

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### TOBRADEX

3 mg / g + 1 mg / g eye ointment

TOBRAMYCIN, DEXAMETHASONE

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*• 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.*

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*• 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 •*

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#### 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

#### 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)
  - Tuberculosis 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***

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

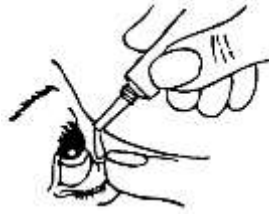
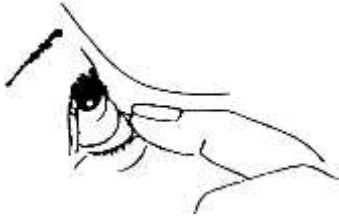
## ***3. HOW TO TAKE TOBRADEX***

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 a small amount (about 1.5 cm of ointment) in the conjunctival bag three to four times daily. Your doctor will advise you on how long you should use TOBRADEX. Do not stop using it prematurely.

It is not necessary to adjust the dose in patients with liver and kidney disease.

TOBRADEX should be used only for the eyes.



1. Prepare TOBRADEX 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 ointment 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 ointment (picture 2).
9. After applying TOBRADEX, let the lower eyelid, blink a few times so that ointment covers the entire surface of the eye. Keep your eyes gently closed for a few seconds; this helps prevent penetration of TOBRADEX eye ointment to other parts of the body.
10. If you apply the ointment 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 ointment in the eye, try again.

Be sure to use TOBRADEX ointment 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 ointment until the next regular dose.

#### ***If you forget to take TOBRADEX***

If you forgot to apply TOBRADEX ointment 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 ointments 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 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 2 years from the date of manufacture indicated on the packaging of the medicine.

**6. FURTHER INFORMATION****What TOBRADEX contains**

- The active substances are tobramycin 3 mg / g and dexamethasone and 1 mg / g
- The other ingredients are: chlorine butanol anhydride, liquid paraffin (mineral oil), white paraffin.

**What TOBRADEX looks like and contents of the pack**

TOBRADEX is homogeneous white ointment, greyish white or yellowish white in packaging consisting of a tube of 3.5 g with a plastic tip and plastic cap.

**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