



TobraDex[®] ST

(tobramycin/dexamethasone
ophthalmic suspension)
0.3%/0.05%

HAS NO GENERIC SUBSTITUTE

- There is no product that is AB rated against TOBRADEX[®] ST suspension.
- TOBRADEX[®] ST suspension has half the amount of dexamethasone as generic versions of tobramycin/dexamethasone¹.

Prescribers writing for TOBRADEX[®] ST suspension are doing so for a specific reason, and intend for their patients to receive it. Substituting tobramycin/dexamethasone for TOBRADEX[®] ST suspension without prescriber approval is not an appropriate or legal practice.

Indication: TOBRADEX[®] ST Suspension is a topical antibiotic and corticosteroid combination for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.

Dosing and Administration: The recommended dosage is one drop into the conjunctival sac(s) every 4 to 6 hours. During the initial 24-48 hours, dosage may be increased to one drop every 2 hours. Frequency should be decreased gradually as warranted by improvement in clinical signs, but care should be taken not to discontinue therapy prematurely.

IMPORTANT SAFETY INFORMATION

Contraindications: TOBRADEX[®] ST Suspension, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.

- Hypersensitivity to any components of the medication.

Warnings & Precautions: Intraocular pressure (IOP) increase-prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If used for 10 days or longer, IOP should be monitored.

- Sensitivity to topically applied aminoglycosides may occur.
- Cataracts – use of corticosteroids may result in posterior subcapsular cataract formation.
- Delayed healing – the use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.
- Bacterial infections – prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.
- Viral infections – employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).
- Fungal infections – fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use.
- If used in combination with systemic aminoglycoside antibiotics the patient should be monitored for total serum concentration of tobramycin.

Adverse Events: Most common adverse reactions to topical ocular tobramycin are hypersensitivity and localized ocular toxicity, including eye pain, eyelids pruritus, eyelid edema, and conjunctival hyperemia. The reactions due to the steroid component are increases in intraocular pressure with possible development of glaucoma.

To report SUSPECTED ADVERSE REACTIONS, contact Alcon Laboratories, Inc. at 1-800-757-9195 or FDA at 1-800-FDA-1088 or fda.gov/medwatch.

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