NOVARTIS

Tobradex Eye Ointment

Each 1,0 g ointment contains dexamethasone 1,0 mg and tobramycin 3,0 mg

Patient Information Leaflet

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

TOBRADEX* Eye Drops (suspension)

Dexamethasone, 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 your 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 is in this leaflet

1. What TOBRADEX is and what it is used for.

2. What you need to know before you use TOBRADEX**.**

3. How to use TOBRADEX.

4. Possible side effects.

5. How to store TOBRADEX**.**

6. Contents of the pack and other information.

1. What TOBRADEX is and what it is used for

What TOBRADEX is:

TOBRADEX contains dexamethasone a corticosteroid and tobramycin, an antibiotic which is active against a wide range of bacteria that may infect the eye.

What TOBRADEX is used for:

It is used to prevent and treat inflammation and prevent possible infection of the eye after cataract surgery in adults.

2. What you need to know before you use TOBRADEX

Do not use TOBRADEX :

- If you are hypersensitive (allergic) to tobramycin or dexamethasone or any of the other ingredients of TOBRADEX.
- If you have or think that you have any type of infection of the eye. Use of corticosteroids may make infections worse.
- If you have a sticky discharge from your eye.
- If you have a red eye that has not been seen by a doctor.
- If an uncomplicated foreign body was removed from your eye.
- If you have a cut or tearing of the eye that has not been seen by a doctor.

Warnings and precautions

Take special care with TOBRADEX:

- If you have a disorder causing a thinning of the eye tissues, such as rheumatoid arthritis, Fuch's dystrophy or following a corneal transplant. Corticosteroids may cause further thinning and possible perforation, and may delay the healing of your eye wound;
- Topical nonsteroidal anti-inflammatory drugs (NSAIDs) are also known to slow or delay healing. If you use topical NSAIDS and corticosteroids together, it may increase the potential for healing problems;
- If you experience allergic reactions with TOBRADEX, 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 (skin rash, hives and blisters);
- These allergic reactions may occur with other topical or systemic antibiotics of the same family (aminoglycoside type);
- If your symptoms get worse or suddenly return, please consult your doctor. You may become more susceptible to eye infections with the use of this product;
- If you are diabetic please consult your doctor. The risk of corticosteroid-induced increase intraocular pressure and / or cataract formation is increased in diabetic patients;
- Contact your doctor if you experience blurred vision or other visual disturbances;
- The local administration of medicines containing corticosteroids such as TOBRADEX to infected eyes may mask evidence of progression of infection until sight is lost.
- If you are using other antibiotic treatment, including oral, with TOBRADEX, ask your doctor for advice;

- If you have or if you have ever had conditions such as myasthenia gravis or Parkinson's disease, ask your doctor for advice. Antibiotics of this kind may worsen muscle weakness;
- If you use TOBRADEX for a long period of time, you may become more susceptible to eye infections, have increased pressure in your eye(s) or develop cataracts;
- Talk to your doctor if you experience swelling and weight gain around the trunk and in the face as these are usually the first manifestations of a syndrome called Cushing's syndrome;
- Suppression of the adrenal gland function may develop after stopping a long-term or intensive treatment with TOBRADEX. Talk to your doctor before stopping the treatment by yourself. These risks are especially important in children and patients treated with a drug called ritonavir or cobicistat;
- Signs and symptoms of adrenal suppression include fatigue; light-headedness upon standing or difficulty standing, muscle weakness, fever, weight loss, anxiety, nausea, vomiting, diarrhoea, headache, sweating, changes in mood or personality, and joint and muscle pains.

Other medicines and TOBRADEX

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- if you are using topical NSAIDs (medicines used to treat inflammation; mild to moderate pain; and fever). If you use topical steroids and topical NSAIDs together, it may increase corneal healing problems.

- if you are using ritonavir or cobicistat (medicines used to treat HIV/AIDS), as this may increase the amount of dexamethasone in the blood.

Pregnancy and breastfeeding and fertility

The safety of TOBRADEX during pregnancy and whilst breastfeeding has not been established. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using TOBRADEX.

Driving and using machinery

Temporarily blurred vision or other visual disturbances with use of TOBRADEX may affect mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

It is not always possible to predict to what extent TOBRADEX may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TOBRADEX affects them.

TOBRADEX contains benzalkonium chloride

- 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.
- In case patients are allowed to wear contact lenses, they must be instructed to remove contact lenses prior to application of TOBRADEX Eye Drops and wait at least 15 minutes before reinsertion.

- As the possibility of adverse effects on the corneal permeability and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved ophthalmological preparations such as TOBRADEX Eye Drops cannot be excluded, regular ophthalmological examination is required. Caution should be exercised in the use of benzalkonium chloride preserved topical medication such as TOBRADEX over an extended period in patients with extensive ocular surface disease.

3. How to use TOBRADEX

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

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

For ocular use.

The usual dose is:

TOBRADEX Eye Drops:

- Instil one drop into the operative eye every four hours whilst awake for three days prior to surgery and one drop immediately upon conclusion of surgery.
- Beginning at the first dressing change one day following surgery, instil two drops every two hours whilst awake for two days.
- From post-operative day three, instil one drop into the eye four times a day for one week. Thereafter, instil one drop per day for ten days as maintenance therapy.
- Not more than 20 ml should be prescribed initially and the prescription should not be repeated without further evaluation.

- SHAKE WELL BEFORE USE.
- STORE UPRIGHT.
- When removing the cap for the first time, remove and discard the snap collar, in order to prevent the snap collar from falling into the patient's eye.

Your doctor will tell you how long your treatment with TOBRADEX will last.

If you have the impression that the effect of TOBRADEX is too strong or too weak, tell your doctor or pharmacist.

If you use more TOBRADEX than you should

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

If you missed a dose of TOBRADEX

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

TOBRADEX

4. Possible side effects

TOBRADEX can have side effects.

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

If any of the following happens, stop using TOBRADEX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- shortness of breath/wheezing;
- fainting.
- severe skin reactions such as blistering which may be accompanied by sore throat, fever or headache

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TOBRADEX. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Erythema multiforme (a skin reaction as a rash on the body where each mark resembles a red hive)**;**
- tightness of the throat.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported less frequently:

- increased pressure in your eye (s);
- eye irritation, eye pain, eye itching;

- watery eyes, eye discomfort;
- redness;
- blurred vision;
- dry eye;
- eye allergy;
- eye surface inflammation;
- increase in pupil size;
- eyelid redness, eyelid swelling;
- increased tear production;
- dizziness;
- nausea;
- abdominal discomfort;
- headache;
- runny nose;
- bad taste.

The following side effects have been reported but the frequency is unknown:

- Hormone problems: growth of extra body hair (particularly in women), muscle weakness and wasting, purple stretch marks on body skin, increased blood pressure, irregular or missing periods, changes in the levels of protein and calcium in your body, stunted growth in children and teenagers and swelling and weight gain of the body and face (called ‘Cushing’s syndrome') (*see section 2 Warnings and precautions)*.
- If TOBRADEX is used for more than 24 days, it may cause you to get an infection and the healing of your wound may also be delayed.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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/. By reporting side effects, you can help provide more information on the safety of TOBRADEX.

5. How to store TOBRADEX

- After the first opening of the container, the sterile ophthalmic suspension should not be used longer than four weeks.
- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in the original package / container.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TOBRADEX contains:

The active substance is:

The active substances are tobramycin 3 mg/ml and dexamethasone 1 mg/ml

The other ingredients are*:*

TOBRADEX Eye Drops

Disodium edetate, hydroxylethycellulose, sodium chloride, sodium sulphate anhydrous, tyloxapol,purified water.

Sulphuric acid or sodium hydroxide (pH adjusters).

What TOBRADEX looks like and contents of the pack

What TOBRADEX looks like:

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

Contents of the pack:

- TOBRADEX Eye Drops: Low density polyethylene DROP-TAINER® dispenser containing 5 ml.

Holder of Certificate of Registration and Manufacturer

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City

Jukskei View 2090

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Registration number

TOBRADEX* Eye Drops: X/15.3/91

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website