

**TOBRAMYCIN OPHTHALMIC SOLUTION - tobramycin ophthalmic solution solution/ drops**  
**Alembic Pharmaceuticals Inc.**

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**Tobramycin Ophthalmic Solution USP, 0.3 %**

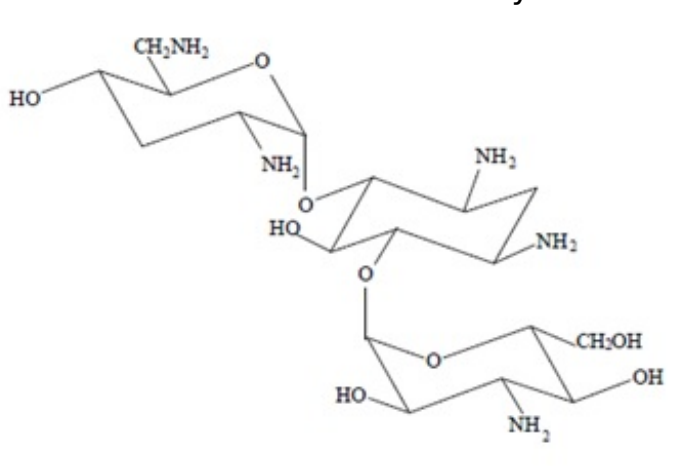
**DESCRIPTION**

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: C<sub>18</sub>H<sub>37</sub>N<sub>5</sub>O<sub>9</sub>

Chemical name:

0-{3-amino-3-deoxy-α-D-glucopyranosyl-(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 ONLY. NOT FOR INJECTION INTO THE EYE. 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 two months has not been established.

## **GERIATRIC USE**

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

## **ADVERSE REACTIONS**

**ADVERSE REACTIONS:** The most frequent adverse reactions to Tobramycin 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 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 & 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 62332-518-05).

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

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

**Manufactured for:**

Alembic Pharmaceuticals, Inc.  
Bedminster, NJ 07921  
USA

Made in India

**Manufactured by:**

Gland Pharma Limited  
D.P. Pally, Dundigal Post,  
Hyderabad-500 043, India (IND)

Revised: July, 2021

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

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

The image shows a template for the principal display panel of a bottle label for Tobramycin Ophthalmic Solution USP, 0.3%. The label is divided into several sections:

- Top Left:** A graphic of a bottle with pink diagonal lines.
- Top Center:** "5 mL" and "Rx only".
- Top Right:** "NDC 62332-518-05".
- Middle Left:** "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° to 25°C (36° to 77°F)." and the Alembic logo.
- Middle Center:** "Tobramycin Ophthalmic Solution USP, 0.3%" and "FOR TOPICAL APPLICATION IN THE EYE".
- Middle Right:** "Manufactured for: Alembic Pharmaceuticals, Inc. Bedminster, NJ 07921, USA" and "Made in India".
- Bottom Left:** A barcode.
- Bottom Center:** "LOT:" and "EXP:".
- Bottom Right:** "PSLAB-020502-03", "Mfg. Lic. No. 103/AP/RR/97/F/R", and "06/2021".

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



## TOBRAMYCIN OPHTHALMIC SOLUTION

tobramycin ophthalmic solution solution/ drops

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:62332-518
<b>Route of Administration</b>	OPHTHALMIC		

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62332-518-05	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 Inc. (079288842)

## Establishment

Name	Address	ID/FEI	Business Operations
Gland Pharma Limited		918601238	MANUFACTURE(62332-518)

Revised: 6/2022

Alembic Pharmaceuticals Inc.