Tobramycin Ophthalmic Solution, USP 0.3% (Steril)

Rx only

DESCRIPTION
Tobramycin Ophthalmic Solution, USP 0.3% is a sterile topical ophthalmic antibiotic formulation prepared specifically for topical therapy of external ocular infections.

Each mL contains:
Active: Tobramycin 3 mg (0.3%). Inactive: Boric Acid, Sodium Sulfate, Sodium Chloride, Tryptoosin and Purified Water. Sodium Hydroxide and/or Sulfuric Acid (to adjust pH). Tobramycin Ophthalmic Solution, USP 0.3% has a pH range between 7.0 and 8.0.
Preservative Added: Boric Acid and Chloride (0.5%)

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 formula: C_{18}H_{37}N_{9}O_{15}S
Molecular weight: 467.52

CLINICAL PHARMACOLOGY
In Vitro: In vitro studies have demonstrated tobramycin is active against susceptible strains of the following microorganisms: Staphylococci, including coagulase 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.
Pneumococci aerogenes, Esherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, Proteus mirabilis, Morganella morganii, most Proteus vulgaris strains, Neisseria gonococci and N. meningitidis. Some N. meningitidis 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. 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.

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
It is not known whether tobramycin is excreted in breast milk. Because animal studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Pediatric Use
Safety and effectiveness in pediatric patients below the age of two months have not been established.

Geriatic 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 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. Similar reactions may occur with the topical use of other aminoglycoside antibiotics. Other adverse reactions have not been reported from tobramycin therapy; however, topical ocular tobramycin is administered concurrently with systemic aminoglycoside antibiotics; care should be taken to monitor the total serum concentration.

To report SUSPECTED ADVERSE REACTIONS, contact Bausch & Lomb, a division of Valeant Pharmaceuticals North America LLC, at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE
Clinically significant 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.

DOSE 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.

DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.

FOR TOPICAL OPHTHALMIC USE ONLY
HOW SUPPLIED
Tobramycin Ophthalmic Solution, USP 0.3% is supplied in a plastic bottle with a controlled drop tip and a white polypropylene cap in the following size:
NDC 24208-290-05 - 10 mL bottle (5 mL fill)

Storage

KEEP OUT OF REACH OF CHILDREN.

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Bausch & Lomb, a division of Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA

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