TOBRAMYCIN- tobramycin solution/ drops
MWI

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:

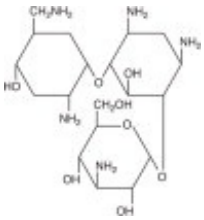
Active: tobramycin 0.3% (3 mg). **Inactives:** boric acid, sodium chloride, sodium sulfate, tyloxapol, sodium hydroxide and/or sulfuric acid to adjust pH (7.0 to 8.0), and water for injection. **Preservative:** benzalkonium chloride 0.01% (0.1 mg).

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: O-{3-amino-3-deoxy-β-D-gluco-pyranosyl (1→4)}-O-{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. Sensitivity to topically applied aminoglycosides may occur in some patients. 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, discontinueuse 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 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, 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 clinical differences in safety or effectiveness have been observed between the elderly and other adult patients.

ADVERSE REACTIONS:

The most frequent adverse reactions to tobramycin ophthalmic solution 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.

Postmarketing Experience: Additional adverse reactions identified from postmarketing 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 AND 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 as a sterile solution in white low-density polyethylene (LDPE) plastic dropper bottle:

NDC 13985-604-05 5 mL

STORAGE:

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Keep container tightly closed. Protect from excessive heat."

apexa™
Manufactured by: Akorn
Lake Forest, IL 60045

Distributed by: MWI
Boise, ID 83705"
MWTM00N Rev. 09/21

Principal Display Panel Text for Container Label:

NDC 13985-604-05

Tobramycin Ophthalmic

Solution, USP 0.3%

FOR TOPICAL

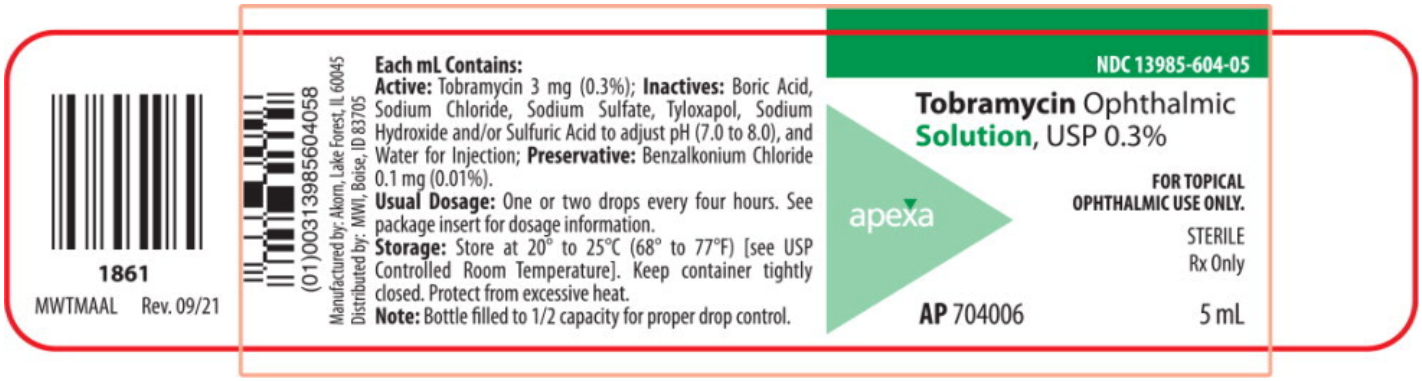
OPHTHALMIC USE ONLY.

Apexa logo

STERILE

Rx Only

AP 704006 5 mL



Principal Display Panel Text for Carton Label:

NDC 13985-604-05

Tobramycin

Ophthalmic

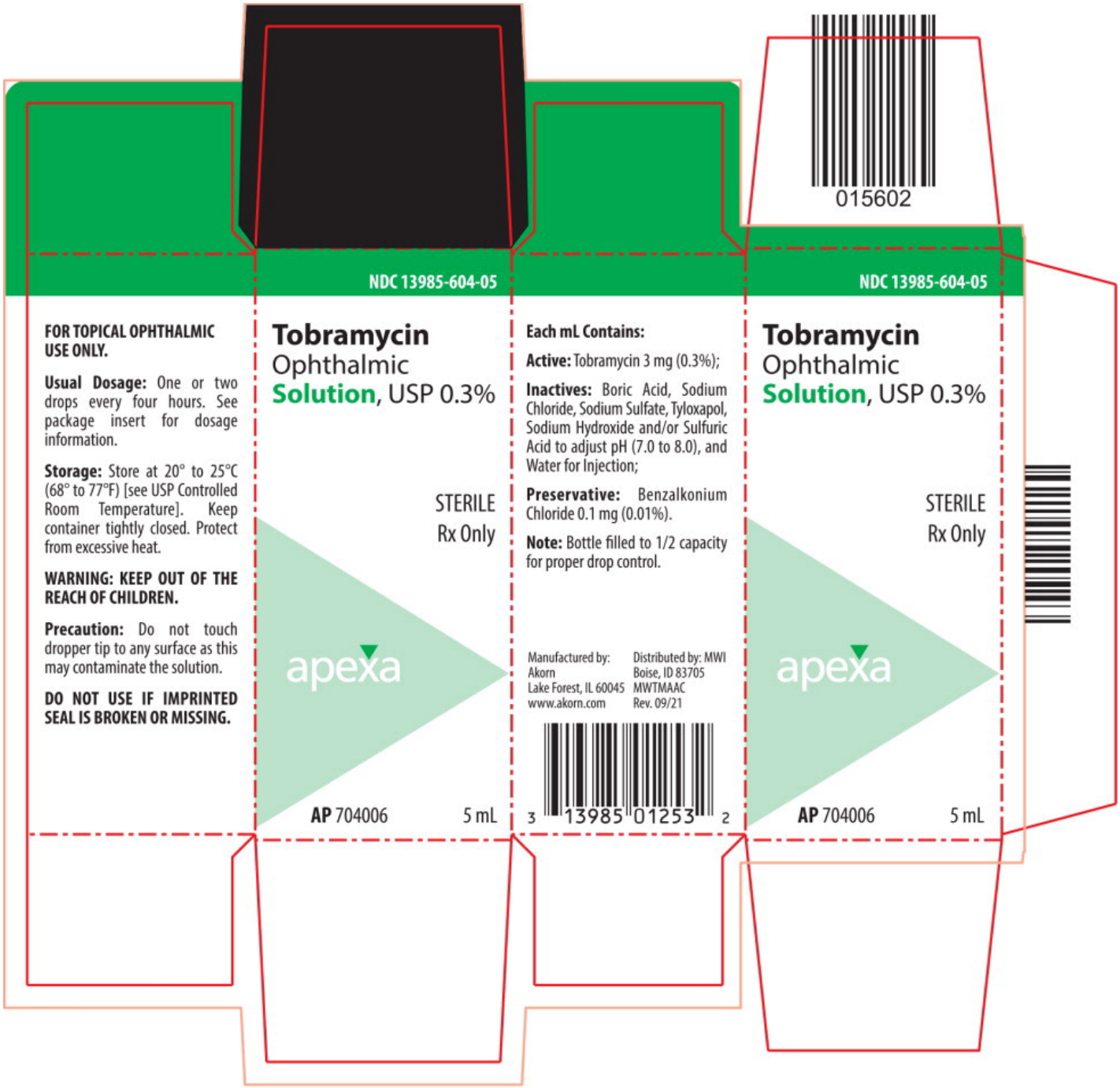
Solution, USP 0.3%

STERILE

Rx Only

Apexa logo

AP 704006 5 mL



TOBRAMYCIN

tobramycin solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:13985-604
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)	
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Sulfate (UNII: 0YPR65R21J)	
Tyloxapol (UNII: Y27PUL9H56)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Sulfuric Acid (UNII: O40UQP6WCF)	
Water (UNII: 059QF0KO0R)	
Benzalkonium Chloride (UNII: F5UM2KM3W7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13985-604-05	1 in 1 CARTON	03/27/2015	
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	ANDA064096	03/27/2015	

Labeler - MWI (019926120)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(13985-604) , STERILIZE(13985-604) , ANALYSIS(13985-604) , PACK(13985-604) , LABEL(13985-604)

Revised: 2/2022 MWI