TOBREX - tobramycin solution
Alcon Laboratories, Inc.

Tobrex®
(tobramycin ophthalmic solution) 0.3%

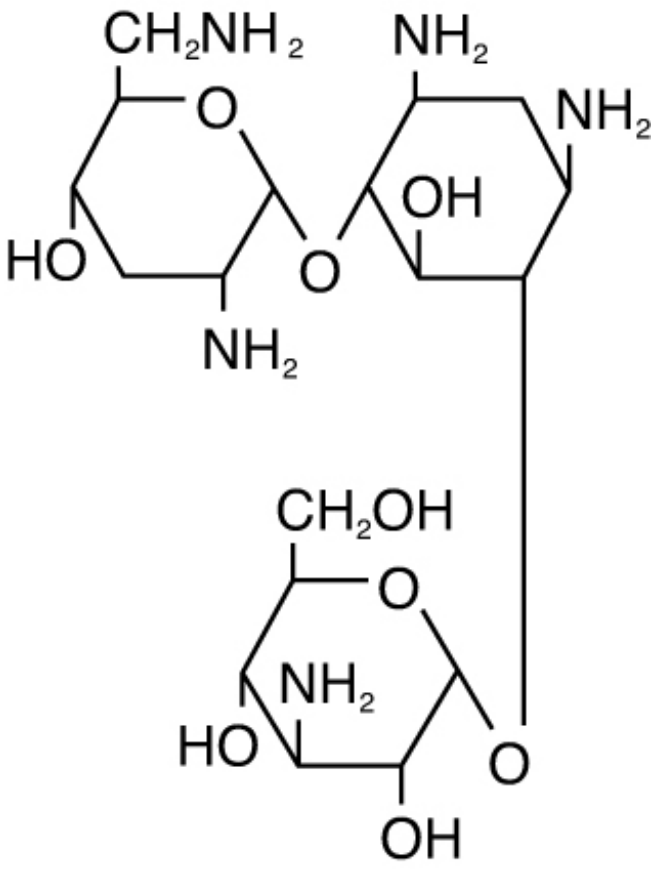
DESCRIPTION

TOBREX® (tobramycin ophthalmic solution) 0.3% is a sterile topical ophthalmic antibiotic formulation prepared specifically for topical therapy of external ophthalmic infections.

Each mL of TOBREX® solution contains: **Active:** tobramycin 0.3% (3 mg). **Preservative:** benzalkonium chloride 0.01% (0.1 mg). **Inactives:** boric acid, sodium sulfate, sodium chloride, tyloxapol, sodium hydroxide and/or sulfuric acid (to adjust pH) and purified water. TOBREX® (tobramycin ophthalmic solution) 0.3% has a pH range between 7.0 and 8.0 and an osmolality of 260-320 mOsm/kg.

Tobramycin is a water-soluble aminoglycoside antibiotic active against a wide variety of gram-negative and gram-positive ophthalmic pathogens.

The chemical structure of tobramycin is:



Molecular Weight = 467.52

Molecular Formula: $C_{18}H_{37}N_5O_9$

Chemical name: 0-{3-amino-3-deoxy-α-D-gluco-pyranosyl-(1→4) }-0-{2,6-diamino-2,3,6-trideoxy-α-D-ribohexo-pyranosyl-(1→6) }-2-deoxystreptamine.

CLINICAL PHARMACOLOGY

In Vitro Data: In vitro studies have demonstrated tobramycin is active against susceptible strains of the following microorganisms: Staphylococci, including *S. aureus* and *S. epidermidis* (coagulase-positive and coagulase-negative), including penicillin-resistant strains.

Streptococci, including some of the Group A-beta-hemolytic species, some nonhemolytic species, and some *Streptococcus pneumoniae*.

Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, Proteus mirabilis, Morganella morganii, most *Proteus vulgaris* strains, *Haemophilus influenzae* and *H. aegyptius, Moraxella lacunata, Acinetobacter calcoaceticus* and some *Neisseria* species. Bacterial susceptibility studies demonstrate that in some cases, microorganisms resistant to gentamicin retain susceptibility to tobramycin.

INDICATIONS AND USAGE

TOBREX® (tobramycin ophthalmic solution) 0.3% is a topical antibiotic indicated in the treatment of external infections of the eye and its adnexa caused by susceptible bacteria. Appropriate monitoring of bacterial response to topical antibiotic therapy should accompany the use of TOBREX®. Clinical studies have shown tobramycin to be safe and effective for use in children.

CONTRAINDICATIONS

TOBREX® (tobramycin ophthalmic solution) 0.3% is contraindicated in patients with known hyper sensitivity to any of its components.

WARNINGS

FOR TOPICAL OPHTHALMIC USE ONLY. NOT FOR INJECTION INTO THE EYE. Sensitivity to topically applied aminoglycosides may occur in some patients. If a sensitivity reaction to TOBREX® (tobramycin ophthalmic solution) 0.3% occurs, discontinue use.

PRECAUTIONS

General

As with other antibiotic preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be initiated. Cross-sensitivity to other aminoglycoside antibiotics may occur; if hypersensitivity develops with this product, discontinue use and institute appropriate therapy. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial ocular infection.

Information For Patients

Do not touch dropper tip to any surface, as this may contaminate the solution.

Pregnancy Category B

Reproduction studies in three types of animals at doses up to thirty-three times the normal human systemic dose have revealed no evidence of impaired fertility or harm to the fetus due to tobramycin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

Because of the potential for adverse reactions in nursing infants from TOBREX®, a decision should be made whether to discontinue nursing the infant or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in pediatric patients below the age of 2 months has not been established.

Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS

The most frequent adverse reactions to TOBREX® Ophthalmic Solution are hypersensitivity and localized ocular toxicity, including lid itching and swelling, and conjunctival erythema. These reactions occur in less than three of 100 patients treated with TOBREX®. Similar reactions may occur with the topical use of other aminoglycoside antibiotics. Other adverse reactions have not been reported from TOBREX® (tobramycin ophthalmic solution) 0.3% therapy; however, if topical ocular tobramycin is administered concomitantly with systemic aminoglycoside antibiotics, care should be taken to monitor the total serum concentration.

OVERDOSAGE

Clinically apparent signs and symptoms of an overdose of TOBREX® (tobramycin ophthalmic solution) 0.3% (punctate keratitis, erythema, increased lacrimation, edema and lid itching) may be similar to adverse reaction effects seen in some patients.

DOSAGE AND ADMINISTRATION

In mild to moderate disease, instill one or two drops into the affected eye(s) every four hours. In severe infections, instill two drops into the eye(s) hourly until improvement, following which treatment should be reduced prior to discontinuation.

HOW SUPPLIED

5 mL sterile solution is packaged in a 8 mL low density polyethylene white DROP-TAINER® bottle and natural dispensing plug and white polypropylene closure (NDC 0065-0643-05) containing tobramycin 0.3% (3 mg/mL).

Storage: Store at 2° - 25°C (36° - 77°F).

Rx Only
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ALCON LABORATORIES, INC.
Fort Worth, Texas 76134 USA
Printed in USA

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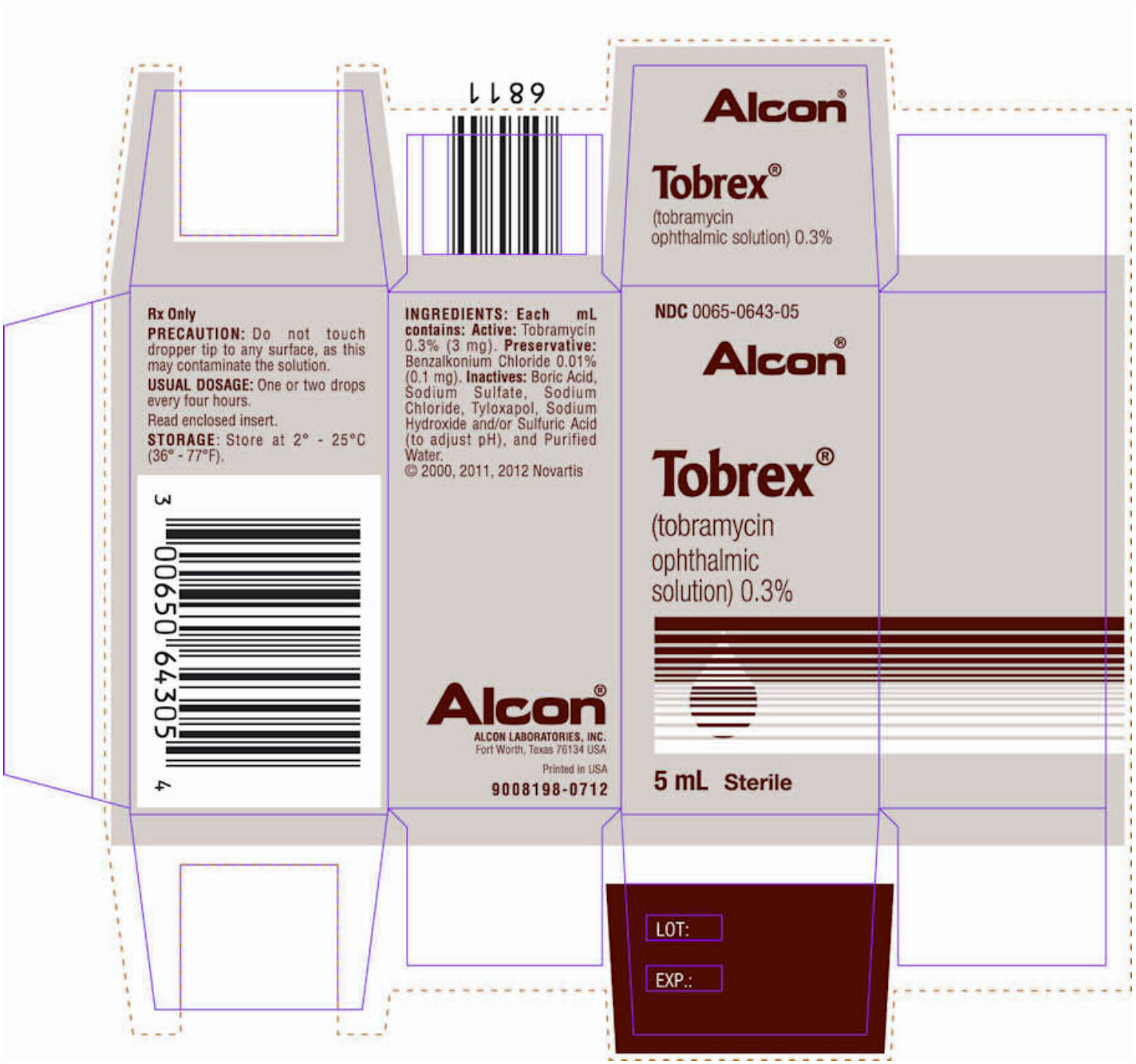
PRINCIPAL DISPLAY PANEL

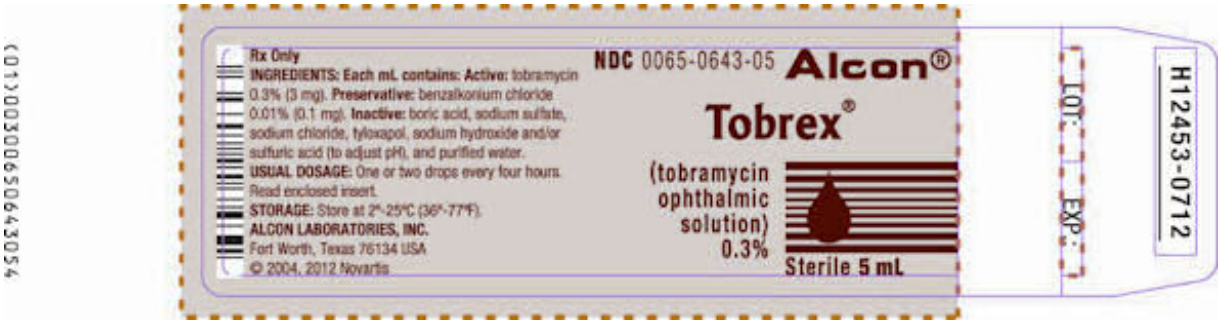
NDC 0065-0643-05

Alcon®

Tobrex®
(tobramycin ophthalmic solution) 0.3%

5mL Sterile





TOBREX

tobramycin solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0065-0643
Route of Administration	OPHTHALMIC	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOBRAMYCIN (UNII: VZ8RRZ51VK) (TOBRAMYCIN - UNII:VZ8RRZ51VK)	TOBRAMYCIN	3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TYLOXAPOL (UNII: Y27PUL9H56)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SULFURIC ACID (UNII: O40UQP6WCF)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-0643-05	5 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA050541	03/15/1981	

Labeler - Alcon Laboratories, Inc. (008018525)

Registrant - Alcon Laboratories, Inc. (008018525)

Establishment

Name	Address	ID/FEI	Business Operations
Alcon Laboratories, Inc.		008018525	MANUFACTURE(0065-0643)