

PACKAGE LEAFLET: INFORMATION FOR THE USER

TOBREX

3 mg / 1 ml, eye drops, solution

TOBRAMYCIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What TOBREX is and what it is used for
2. Before you take TOBREX
3. How to use TOBREX
4. Possible side effects
5. How to store TOBREX
6. Further information

1. WHAT TOBREX IS AND WHAT IT IS USED FOR

TOBREX is an antibiotic that is indicated for the treatment of eye infections.

TOBREX is an antibiotic that is used for the local treatment of external infections of the eye and its adnexa caused by susceptible bacteria (bacteria which are resistant to most other antibiotics, especially *Pseudomonas aeruginosa*).

2. BEFORE YOU TAKE TOBREX

Do not take TOBREX

- If you are hypersensitive (allergic) to tobramycin or any ingredient of TOBREX (see section 6).

Take special care with TOBREX

- If you experience allergic reactions such as itching of the eyelid, swelling or redness of the eye, discontinue the treatment and consult a doctor. These allergic reactions can occur with other local or systemic aminoglycoside antibiotics.
- If your symptoms worsen or suddenly return, consult your doctor. By using this medicine you may become susceptible to eye infections.
- If you are taking other antibiotic therapy simultaneously with TOBREX, consult your doctor.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using any medicine.

If you are pregnant or if there is a possibility of pregnancy, if you are breast-feeding, consult your doctor before using this medicine.

The use of TOBREX is not recommended during pregnancy or breastfeeding.

Driving and using machines

There is possibility for occasionally blurred vision directly after application of TOBREX. Do not drive or operate machinery until the vision is cleared again.

Tobrex contains benzalkonium chloride

A preservative in Tobrex drops (benzalkonium chloride) may cause eye irritation and can discolour soft contact lenses. Avoid contact with soft contact lenses. Before applying drops remove contact lenses from the eyes and wait at least 15 minutes before you put them back in the eye.

3. HOW TO TAKE TOBREX

Always use TOBREX exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

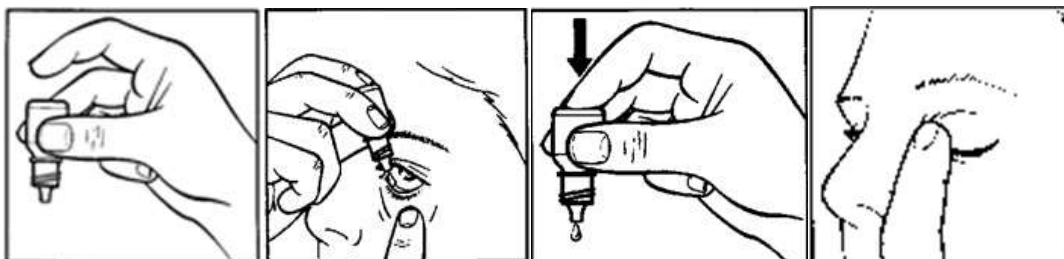
For mild to moderate inflammation, the usual dose is one to two drops in the eye (s) every four hours.

In case of serious inflammation, the usual dose is one or two drops in the eye (s) every hour until improvement, after which the dosage is reduced prior to completely terminate the application of medicine.

The usual duration of treatment is 7 to 10 days. Your doctor will advise you on how long you should use TOBREX.

TOBREX should be used for the eyes only.

Instructions for use:



1. Prepare TOBREX and a mirror.
2. Wash your hands.
3. Unscrew the cap.
4. Hold the tube between thumb and forefinger.
5. Tilt your head back. Using your index finger, pull the lower eyelid away from your eye to form a pouch. Squeeze a thin strip of drops into the pouch (picture 1).
6. Bring the hole of the tube to the eye. If you need help, use a mirror.
7. To prevent germs from contaminating your medicine, do not touch the applicator tip to any surface, including the eye.
8. Gently squeeze the tube in order to apply the drops (picture 2).
9. After applying TOBREX, let the lower eyelid, blink a few times so that drops covers the entire surface of the eye. Keep your eyes gently closed for a few seconds; this helps prevent penetration of TOBREX eye drops to other parts of the body.
10. If you apply the drops in both eyes, repeat the same procedure for the other eye.
11. Firmly tighten cap of the tube immediately after use.
12. Use only one tube at the time.

If you are not able to apply the drops in the eye, try again.

Be sure to use TOBREX drops for the full course of treatment. If you do not, the medicine may not clear up your infection completely.

If you use more TOBREX than you should

If necessary, TOBREX can be washed out of the eyes with warm water. Do not apply more drops until the next regular dose.

If you forget to take TOBREX

If you forgot to apply TOBREX drops do it as soon as possible and then continue as usual. Do not apply double dose to make up for a forgotten dose.

In case of concomitant therapy with other topical ophthalmic medicinal products, an interval of 5 minutes should be allowed between successive applications.

Eye ointment should be administered last.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, TOBREX can cause side effects, although not everybody gets them.

The following side effects have been observed with the use of TOBREX:

Common (may occur in fewer than 1 in 10 people):

Discomfort in the eye, eye redness, eye allergies.

Uncommon (may occur in less than 1 in 100 people):

- Inflammation of the eye surface, corneal damage, vision problems, blurred vision, redness of the eyelids, swelling of the eye and eyelids, eye pain, dry eye, eye discharge, eye pruritus, increased production of tears.
- Allergy (hypersensitivity),
- Headache,
- Hives, skin inflammation, decreased growth of eyelashes, weakened pigmentation of the skin, itching and dry skin.

Not known (cannot be estimated from the available data):

- Eye irritation, itching of the eyelids,
- Rash

You usually can continue to use the drops, except in case of serious adverse reactions. If you are worried, consult your doctor or pharmacist.

Reporting of suspected side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE TOBREX

Keep out of the reach and sight of children.

Throw the opened tube four weeks after opening to prevent infection. Write down the date when you opened the tube.

Store below 25 °C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

The shelf life of medicine is 3 years from the date of manufacture indicated on the packaging of the medicine.

6. FURTHER INFORMATION

What TOBREX contains

The active substance is tobramycin (3 mg / 1 ml).

The other ingredients are benzalkonium chloride, boric acid, anhydrous sodium sulphate, sodium chloride, tyloxapol and purified water.

Small amounts of sulfuric acid and / or sodium hydroxide sometimes added to keep acidity levels (pH levels) normal.

Please refer to section 2 "Tobrex contains benzalkonium chloride".

What TOBREX looks like and contents of the pack

Tobrex eye drops, solution, comes in a 5 ml plastic bottle with a dropper (DROPTAINER®) and screw cap.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Manufacturer

Alcon Pharmaceuticals Ltd. Rue Louis d`Affry 6, Case Postale, 1701 Fribourg, Switzerland

Manufacturer of the medicinal product

SA Alcon-Couvreur NV, Rijsksweg 14, B-2870 Puurs, Belgium