NOVARTIS

TOBREX® Eye Drops (tobramycin)

3,0 mg/mL, Eye Drops, Solution

TOBREX® Eye Ointment (tobramycin)

3 mg/g, Eye Ointment

Patient Information Leaflet

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TOBREX® Eye drops, Solution

Tobramycin, 3 mg/mL

TOBREX® Ointment

Tobramycin, 3 mg/g

Read all of this leaflet carefully before you start using TOBREX

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider
- TOBREX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TOBREX is and what it is used for
2. What you need to know before you use TOBREX
3. How to use TOBREX
4. Possible side effects
5. How to store TOBREX
6. Contents of the pack and other information

1. What TOBREX is and what it is used for

A15.1. Ophthalmic preparations with antibiotics and/or sulphonamides.

TOBREX is a topical antibiotic that contains the active ingredient called tobramycin. Tobramycin belongs to a class of antibiotics called aminoglycoside.

TOBREX is used to treat bacterial infections of the external part of the eye.

2. What you need to know before you use TOBREX

Do not use TOBREX

- If you are hypersensitive (allergic) to tobramycin or any of the other ingredients of TOBREX.

Warnings and precautions

- If you experience allergic reactions with TOBREX, discontinue use and consult your doctor. Allergic reactions may vary from localized itching or skin redness to severe allergic reactions (anaphylactic reaction) or serious skin reactions. These allergic reactions may occur with other topical or systemic antibiotics of the same family (aminoglycosides).
- If you are using other antibiotic treatment with TOBREX, ask your doctor for advice
- If you have or if you have ever had conditions such as myasthenia or Parkinson's disease, ask your doctor for advice. Antibiotics of this kind may worsen muscle weakness.

- If your symptoms get worse or suddenly return, please consult your doctor. If you use TOBREX for a long period of time you may become more susceptible to eye infections.
- **Wearing contact lenses is not recommended** during treatment of an eye infection. If you wear lenses, you should remove them before using this product and wait at least 15 minutes before putting your lenses back in.
- Have your eyes examined regularly when using TOBREX for an extended period to check for possible side effects of TOBREX on the eye

Other medicines and TOBREX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby while using TOBREX, please consult your doctor, pharmacist or other health care professional for advice.

If you are pregnant, you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. TOBREX is not recommended during breastfeeding.

Driving and using machines

Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs, you must wait until your vision clears before driving or using machinery.

TOBREX contains benzalkonium chloride:

TOBREX Eye Drops contains benzalkonium chloride, which may cause eye irritation and is known to discolour soft contact lenses

3. How use TOBREX

Do not share medicines prescribed for you with any other person.

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

The usual dose is:

TOBREX eye drops

- One or two drops into the affected eye(s) every four hours for 7 days.
- In severe infections instil two drops into the eye(s) every hour until improvement following which, treatment should be reduced prior to discontinuation.

TOBREX eye ointment

- In mild to moderate disease, apply a ribbon of about 10 mm (1/2 inch) into the affected eye(s) two or three times per day.
- In severe infections, instil a ribbon of about 10 mm (1/2 inch) into the affected eye(s) every three to four hours until improvement following which, treatment should be reduced prior to discontinuation.

If you use more TOBREX than you should

Rinse it all out with warm water. However, no undesirable effects are to be expected. Do not put in any more drops / ointment until it is time for your next regular dose.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use TOBREX

If you miss a dose, instil the drops as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule.

Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

TOBREX can have side effects.

Not all side effects reported for TOBREX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using TOBREX, please consult your health care provider for advice.

The following side effects have been seen with TOBREX:

Common side effects *(may affect up to 1 in every 10 people)*

- Effects in the eye: eye discomfort, redness of the eye

Uncommon side effects (may affect up to 1 in every 100 people)

- Effects in the eye: eye surface inflammation, corneal damage, visual impairment, blurred vision, eyelid redness, swelling of the eye and eyelid, eye pain, dry eye, eye discharge, itchy eye, increased tear production
- General side effects: allergy (hypersensitivity), headache, hives, skin inflammation, decreased growth or number of eyelashes, loss of pigmentation of the skin, itching, and dry skin

Not known (frequency cannot be estimated from available data)

- Effects in the eye: eye allergy, eye irritation, eyelid itching
- General side effects: rash

Localised ocular toxicity and hypersensitivity can occur. If topical ocular tobramycin is administered concomitantly with systemic aminoglycoside antibiotics, care should be taken to monitor the total serum concentration.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TOBREX.

5. How to store TOBREX

- KEEP OUT OF REACH OF CHILDREN
- Do not use this medicine after the expiration date, which is stated on the bottle / tube
- Store in the original package

TOBREX eye drops: Protect from light. Store at or below 25 °C.

DO NOT USE MORE THAN 30 DAYS AFTER OPENING.

TOBREX eye ointment: Protect from light. Store at or below 25 °C.

Return all unused medicine to your pharmacist

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What TOBREX CONTAINS

TOBREX eye drops:

- The active substance is tobramycin base 3 mg per mL
- The other ingredients are benzalkonium chloride, boric acid, tyloxapol, sodium chloride, sodium sulphate anhydrous, sulphuric acid (to adjust pH), sodium hydroxide (to adjust pH)

TOBREX eye ointment:

- The active substance is tobramycin 3 mg per g
- The other ingredients are chlorobutanol, liquid paraffin and white soft paraffin

What TOBREX looks like and contents of the pack

What TOBREX looks like

TOBREX eye drops: A colourless to pale yellow or brown solution.

TOBREX eye ointment: White or off-white homogeneous ointment.

Contents of pack

TOBREX Eye Drops: Low density polyethylene plastic bottle of 5 mL, with a plastic dispensing plug.

TOBREX Eye Ointment: Ophthalmic ointment tube containing 3,5 g.

Holder of Certificate of Registration

Novartis South Africa (Pty) Ltd

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2090

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TOBREX eye ointment: P/15.1/205.

TOBREX® eye drops

Botswana: S2

TOBREX® eye ointment

Botswana: S2

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