

TOBRAMYCIN OPHTHALMIC SOLUTION - tobramycin ophthalmic solution solution/ drops
Alembic Pharmaceuticals Limited

Tobramycin Ophthalmic Solution USP, 0.3%

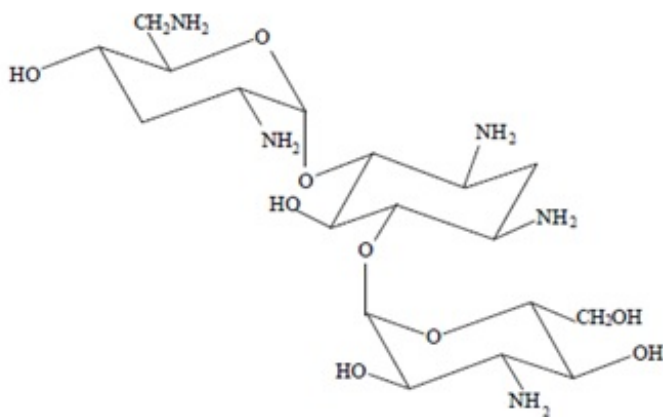
DESCRIPTION

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 contains: Active: tobramycin 0.3% (3 mg). **Preservative:** benzalkonium chloride 0.01% (0.1 mg). **Inactives:** boric acid, sodium sulfate decahydrate, sodium chloride, tyloxapol, sodium hydroxide and/or sulfuric acid (to adjust pH) and water for injection. Tobramycin ophthalmic solution USP, 0.3% has a pH range between 7.0 and 8.0 and an osmolality of 260 to 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: C₁₈H₃₇N₅O₉

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

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. 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, 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 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.

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

Tobramycin ophthalmic solution USP, 0.3% is supplied in opaque white low density polyethylene bottle which is closed with natural low density polyethylene nozzle and then with tan colored high density polyethylene cap containing tobramycin 0.3% (3 mg/mL).

5 mL in a 5 mL bottle (NDC 46708-518-05)

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

After opening, Tobramycin ophthalmic solution USP, 0.3% can be used until the expiration date on the bottle.

Manufactured by:

Alembic Pharmaceuticals Limited

Karakhadi - 391 450, Gujarat, India.

Revised: 04/2024

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL


Tobramycin Ophthalmic Solution USP, 0.3 % - Bottle Label: Alembic

5 mL Rx only NDC 46708-518-05

INGREDIENTS: Each mL contains:
Active: tobramycin 0.3% (3 mg)
Preservative: benzalkonium chloride 0.01% (0.1 mg). **Inactives:** Boric Acid, Sodium Sulfate Decahydrate, Sodium Chloride, Tyloxapol, Sodium Hydroxide and/or Sulfuric Acid (to adjust pH), and Water for Injection.
USUAL DOSAGE: One or two drops every four hours. Read enclosed insert.
STORAGE: Store at 2°C to 25°C (36°F to 77°F).

Tobramycin Ophthalmic Solution USP, 0.3%

FOR TOPICAL APPLICATION IN THE EYE



(01) 0 0346708 51805 9

200XXXXX

LOT: **Unvarnished Area for Over Coding (17 x 7 mm)**
EXP.:

Mfd. by: Alembic Pharmaceuticals Limited, Karakhadi - 391 450, Gujarat, India. M.L.No: G/28/1704

04/2024

Tobramycin Ophthalmic Solution USP, 0.3 % - Carton Label: Alembic



TOBRAMYCIN OPHTHALMIC SOLUTION

tobramycin ophthalmic solution solution/ drops

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:46708-518
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)	
BORIC ACID (UNII: R57ZHV85D4)	
TYLOXAPOL (UNII: Y27PUL9H56)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SULFURIC ACID (UNII: O40UQP6WCF)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46708-518-05	1 in 1 CARTON	04/19/2019	
1		5 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211847	04/19/2019	

Labeler - Alembic Pharmaceuticals Limited (650574663)

Establishment			
Name	Address	ID/FEI	Business Operations
Alembic Pharmaceuticals Limited (F3)		675480734	MANUFACTURE(46708-518)

Revised: 6/2024

Alembic Pharmaceuticals Limited