

PACKAGE LEAFLET: INFORMATION FOR THE USER

TOBRADEX

3mg/ml + 1mg/ml eye drops, suspension

TOBRAMYCIN, DEXAMETHASONE

• 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 TOBRADEX is and what it is used for
2. Before you take TOBRADEX
3. How to take TOBRADEX
4. Possible side effects
5. How to store TOBRADEX
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1. WHAT TOBRADEX IS AND WHAT IS IT USED FOR

TOBRADEX contains dexamethasone and tobramycin.

This medicine is used for the treatment of inflammation and possible eye infections. Inflammation can occur due to eye surgery, infection or an eye injury.

TOBRADEX is a combination of tobramycin and dexamethasone. Corticosteroids (dexamethasone) help to prevent inflammation in the eye. Anti-infectives (tobramycin) have effect on a broad range of microorganisms which can cause infection of the eye.

2. BEFORE YOU TAKE TOBRADEX

Do not take TOBRADEX

- If you are hypersensitive (allergic) to tobramycin and / or dexamethasone or any ingredient of TOBRADEX.
- If you think you have:
 - Herpes simplex keratitis, measles, chicken pox (varicella), or any other viral infection)
 - Bacterial conjunctivitis of the eye

- Fungal diseases of the eye

Only your doctor can prescribe the appropriate therapy.

Take special care with TOBRADEX

Talk to your doctor before applying TOBRADEX.

- This product is dripped into the eyes
- 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 TOBRADEX, consult your doctor.
- If you continuously use TOBRADEX (over 24 days) there is a possibility to:
 - become susceptible to eye infections
 - have high pressure in the eye (eyes)
 - develop cataracts
- The pressure in the eye must be regularly checked while applying TOBRADEX. Consult a doctor. This is especially important in pediatric patients, since the risk of glucocorticoid-induced ocular hypertension is higher in children than in adults.
- Steroids applied to the eye may slow down the process of treatment of wounds in the eye. Local NSAIDs (nonsteroidal anti-inflammatory drugs) slow down the healing process. Co-administration of local NSAIDs and topical steroids may increase the potential for healing problems.
- Before taking this medicine consult your doctor or pharmacist if you have a disorder that causes thinning of the eye tissues.

Taking other medicines

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

Tell your doctor if you are taking local NSAIDs. Concomitant use of topical steroids and local NSAIDs can slow down the process of treatment of the cornea.

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 TOBRADEX is not recommended during pregnancy or breastfeeding.

Driving and using machines

As with any eye drop, temporarily blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs, the patient must wait until the vision is clear before driving or using machines.

TOBRADEX contains benzalkonium chloride

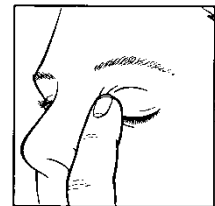
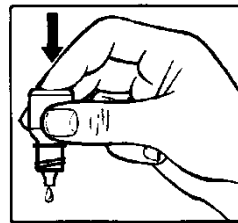
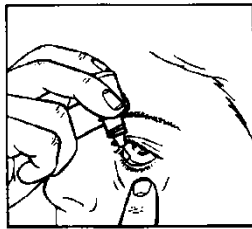
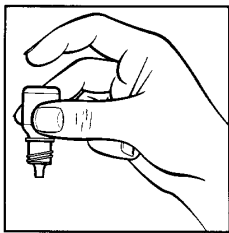
Benzalkonium chloride, used as a preservative in this product, has been reported to cause punctate keratopathy and/or toxic ulcerative keratopathy. Benzalkonium chloride may cause eye irritation and discolor soft contact lenses.

Avoid contact with soft contact lenses. Contact lens wear is not recommended during treatment of an ocular infection or inflammation. If patients are allowed to wear contact lenses, they must be instructed to remove lenses prior to application of TOBRADEX and wait at least 15 minutes before reinsertion.

3. HOW TO TAKE TOBRADEX

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

The usual dose is one drop instilled into the conjunctival sac(s) every 4 to 6 hours while the patient is awake. During the initial 48 hours, the dosage may be increased to one drop every two hours while the patient is awake.



TOBRADEX should be used only for the eyes.

1. Prepare TOBRADEX and a mirror.
2. Wash your hands.
3. Shake the bottle well before use.
4. After cap is removed, if tamper evident snap collar is loose, remove before using product.
5. Face the bottle downwards holding it between thumb and middle finger (Picture 1).
6. Tilt your head back. Using your index finger, pull the lower eyelid away from your eye to form a pouch. Place the eye drops into the pouch (picture 2).
7. Bring the bottle to the eye. If you need help, use a mirror.
8. To prevent germs from contaminating your medicine, do not touch the dropper tip of the bottle to any surface, including the eye.
9. Gently squeeze the bottle in order to apply the eye drops (picture 3).
10. After applying TOBRADEX, let the lower eyelid, close the eye and using the finger gently press the corner of the eye next to the nose. Keep your eyes gently closed for a few seconds; this helps prevent penetration of TOBRADEX eye drops to other parts of the body.
11. If you apply the eye drops in both eyes, repeat the same procedure for the other eye.
12. Firmly tighten cap of the bottle immediately after use.
13. Use only one bottle at the time.

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

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

If you use more TOBRADEX than you should

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

If you forget to take TOBRADEX

If you forgot to apply TOBRADEX eye 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, **TOBRADEX** can cause side effects, although not everybody gets them.

The following adverse reactions have been observed with the use of TOBRADEX:

Uncommon adverse reactions

(May occur in less than 1 in 100 people)

Adverse reactions in the eye: increased intraocular pressure, eye pain, eye pruritus, eye discomfort, eye irritation, redness of the eyelid

Rare adverse reactions

(May occur in less than 1 in 1,000 people)

Adverse reactions in the eye: eye allergies, blurred vision, dryness, inflammation of the surface of the eye, redness, swelling of the eyelid.

General adverse reactions

Bad taste

Not known (cannot be estimated from available data)

Adverse reactions in the eye: increased pupil, increased production of tears

General adverse reactions

Allergy (hypersensitivity), dizziness, headache, nausea, abdominal discomfort, rash, itching, swelling of the face.

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 TOBRADEX

Keep out of the reach and sight of children.

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

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 2 years from the date of manufacture indicated on the packaging of the medicine.

6. FURTHER INFORMATION

What TOBRADEX contains

- The active substance tobramycin 3 mg / ml and dexamethasone 1 mg / ml.
- The other ingredients are: benzalkonium chloride, disodium edetate, sodium chloride, sodium sulfate anhydrate (E514), tyloxapol, hydroxymethyl cellulose and purified water. Small amounts of sulfuric acid and / or sodium hydroxide are added to maintain a normal level of acidity (pH level).

What TOBRADEX looks like and contents of the pack

TOBRADEX liquid (suspension), white, greyish white or yellowish white color in the package that consists of 5 ml of solution in a plastic bottle with a tamper protection (DROP-TAINER) and threaded cap, which protects against unauthorized opening.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

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

Manufacturer of the medicinal product

Alcon - Couvreur, Puurs, Belgium

ALCON CUSI, Barcelona, Spain