TOBRAMYCIN- tobramycin solution
Bausch & Lomb Incorporated

Tobramycin
Ophthalmic Solution, USP
0.3% (Sterile)

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 contains

Active: Tobramycin 3 mg (0.3%). **Inactives**: Boric Acid, Sodium Sulfate, Sodium Chloride, Tyloxapol 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: Benzalkonium Chloride 0.1 mg (0.01%).

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: $C_{18}H_{37}N_5O_9$

Chemical name:

(2S,3R,4S,5S,6R)-4-amino-2-[(1S,2S,3R,4S,6R)-4,6-diamino-3-[(2R,3R,5S,6R)-3-amino-6-(aminomethyl)-5-hydroxyoxan-2-yl]oxy-2-hydroxycyclohexyl]oxy-6-(hydroxymethyl)oxane-3,5-diol;sulfuric acid

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 two months has not been established.

Geriatric 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, 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 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 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.

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

Store at 2°-25°C (36°-77°F). Avoid excessive heat.

KEEP OUT OF REACH OF CHILDREN.

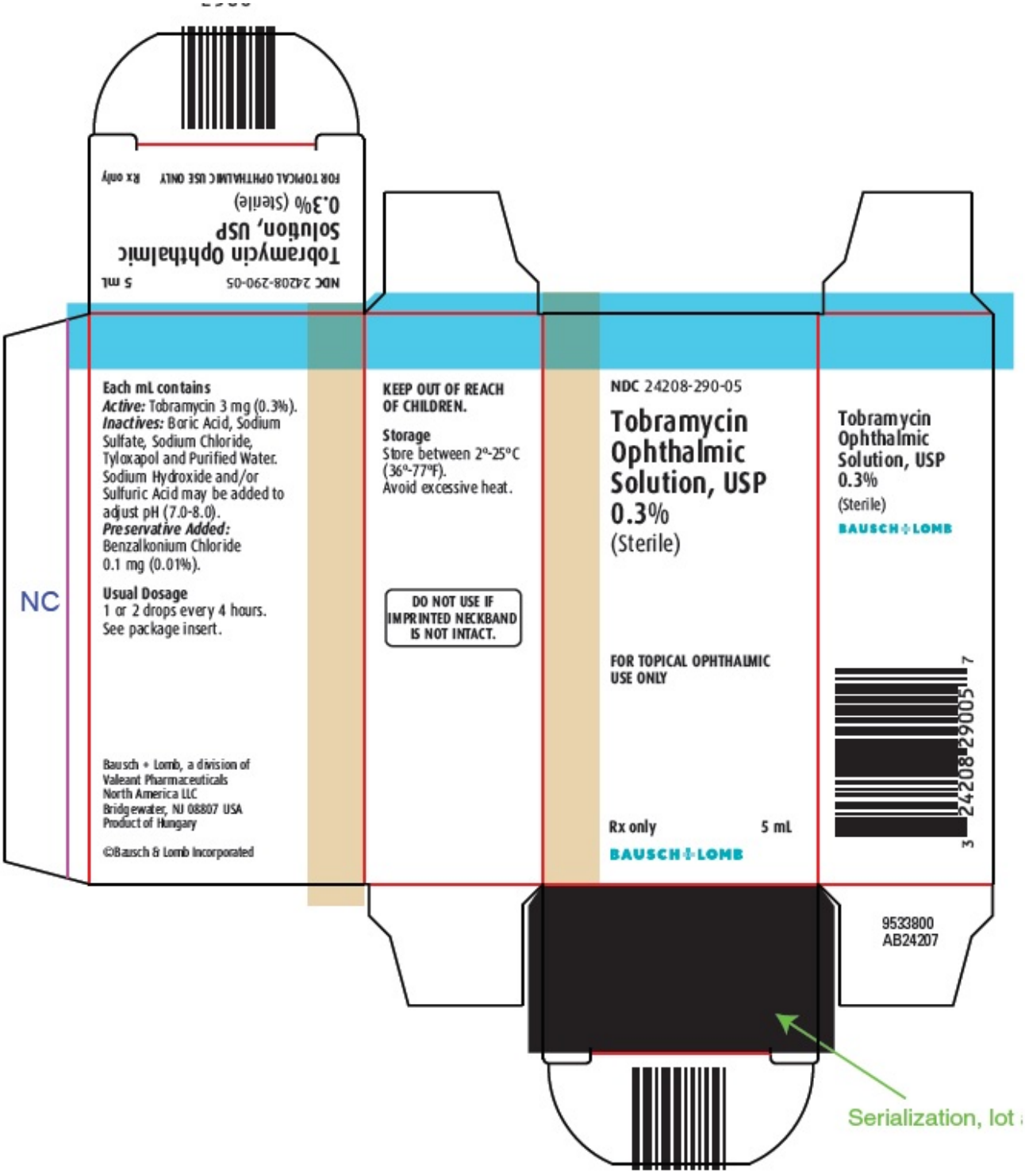
Revised June 2017

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

9116805 (folded)

9116905 (flat)

Principal Display Panel



NDC 24208-290-05

Tobramycin Ophthalmic Solution, USP

0.3%
(Sterile)

FOR TOPICAL OPHTHALMIC USE ONLY

Rx only

5 mL

Bausch + Lomb

TOBRAMYCIN

tobramycin solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:24208-290
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**
BORIC ACID (UNII: R57ZHV85D4)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
SULFURIC ACID (UNII: O40UQP6WCF)	
TYLOXAPOL (UNII: Y27PUL9H56)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:24208-290-05	1 in 1 CARTON	11/29/1993	
1		5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064052	11/29/1993	

Labeler - Bausch & Lomb Incorporated (196603781)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	MANUFACTURE(24208-290) , PACK(24208-290) , LABEL(24208-290)

Establishment

Name	Address	ID/FEI	Business Operations
Quality Packaging Specialists International LLC		078440982	LABEL(24208-290) , PACK(24208-290)

Revised: 6/2017 Bausch & Lomb Incorporated