TOBRAMYCIN- tobramycin solution
TOBRAMYCIN- tobramycin solution/ drops
DirectRX

TOBRAMYCIN OPTH SOLN

Tobramycin Ophthalmic Solution USP, 0.3% is a sterile topical ophthalmic antibiotic formulation prepared specifically for topical therapy of external ophthalmic infections. Each mL of Tobramycin Ophthalmic Solution USP, 0.3% 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.

Tobramycin Ophthalmic Solution USP, 0.3% has a pH range between 7.0 and 8.0.

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:

[chemical]

MW=467.2

Molecular Formula

C18H37N5O9

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

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.

Tobramycin Ophthalmic Solution USP, 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 Tobramycin Ophthalmic Solution USP, 0.3%. Clinical studies have shown tobramycin to be safe and effective for use in children

Tobramycin Ophthalmic Solution USP, 0.3% is contraindicated in patients with known hypersensitivity to any of its components.

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 Tobramycin Ophthalmic Solution USP, 0.3% occurs, discontinue use.

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 conjunctivitis.

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 Tobramycin Ophthalmic Solution USP, 0.3%, 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 other adult patients.

The most frequent adverse reactions to Tobramycin Ophthalmic Solution USP, 0.3% 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 Tobramycin Ophthalmic Solution USP, 0.3%. Similar reactions may occur with the topical use of other aminoglycoside antibiotics. Other adverse reactions have not been reported from Tobramycin Ophthalmic Solution USP, 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.

Clinically apparent signs and symptoms of an overdose of Tobramycin Ophthalmic Solution USP, 0.3% (punctate keratitis, erythema, increased lacrimation, edema and lid itching) may be similar to adverse reaction effects seen in some patients.

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.

5 mL sterile solution is packaged in a 5 mL white plastic DROP-TAINER* bottle with a plastic dispensing plug and white plastic closure (NDC 61314-643-05) containing tobramycin 0.3% (3 mg/mL).

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

Rx Only

*DROP-TAINER is a registered trademark of Alcon Manufacturing, Ltd.

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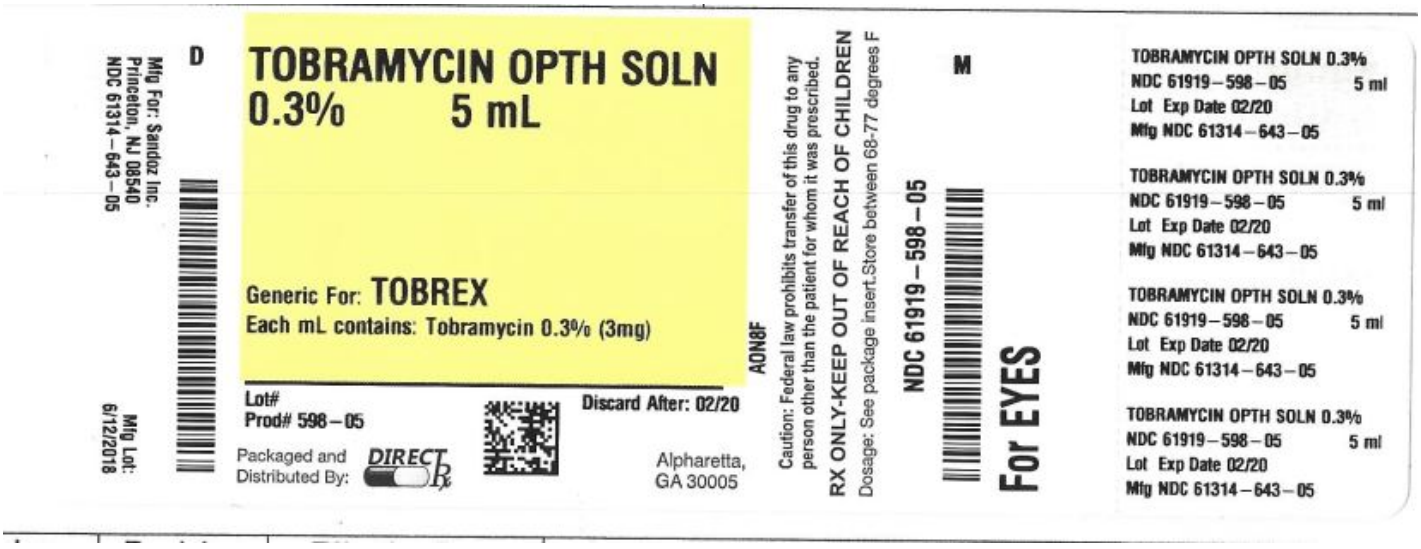
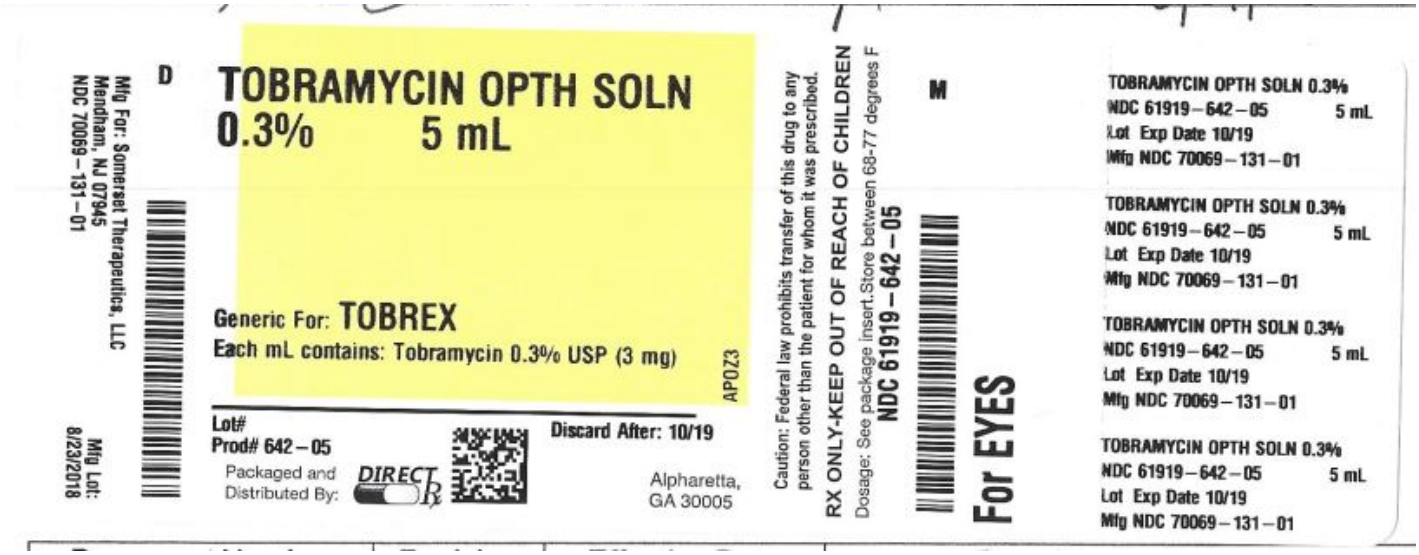
SANDOZ

Manufactured by
Alcon Laboratories, Inc.
Fort Worth, Texas 76134 for
Sandoz Inc.
Princeton, NJ 08540
Printed in USA





TOBRAMYCIN

tobramycin solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61919-598(NDC:61314-643)
Route of Administration	OPHTHALMIC		

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61919-598-05	5 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2019	12/31/2023

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062535	04/23/2019	12/31/2023

TOBRAMYCIN

tobramycin solution/ drops

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61919-642(NDC:70069-131)
Route of Administration	OPHTHALMIC		

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
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
SODIUM SULFATE ANHYDROUS (UNII: 36KCS0R750)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	
TYLOXAPOL (UNII: Y27PUL9H56)	
SULFURIC ACID (UNII: O40UQP6WCF)	

Product Characteristics

Color	white (Clear, colorless solution)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-642-05	5 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207444	04/23/2019	

Labeler - DirectRX (079254320)

Registrant - DirectRX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DirectRX		079254320	relabel(61919-598) , repack(61919-642)

Revised: 1/2024 DirectRX