**TOBRAMYCIN- tobramycin solution**
**Medsource Pharmaceuticals**

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**Tobramycin Ophthalmic Solution USP, 0.3%**

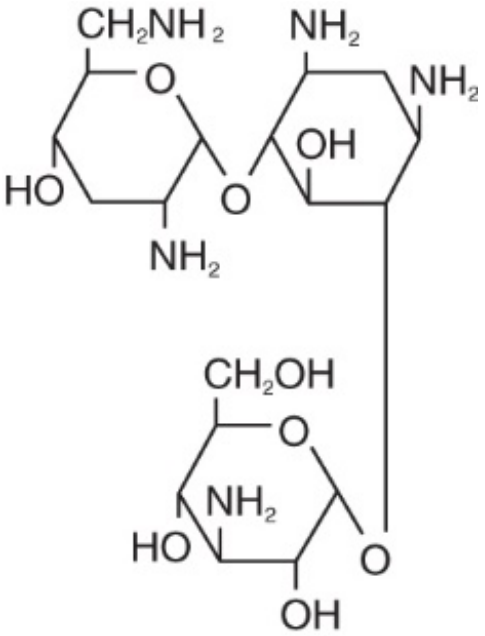
## DESCRIPTION

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, 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:




MW=467.2

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 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.

## 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.

## 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

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.

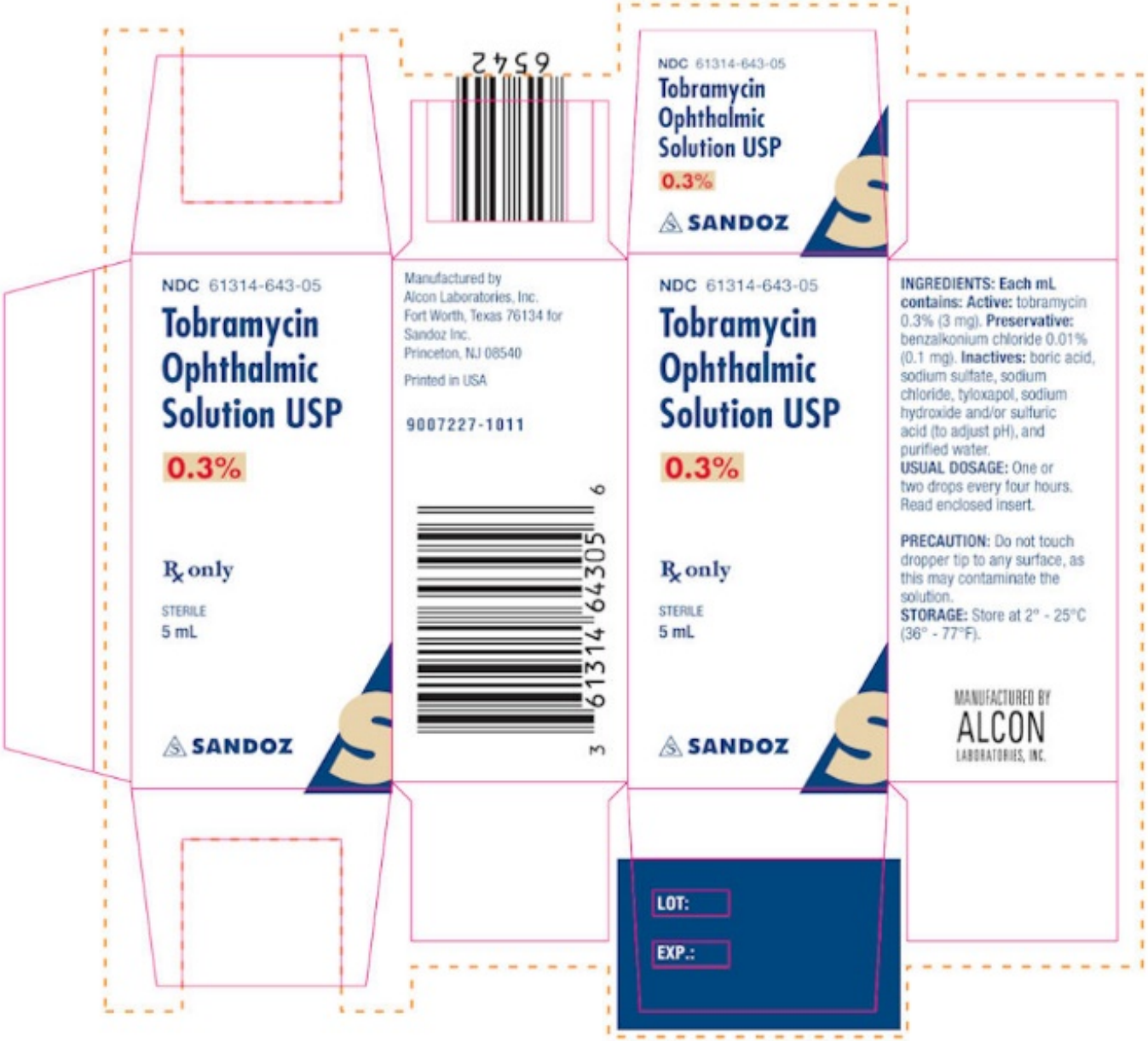
**9007228-1011**

**SANDOZ**

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

## PRINCIPAL DISPLAY PANEL


TOBRAMYCIN
OPHTHALMIC SOLN 5ML
0.3%
GENERIC FOR TOBREX
LOT:
NDC: 45865-0427-1
EXP:
#1
SEE PACKAGE INSERT
ALCON LABORATORIES
FT. WORTH, TX
SEE PACKAGE INSERT FOR COMPLETE PRODUCT INFORMATION.
____ DROPS EVERY ____ HOURS.
PATIENT LOG CHART CLAIM
PEEL HERE
PEEL HERE


NDC 61314-643-05
Tobramycin Ophthalmic Solution USP
0.3%
Rx only
STERILE
5 mL
SANDOZ
Manufactured by
Alcon Laboratories, Inc.
Fort Worth, Texas 76134 for
Sandoz Inc.
Princeton, NJ 08540
Printed in USA
9007227-1011
3 61314 64305 6
INGREDIENTS: Each mL 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.
USUAL DOSAGE: One or two drops every four hours. Read enclosed insert.
PRECAUTION: Do not touch dropper tip to any surface, as this may contaminate the solution.
STORAGE: Store at 2° - 25°C (36° - 77°F).
MANUFACTURED BY
ALCON
LABORATORIES, INC.
LOT:
EXP.:


# TOBRAMYCIN

tobramycin solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:45865-427(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) | |
| **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:45865-427-01 | 5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 01/01/2018 | |

## Marketing Information

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

## Labeler - Medsource Pharmaceuticals (833685915)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Medsource Pharmaceuticals | | 833685915 | repack(45865-427) |

Revised: 7/2018 Medsource Pharmaceuticals