

TobraDex® ST

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



TOBRADEX® ST Suspension provides:

- Treatment of the signs and symptoms associated with blepharitis
- Increased viscosity, which allows for comparable levels of tissue concentration† with half the amount of dexamethasone^{1,2}

Indications and Usage

TOBRADEX® ST ophthalmic suspension is indicated 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. Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe where the inherent risk of steroid use in certain infective conjunctivitides is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies. The use of a combination drug with an anti-infective component is indicated where the risk of superficial ocular infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.

U.S. Market Information

- In a recent survey, 37% of ophthalmologists and 47% of optometrists reported that patients they saw presented with some form of blepharitis.³
- In a 2008 survey, 79% of the patients report experiencing at least one symptom of blepharitis in the last 12 months.³
- 63% of blepharitis patients initially seek treatment for other symptoms.³
- Reasons blepharitis patients seek treatment are: blepharitis symptoms, dry eye symptoms, surgical evaluation, routine exam/vision complaints.

Alcon Laboratories, Inc.

Alcon maintains a highly trained, specialized sales force promoting TOBRADEX® ST Suspension to ophthalmologists and optometrists.

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 and 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 with patient should be monitored for total serum concentration of tobramycin.

Before prescribing TOBRADEX® ST Suspension, please read the full prescribing information.

†compared to TOBRADEX® Suspension

5 mL Bottle

NDC#	0065065205
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Wholesaler _____

PIC# _____

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use TOBRADEX® ST ophthalmic suspension safely and effectively. See full prescribing information for TOBRADEX® ST suspension.

**TOBRADEX® ST (tobramycin / dexamethasone ophthalmic suspension)
0.3%/0.05%**

Initial U.S. Approval: 1988

-----INDICATIONS AND USAGE-----

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.

-----DOSAGE AND ADMINISTRATION-----

- Instill one drop into the conjunctival sac(s) every 4 to 6 hours. (2.1)
- During the initial 24 to 48 hours, dosage may be increased to one drop every 2 hours. (2.1)
- Frequency should be decreased gradually as warranted by improvement in clinical signs, but care should be taken not to discontinue therapy prematurely. (2.1)

-----DOSAGE FORMS AND STRENGTHS-----

TOBRADEX® ST suspension contains 3 mg/mL tobramycin and 0.5 mg/mL dexamethasone.

-----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. (4.1)
- Hypersensitivity to any component of the medication (4.2)

-----WARNINGS AND 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 this product is used for 10 days or longer, IOP should be monitored. (5.1).
- Sensitivity to topically applied aminoglycosides may occur. (5.2)
- Cataracts- Use of corticosteroids may result in posterior subcapsular cataract formation. (5.3)

- 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. (5.4)
- 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. (5.5)
- 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). (5.6)
- 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. (5.7)
- If product is used in combination with systemic aminoglycoside antibiotics the patient should be monitored for total serum concentration of tobramycin. (5.8)

-----ADVERSE REACTIONS-----

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 www.fda.gov/medwatch.

See 17 for **PATIENT COUNSELING INFORMATION**.

Revised: February 2009

REFERENCES:

- 1 TOBRADEX® ST suspension package insert. Fort Worth, TX: Alcon, Inc. 2009.
- 2 Scoper SV, Kabat AG, Owen GR, et al. Ocular distribution, bactericidal activity and settling characteristics of TOBRADEX® ST Ophthalmic Suspension compared with TOBRADEX® Ophthalmic Suspension. *Adv Ther.* 2008;25:77-88.
- 3 Lemp M, Nichols K et al. Blepharitis in the United States 2009: A Survey-based Perspective on Prevalence and Treatment. *The Ocular Surface*, April, 2009; Vol. 7; No 2; Supplement.

