

TOBRADEX OPHTHALMIC SUSPENSION/OINTMENT

Tobramycin/ Dexamethasone (3mg/ml / 1mg/ml or 3mg/g / 1mg/g)

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What TOBRADEX is used for

Tobradex is used to treat eye inflammation which is responsive to steroid and to treat or prevent bacterial infection of the eye.

How TOBRADEX works

Tobradex exerts an anti-inflammatory and anti-bacterial action.

Before you use TOBRADEX

- When you must not use it

If you are allergic to dexamethasone, tobramycin or any of the other ingredients of this medicine.

If you think you have:

- Herpes simplex keratitis, Smallpox, Chickenpox/Herpes Zoster, or any other viral infection of the eye
- Tuberculosis of the eye
- Fungal diseases of the eye or an untreated parasitic eye infections

Pregnancy and breast-feeding

If you are pregnant or might get pregnant, or if you are breast-feeding, talk to your doctor before you use this medicine.

Tobradex is not recommended during pregnancy or breastfeeding.

- Before you start to use it

Tobradex contains benzalkonium chloride. Wearing contact lenses (hard or soft) is not advisable during treatment of eye inflammation as it may make your condition worse.

A preservative in Tobradex (benzalkonium chloride) may cause eye irritation and is also known to discolor soft contact lenses. If your healthcare provider considers that you can use contact lenses, you should remove them before using Tobradex and wait 15 minutes before putting your lenses back in. *[Only applicable for Ophthalmic Suspension (Eye Drops)]*

- Taking other medicines

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Especially tell your doctor if you are using topical NSAIDs. Concomitant use of topical steroids and topical NSAIDs may increase corneal healing problems.

If you are using other eye drop or eye ointment medicines, leave at least 5 minutes between each medicine. Eye ointments should be administered last.

Tell your doctor if you are using ritonavir or cobicistat, as this may increase the amount of dexamethasone in the blood.

How to use TOBRADEX

- How much to use

Ophthalmic Suspension (Eye Drops): One or two drops instilled into the conjunctival sac(s) every 4 to 6 hours.

Ointment: Apply a small amount into the conjunctival sac(s) up to 3 or 4 times daily. May be used adjunctively with drops at bedtime.

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

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue using Tobradex for as long as your doctor recommends.

- If you forget to use it

If you forget to use Tobradex, continue with the next dose as planned. 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.

- If you use too much (overdose)

If you use more Tobradex than you should, rinse it all out with warm water. Do not put in any more drops

until it is time for your next regular dose.

While you are using TOBRADEX

- Things you must do

Only used Tobradex for dropping in your eye(s).

The bottle must be well shaken before use.

Keep the eyelid closed, while simultaneously applying gentle pressure to the lachrymal canal with a finger to limit the amount of medicine that will come into the blood after application of the eye drops.

If a drop misses your eye, try again.

After cap is removed, if tamper evident snap collar is loose, remove before using product. *[Only applicable for Eye Drop]*

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. These allergic reactions may occur with other topical or systemic antibiotics of the same family (aminoglycosides).

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 using other antibiotic treatment, including oral, with Tobradex ask your doctor for advice.

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)
- develop cataract
- develop Cushing's Syndrome due to the medicine getting into your blood. 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 the 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 medicines containing ritonavir or cobicistat.
- You should have your eye pressure checked regularly while using Tobradex. Ask your doctor for advice. This is especially important in pediatric patients, as the risk of corticosteroid-induced ocular hypertension may be greater in children and may occur earlier than in adults. Tobradex is not approved for use in pediatric patients. The risk of corticosteroid-induced increase intraocular pressure and/or cataract formation is increased in predisposed patients (e.g. diabetes).

Steroids applied to the eye may delay the healing of your eye wound. Topical NSAIDs (Non-Steroidal Anti Inflammatory Drugs-Medications) are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

Consult your doctor or pharmacist if you have a disorder causing thinning of the eye tissues before using this medicine.

- Things you must not do

Do not stop using this medicine unless advised by your doctor.

- Things to be careful of

You may find your vision is blurred for a time after you use Tobradex. Do not drive or use machines until this has worn off.

To prevent contamination of the dropper tip and suspension, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip of the bottle.

Side effects of TOBRADEX

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been seen with Tobradex:

Uncommon side effects (affects 1 to 10 users in 1,000)

Effects in the eyes: increased pressure in your eye(s), eye pain, eye itching, eye discomfort, eye irritation

Rare side effects (affects 1 to 10 users in 10,000)

Effects in the eye: eye allergy, blurred vision, dryness, eye surface inflammation, redness

General side effects: bad taste

Additional side effects from post-marketing experience that have been reported for which the frequency is not known:

Effects in the eye: eyelid swelling, eyelid redness, increase in pupil size, increased tear production

General side effects: severe allergic reaction (hypersensitivity), dizziness,

headache, nausea, abdominal discomfort, serious skin reactions (erythema multiforme), itching, swelling of the face.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of TOBRADEX

- Storage

Ophthalmic Suspension (Eye Drops): Do not store above 30°C. Store upright. Do not freeze.

Ointment: Store below 25°C. Do not refrigerate. Keep this medicine out of the sight and reach of children.

- Disposal

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.

Product Description

- What it looks like

Ophthalmic Suspension (Eye Drops): white to off-white suspension. It is supplied in 5ml dispensers.

Ointment: white to off-white ointment

- Ingredients

- Active ingredient(s)

Ophthalmic Suspension (Eye Drops):

Tobramycin 3mg/ml

Dexamethasone 1mg/ml

Ointment:

Tobramycin 3mg/g

Dexamethasone 1mg/g

- Inactive ingredients

Ophthalmic Suspension (Eye Drops):

Benzalkonium chloride, tyloxapol, disodium edetate, sodium chloride, hydroxyethylcellulose, anhydrous sodium sulphate, sulphuric acid and/or sodium hydroxide (to adjust pH), purified water

Ointment:

Chlorobutanol, anhydrous, mineral oil, white petrolatum

- MAL number:

Ophthalmic Suspension (Eye Drops):

MAL19920042ARZ

Ointment: MAL19921132ARZ

Manufacturer

Novartis Manufacturing N.V.

Rijksweg 14,

2870 Puurs-Sint-Amands

Belgium

Product Registration Holder

Novartis Corporation (M) Sdn. Bhd.

Level 18, Imazium,

No. 8, Jalan SS21/37,

Damansara Uptown,

47400 Petaling Jaya, Selangor,

Malaysia.

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