**TOBRAMYCIN- tobramycin solution**
**A-S Medication Solutions**

---

**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, 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.

## CONTRAINDICATIONS

Tobramycin ophthalmic solution, USP 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. Sensitivity to topically applied aminoglycosides may occur in some patients. If a sensitivity reaction to tobramycin ophthalmic solution, USP 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 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 younger patients.

## ADVERSE REACTIONS

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.

**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.**

## OVERDOSAGE

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.

## 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

Product: 50090-3569

NDC: 50090-3569-0 5 mL in a BOTTLE, PLASTIC

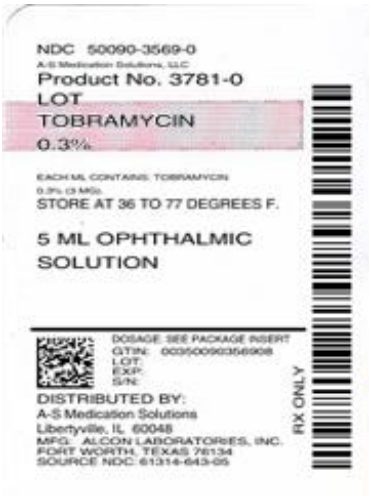
Manufactured by Alcon Laboratories, Inc.
Fort Worth, Texas 76134 for
Sandoz Inc., Princeton, NJ 08540

Revised: August 2019
9017853

### Storage

Store at 2° - 25°C (36° - 77°F).

### Tobramycin




| **TOBRAMYCIN** |
| --- |
| tobramycin solution |

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:50090-3569(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:50090-3569-0 | 5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/04/2018 | |

## Marketing Information

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

## Labeler - A-S Medication Solutions (830016429)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| A-S Medication Solutions | | 830016429 | RELABEL(50090-3569) |