TOBRAMYCIN- tobramycin solution
RPK Pharmaceuticals, Inc.

Tobramycin Ophthalmic Solution, USP 0.3%
Rx Only

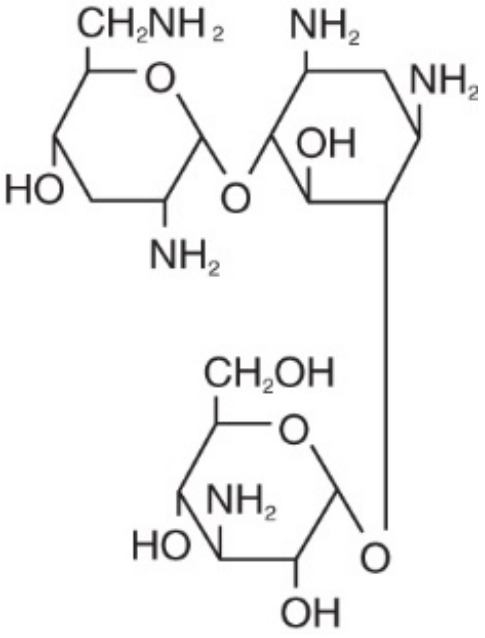
DESCRIPTION

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 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:



MW=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-ribohexopyranosyl-(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

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 tobramycin ophthalmic solution, 0.3%. Clinical studies have shown tobramycin to be safe and effective for use in children.

CONTRAINDICATIONS

Tobramycin ophthalmic solution, 0.3% is contraindicated in patients with known hypersensitivity to any of its components.

WARNINGS

FOR TOPICAL OPHTHALMIC USE. NOT FOR INJECTION INTO THE EYE. Sensitivity to topically applied aminoglycosides may occur in some patients. Severity of hypersensitivity reactions may vary from local effects to generalized reactions such as erythema, itching, urticaria, skin rash, anaphylaxis, anaphylactoid reactions, or bullous reactions. If a sensitivity reaction to 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

Reproduction studies in 3 types of animals at doses up to 33 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, 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 clinical differences in safety or effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS

The most frequent adverse reactions to tobramycin ophthalmic solution, 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, 0.3%.

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Postmarketing Experience

Additional adverse reactions identified from post-marketing use include anaphylactic reaction, Stevens-Johnson syndrome, and erythema multiforme.

The following additional adverse reactions have been reported with systemic aminoglycosides: Neurotoxicity, ototoxicity and nephrotoxicity have occurred in patients receiving systemic aminoglycoside therapy. Aminoglycosides may aggravate muscle weakness in patients with known or suspected neuromuscular disorders, such as myasthenia gravis or Parkinson’s disease, because of their potential effect on neuromuscular function.

DOSAGE AND ADMINISTRATION

In mild to moderate disease, instill 1 or 2 drops into the affected eye(s) every 4 hours. In severe infections, instill 2 drops into the eye(s) hourly until improvement, following which

treatment should be reduced prior to discontinuation.

HOW SUPPLIED

Product: 53002-9232

NDC: 53002-9232-1 5 mL in a BOTTLE, DROPPER

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

Revised: August 2021

300049864-0821

Tobramycin Ophthalmic Solution 0.3%

TOBRAMYCIN

tobramycin solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53002-9232(NDC:61314-643)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TOBRAMYCIN (UNII: VZ8RRZ51VK) (TOBRAMYCIN - UNII:VZ8RRZ51VK)	TOBRAMYCIN	3.0 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:53002-9232-1	5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	10/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062535	01/09/1995	

Labeler - RPK Pharmaceuticals, Inc. (147096275)

Establishment

Name	Address	ID/FEI	Business Operations
RPK Pharmaceuticals, Inc.		147096275	RELABEL(53002-9232) , REPACK(53002-9232)

Revised: 6/2023 RPK Pharmaceuticals, Inc.