1 INDICATIONS AND USAGE

- Cataracts: Use of corticosteroids may result in posterior optic nerve, defects in visual acuity and fields of vision. If corticosteroids may result in glaucoma with damage to the ocular structures.

2 DOSAGE AND ADMINISTRATION

- Instill one drop into the conjunctival sac 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)

3 DOSAGE FORMS AND STRENGTHS

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

4 CONTRAINDICATIONS

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

5 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 topicaly applied aminoglycosides may occur. (5.2)

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15.2 Avoid Contamination
15.3 Contact Lens Wear

*Sections or subsections omitted from the full prescribing information are not listed.

Revised: February 2009
5.5 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.

5.6 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).

5.7 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.

5.8 Use with systemic aminoglycosides
If product is used in combination with systemic aminoglycoside antibiotics the patient should be monitored for total serum concentration.

6 ADVERSE REACTIONS
Adverse reactions have occurred with standard anti-infective combination drugs which can be attributed to the steroid component, the anti-infective component, or the combination. Exact incidence figures are not available.

The most frequent adverse reactions to topical ocular tobramycin (TOBREX®) are hypersensitivity and localized ocular toxicity, including eye pain, eyelids pruritus, eyelid edema, and periocular hyperemia. These reactions occur in less than 4% of patients. Similar reactions may occur with the topical use of other aminoglycoside antibiotics.

The reactions due to the steroid component are: increased intraocular pressure (IOP) with possible development of glaucoma, and infrequent optic nerve disorder; subcutaneous edema; and impaired healing.

6.1 Pregnancy
Pregnancy Category C. Corticosteroids have been shown to be teratogenic in animal studies. Ocular administration of 0.1% dexamethasone resulted in 15.6% and 32.3% incidence of fetal anomalies in two groups of pregnant rabbits. Fetal growth retardation and increased mortality rates have been observed in rats with tobramycin administration of 0.1% dexamethasone resulted in approximately 2% and 5% of fetal anomalies in two groups of pregnant rabbits. Fetal growth retardation and increased mortality rates have been observed in rats with chronic dexamethasone therapy. Reproduction studies have been performed in rats and rabbits with tobramycin at doses of 3.6 and 30 mg/kg/day (equivalent to human doses of 16 and 32 mg/kg/day, respectively) and have revealed no evidence of impaired fertility or harm to the fetus. There are no adequate and well controlled studies in pregnant women. TOBRADEX® ST ophthalmic suspension should not be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

6.2 Nursing Mothers
Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with normal growth and development, and inhibit the body’s defense mechanism against infection, a concomitant antimicrobial drug may be used when this inhibition is considered to be clinically significant. TOBRADEX® is an antibacterial drug. It inhibits the growth of bacteria by inhibiting protein synthesis. Tobramycin is included in this combination product to provide action against susceptible bacteria.

6.3 Pediatric Use
Safety and effectiveness in pediatric patients below the age of 2 years have not been established. Safety and effectiveness in pediatric patients below the age of 2 years have not been established.

The chemical name of demeclocycline is 9-fluoro-17-21-hydroxy-16β-methylprop-1,4-diene-3,20-dione. It has a molecular formula of C₂₀H₂₁NO₆ and a molecular weight of 392.47. The chemical structure is:

Each mL of TOBRADEX® ST contains: Active(s): tobramycin 3 mg and demeclocycline 0.5 mg. Preservative: benzalkonium chloride 0.1 mg.

11 DESCRIPTION
TOBRADEX® ST (tobramycin / demeclocycline ophthalmic suspension) 0.3%/0.05% is a sterile, isotonic, white, aqueous antibiotic and steroid suspension with a pH of approximately 5.7 and an osmolality of approximately 290 mOsm/kg.

The chemical name of tobramycin is 3,20-dione.

The molecular formula is C₁₈H₃₇N₅O₉ and a molecular weight of 467.52. The chemical structure is:

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13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
No studies have been conducted to evaluate the carcinogenic or mutagenic potential. No impairment of fertility was noted in studies of subcutaneous tobramycin in rats at doses of 50 and 100 mg/kg/day (equivalent to human doses of 8 and 16 mg/kg/day, at least 2 orders of magnitude greater than the topical ocular dose). Tobramycin is included in this combination product to provide action against susceptible bacteria.

16 HOW SUPPLIED/STORAGE AND HANDLING
TOBRADEX® ST is supplied as a 2.5 mL, 5 mL, or 10 mL suspension in a 4 mL, 8 mL, or 10 mL natural polyethylene DROP-TAINER® bottle with a natural polyethylene dispenser tip and a pink polypropylene overcap. Tamper evidence is provided with a shrink band around the closure and neck area of the bottle.

NDC 0065-0552-25: 2.5 mL
NDC 0065-0552-50: 5 mL
NDC 0065-0552-10: 10 mL
Storage: Store at 2° to 25°C (36° to 77°F). Protect from light.

17 PATIENT COUNSELING INFORMATION
17.1 Storage and Handling
Patients should be instructed to store the bottle upright and away from light. Shake well before using.

17.2 Avoid Contamination
Patients should be instructed not to touch dropper tip to any surface, as this may contaminate the contents.

17.3 Contact Lens Wear
Contact lenses should not be worn during the use of this product.

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