

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

TOBRADEX* Eye Drops 1 mg/ml 3 mg/ml suspension

Dexamethasone and tobramycin

TOBRADEX* Eye Ointment 1 mg/g 3 mg/g ointment

Dexamethasone and tobramycin

Read all of this leaflet carefully before you start using TOBRADEX*.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- **TOBRADEX** 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 TOBRADEX* CONTAINS

TOBRADEX Eye Drops

The active substances are 1 mg dexamethasone hydrochloride and 3 mg tobramycin in every ml.

The other substances are 0,1 mg of benzalkonium chloride in each ml of solution as a preservative, disodium edetate, hydroxyethylcellulose,

sodium chloride, sodium sulphate anhydrous, tyloxapol and purified water.

TOBRADEX Eye Ointment

The active substances are 1 mg dexamethasone hydrochloride and 3 mg tobramycin in every 1 g.

The other substances are 5 mg chlorobutanol in each g of ointment as a preservative, liquid paraffin and white soft paraffin.

WHAT TOBRADEX* IS USED FOR

TOBRADEX Eye Drops and **TOBRADEX Eye Ointment** are used to reduce inflammation and to prevent infection of the eye following surgery to the eye.

BEFORE YOU USE TOBRADEX*

Do not use **TOBRADEX** if you suffer from any of the following conditions:

1. If you have ever had any unusual or allergic reaction to tobramycin or dexamethasone or any of the other ingredients.
2. If you suffer from a herpes infection of the eye.
3. If you suffer from any viral or fungal infection of the eye.
4. If you require treatment for injury to the cornea or surface of the eye.
5. **TOBRADEX** is not recommended for use whilst soft contact lenses are being worn.

Take special care with TOBRADEX

If any of the following conditions apply to you please consult your doctor, pharmacist or other healthcare professional for advice before using

TOBRADEX:

- if you suffer from diabetes mellitus (sugar diabetes) you may be more likely to develop blurred vision (cataracts) or increased pressure inside the eye (glaucoma)
- if you have a family history of increased eye pressure the risk of developing it may be increased
- if you have ulcers or infection of the eye, **TOBRADEX** may aggravate the condition or worsen the infection
- secondary eye infection may develop after prolonged use
- if you are using **TOBRADEX** for 10 days or longer it is important that you have regular eye examinations by your ophthalmologist. This is especially important in children as the risk is greater.

Pregnancy and Breast-feeding

If you are pregnant or breast-feeding your baby while using **TOBRADEX**, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery

Temporarily blurred vision or other visual disturbances with use of

TOBRADEX may affect the ability to drive or use machines. If blurred vision occurs with application, wait until your vision clears before driving or using machinery.

Important information about some of the ingredients of TOBRADEX*

TOBRADEX Eye Drops contains benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses.

If your doctor has allowed you to wear contact lenses while using **TOBRADEX Eye Drops**, you must remove the lenses before applying the drops and wait at least 15 minutes before re-inserting them.

Taking other medicines with TOBRADEX*

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **TOBRADEX** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO USE TOBRADEX*

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

Always use **TOBRADEX** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of **TOBRADEX** is too strong or

too weak, talk to your doctor or pharmacist.

Dosage

TOBRADEX Eye Drops

SHAKE WELL BEFORE USE. STORE BOTTLE UPRIGHT.

When you first open the bottle and remove the cap, remove the snap ring and throw it away. This will prevent the ring falling into the eye and causing injuries.

The usual dose is one drop into the eye to be operated on every 4 hours whilst awake, for three days before surgery.

After surgery put in two drops every two hours for two days beginning with the first dressing change. From the third day put in one drop four times a day for one week. Thereafter put in one drop once daily for ten days. No further treatment should be used.

TOBRADEX Eye Ointment

The usual dose is a 1,5 cm ribbon of ointment into the eye to be operated on three times a day, for three days before surgery.

Beginning at the first dressing change after surgery apply a 1,5 cm ribbon of ointment three times daily for the first 9 days. Then a 1,5 cm ribbon of ointment once daily from day 10 to day 20. No further treatment should be used.

Directions for use

TOBRADEX Eye Drops

1. First wash your hands.
2. Sit down in front of a mirror so that you can see what you are doing.
3. Shake the bottle well. Remove the cap from the bottle.
4. Hold the bottle upside down in one hand between your thumb and middle finger.
5. Tilt your head back and with the index finger of the same hand pull the lower eyelid away from the eye to form a pouch.
6. Place the dropper tip close to, but not touching, your eye and gently tap the base of the bottle with your forefinger so that one drop falls into the gap between the eye and the lower lid.
7. Gently close your eye. Do not blink. Keep the eye closed for 1 or 2 minutes while pressing lightly with your finger on the inner corner of the eye to allow the medicine to be absorbed.
8. Immediately after using the eye drops, wash your hands to remove any medicine that may be on them.
9. To keep the medicine as germ-free as possible, do not touch the applicator tip to any surface (including the eye). Also, keep the container tightly closed.

TOBRADEX Eye Ointment

1. First wash your hands.

2. Tilt your head back and pressing your finger gently on the skin just beneath the lower eyelid, pull the lower eyelid away from the eye to make a space. Squeeze a thin 1,5 cm strip of ointment into this space. Let go of the eyelid and gently close the eyes. Keep the eyes closed for 1 or 2 minutes to allow the medicine to come into contact with that part of the eye that requires treatment.
3. To keep the medicine as germ free as possible, do not touch the applicator tip to any surface (including the eye).
4. After using the Eye Ointment, wipe the tip of the ointment tube with a clean tissue. Do not wash the tip with water. Always keep the tube tightly closed.

If you use more TOBRADEX than you should:

If you put too much **TOBRADEX** into your eye(s) it can be washed out of your eye(s) with warm tap water.

If you missed a dose of TOBRADEX:

If you miss a dose apply the missed dose as soon as possible. However, if it is almost time for your next regular dose, skip the missed dose and go back to your regular dosing schedule. Do not double the dose.

POSSIBLE SIDE EFFECTS

TOBRADEX can have side effects.

The following side effects have been reported in studies with **TOBRADEX**:

Less frequent:

Eye pain, eye itching, eye discomfort, eye irritation, eye infection, eye allergy, blurred vision, dry eye, eye redness, bad taste.

Side effects reported with use of **TOBRADEX** of which the frequencies are unknown:

Hypersensitivity, dizziness, headache, eyelid swelling, eyelid redness, enlarged pupil, excess tears, nausea, stomach discomfort, rash, face swelling, itching.

Side effects that have been reported with use of individual ingredients of TOBRADEX

Side effects with dexamethasone:

Less frequent:

Eye infection, reduced sharpness of vision, increased eye pressure, visual field defects, slow healing.

Side effects with tobramycin:

Less frequent:

Eye infection, hypersensitivity, eye irritation (burning and stinging upon instillation), eye redness, blurred vision, eyelid swelling, eyelid itching, eye pain.

Not all side effects reported for TOBRADEX are included in this pamphlet. If you experience any of the reactions above or any others not listed, or if your general state of health worsens whilst using TOBRADEX, please consult your doctor, pharmacist or other health care professional for advice as soon as possible.

STORAGE AND DISPOSAL INFORMATION

Store all medicines out of reach of children.

Store at or below 25 °C.

The expiry date is printed on each bottle or tube and on the outer packaging. Do not use the product after the expiry date.

You must discard the product one month after opening. You should ask your pharmacist to dispose of any unused medicine for you.

PRESENTATION OF TOBRADEX*

TOBRADEX Eye Drops is supplied in plastic bottles containing 5 ml.

TOBRADEX Eye Ointment is supplied in eye ointment tubes containing 3,5 g.

IDENTIFICATION OF TOBRADEX*

TOBRADEX Eye Drops is a white to off-white sterile suspension.

TOBRADEX Eye Ointment is a white to off-white sterile homogenous ointment.

NOVARTIS SA (PTY) LTD
TOBRADEX Eye Ointment; Eye Drops, suspension
Tobramycin/dexamethasone 3 mg/1mg per g; 3 mg/1mg per ml
PIL Approved: 17 February 2017

REGISTRATION NUMBER

TOBRADEX Eye Drops: X/15.3/91

TOBRADEX Eye Ointment: X/15.3/92

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE
CERTIFICATE OF REGISTRATION**

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City

Jukskei View

2090

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date of registration:

TOBRADEX* Eye Drops: 13/06/1991

TOBRADEX* Eye Ointment: 20/05/1991

Date of revision: 17 February 2017

* trademark of Novartis

© 2015 Novartis