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Information for patients

Read this leaflet carefully before using this medicine. This medicine has been prescribed for you personally. Do not pass it on to anyone else. It may harm them even if their symptoms are the same as yours.

Keep this leaflet. You may want to read it again later.

Tobrex[®] eye drops

What Tobrex eye drops are and what they are used for

Tobrex eye drops contain an antibiotic for the treatment of eye infections. This medicine requires a prescription and may only be used if it has been prescribed by a doctor.

Additional information to be aware of

Tobramycin, the antibiotic contained in Tobrex eye drops, is not effective against all germs that cause eye infections. Incorrect use of this medicine may cause complications. Therefore, never use Tobrex eye drops to treat other conditions or other people. Even if you later develop a new infection in your eye, do not use Tobrex eye drops without obtaining a new prescription from your doctor.

Note for contact lens wearers

Do not wear contact lenses during treatment with Tobrex eye drops. If your doctor allows you to wear them, take the lenses out before treatment and wait at least 15 minutes after treatment before putting them back in.

Do not use Tobrex eye dropsIf you have a known or suspected hypersensitivity (allergy) to any of the ingredients of Tobrex eye drops.

Warnings and precautions

- If you experience allergic eye reactions such as stinging and swelling of the eyelid or redness of the eye, stop treatment and consult your doctor. Allergic reactions may take many different forms, from local itching or skin redness to severe skin reactions. These allergic reactions may also occur with other (local or systemic) treatments with an antibiotic of the same type (aminoglycoside). If you are using other antibiotics together with Tobrex eye
- drops, ask your doctor for advice.

 This medicine may impair your ability to drive or use machines or tools. If you experience blurred vision or any other visual impairment after applying this medicine, you must not drive or use machines until these effects have worn off.
- Tobrex eye drops contain benzalkonium chloride, which may cause eye irritation and discolour soft contact lenses. Contact with soft contact lenses must be avoided.
- Benzalkonium chloride may also cause eye irritation, particularly if you have dry eyes or a disorder affecting the cornea (transparent layer on the front of the eye). Contact your doctor if you experience any unusual sensation, burning or pain in the eye after using this medicine
- Do not use Tobrex eye drops for a prolonged period. Tell your doctor if you have any other illnesses or allergies or are taking any other medicines (including non-prescription medicines) or applying any other medicines to your eye(s), particularly if they are antibiotics.
- If you have or if you have ever had conditions such as myasthenia gravis or Parkinson's disease, ask your doctor for advice. Antibiotics of this kind may worsen muscle weakness.
- This medicine contains boron and may lead to reproductive problems. Do not use Tobrex eye drops in children aged under 2 years. For severe infections do not use this medicine in children aged under 12 years.

Pregnancy and breast-feedingOnly use during pregnancy or while breast-feeding with the express permission of your doctor.

How to use Tobrex eve drops

There is only limited experience with Tobrex eye drops in infants aged under 2 months; therefore, use is not recom-mended in such infants (see "Warnings and precautions"). In mild to moderate infections apply 1-2 drops to the affected eye every 4 hours unless instructed otherwise by your doctor. In severe infections apply 2 drops every hour until the condition improves.

If too much Tobrex gets into your eye, rinse your eye with lukewarm water. Do not use any more drops until your next scheduled dose.

Do not change the prescribed dosage or treatment period

yourself. If you think the effect of your medicine is too weak or too strong, talk to your doctor or pharmacist. If you forget to use Tobrex eye drops, apply 1 drop as soon as you realize you have forgotten to use Tobrex and then continue your treatment as scheduled. Do not apply a double dose to make up for the missed dose. It is important to use Tobrex eye drops regularly. However, if you forget them

once or more, continue treatment as prescribed until you have talked to your doctor.

If you are also using other eye medicines, wait 5 to 10 minutes between applying Tobrex eye drops and other medicines.

Possible side effects

If you notice side effects, do not stop treatment with Tobrex eye drops without speaking to your doctor. If you have any concerns, please contact your doctor or pharmacist. You may experience the following side effects when using Tobrex eye drops:

Common (affects 1 to 10 in 100 users)

Effects on the eye: Discomfort, redness.

Uncommon (affects 1 to 10 in 1,000 users)

Effects on the eye: Corneal inflammation, corneal abrasion (scratched eye), visual disturbance, blurred vision, eyelid redness, conjunctival swelling, eyelid swelling, pain, dry eye, eye discharge, itching, increased tear production.

Effects on the body: Hypersensitivity (allergic reaction), headache, hives, skin inflammation, eyelash loss, itchy skin, dry skin, lightening of skin.

The following side effects were experienced after introduction to the market:

Effects on the eyes: Local allergic reactions in the eye, eye irritation, eyelid itching.

Effects on the body: Hypersensitivity reaction, skin rash, severe skin reaction (Stevens-Johnson syndrome), inflammatory skin changes (erythema multiforme).

If you notice any side effects which are not described here, tell your doctor or pharmacist.

Further information

Do not use after the expiry date (= EXP) printed on the pack. After treatment has ended, please return any remaining fluid to the location from which you obtained it (vour doctor or pharmacist) so that it can be disposed of properly.

Shelf life after opening

Once the bottle has been opened, use within 4 weeks.

Storage instructions

Do not store above 30°C and keep out of the reach of children.

Additional information

After first opening, remove the loosened plastic ring from the cap. To avoid compromising the sterility of the eye drops, do not touch the bottle's dropper tip with your eyes

or hands. Close the bottle tightly immediately after use. Your doctor or pharmacist will be able to give you more information. They have access to the full prescribing information.

What Tobrex eye drops contain

Active substances 1 ml of Tobrex eve drops contains: 3 mg tobramycin

Other ingredients

This medicine contains 0.1 mg of benzalkonium chloride per 1 ml of solution. It also contains boric acid, sodium sulphate Anhydrous, sodium chloride, tyloxapol, sodium hydroxide or sulphuric acid (to adjust pH) and purified water.

Availability/pack sizes

The product can be obtained in pharmacies with a doctor's prescription, which may be used once. Pack size: 5 ml dropper bottle.

Manufactured byAlcon-Couvreur B-2870 Puurs (Belgium) for Novartis Pharma AG Basle, Switzerland.

R = registered trademark

Novartis Pharma AG, Basle, Switzerland

This package leaflet was last reviewed by the Swiss Agency for Therapeutic Products (Swiss medic) in July 2020.

- This is a medicament A medicament is a product, which affects your health, and its consumption contrary to instructions is danger-
- ous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of reach of children

Council of Arab Health Ministers Union of Arab Pharmacists