the eye, itching of the eyelid

#### **Uncommon side effects - effects occurring in 1-10 in 1,000 users:**

- Headaches, hypersensitivity reactions
- Inflammation, itching or other problems on the surface of the eye (e.g., swelling)
- Impaired or blurred vision
- Redness or swelling of the eyelid
- Discharge from the eye, eye pain, eye dryness, itching of the eye, tearing eyes
- Skin problems such as abnormal sensations, skin inflammation, itching or dry skin
- Appearance of patches on the skin
- Loss of eyelashes or eyebrows

#### **Side effects of unknown frequency (effects whose frequency has not yet been determined):**

- Skin rash or redness, eye irritation

If side effects occur, 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](http://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 carton/label. The expiry date refers to the last day of that month.
- Store below 30°C.
- After first opening of the bottle, can be used within 28 days.
- Keep the bottle tightly closed.
- Store in the original package.

### 6. FURTHER INFORMATION

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

Mannitol, trometamol, xanthan gum, boric acid, polysorbate 80, benzododecium bromide (BDAB), sulphuric acid and/or sodium hydroxide, purified water.

What the medicine looks like and the contents of the package:

The preparation is a clear solution in a 5 ml plastic bottle.

**Registration Holder and address:** Novartis Israel Ltd., 36 Shacham St., Petach-Tikva.

**Manufacturer and address:** Alcon Cusi S.A., Barcelona, Spain.

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