GENTAMICIN SULFATE OPTH SOLUTION- gentamicin sulfate opth solution solution/ drops
Direct_Rx

Gentamicin Sulfate Opth Solution

Gentamicin Sulfate Ophthalmic Solution is a sterile, aqueous solution buffered to approximately pH 7.0 and formulated for ophthalmic use.

Each mL contains

Active: Gentamicin Sulfate (equivalent to 3 mg gentamicin).

Inactives: Dibasic Sodium Phosphate, Sodium Chloride, Monobasic Sodium Phosphate, Purified Water. Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH (6.5 - 7.5).

Preservative Added: Benzalkonium Chloride 0.01%.

Gentamicin is an aminoglycoside antibiotic obtained from cultures of Micromonospora purpurea. It is a mixture of the sulfate salts of Gentamicin C1, C2, C1a and C2a. All three components appear to have similar antimicrobial activity.

Gentamicin sulfate occurs as a white to buff powder and is soluble in water and insoluble in alcohol.

The structural formula is as follows:

[Gentamicin Sulfate (structural formula)]

Microbiology

Gentamicin sulfate is active in vitroagainst many strains of the following microorganisms:

Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pyogenes, Streptococcus pneumoniae, Enterobacter aerogenes Escherichia coli; Haemophilus influenzae, Klebsiella pneumoniae, Neisseria gonorrhoeae, Pseudomonas aeruginosa, and Serratia marcescens.

Gentamicin sulfate ophthalmic solution is indicated in the topical treatment of ocular bacterial infections including conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis, blepharoconjunctivitis, acute meibomianitis, and dacryocystitis, caused by susceptible strains of the following microorganisms:

Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pyogenes, Streptococcus pneumoniae, Enterobacter aerogenes, Escherichia coli; Haemophilus influenzae, Klebsiella pneumoniae, Neisseria gonorrhoeae, Pseudomonas aeruginosa, and Serratia marcescens.

Gentamicin sulfate ophthalmic solution is contraindicated in patients with known hypersensitivity to any of its components.

NOT FOR INJECTION INTO THE EYE

Gentamicin sulfate ophthalmic solution is not for injection. It should never be injected subconjunctivally, nor should it be directly introduced into the anterior chamber of the eye.

General

Prolonged use of topical antibiotics may give rise to overgrowth of nonsusceptible organisms including fungi. Bacterial resistance to gentamicin may also develop. If purulent discharge, inflammation or pain becomes aggravated, the patient should discontinue use of the medication and consult a physician. If irritation or hypersensitivity to any component of the drug develops, the patient should discontinue use of this preparation and appropriate therapy should be instituted.

Information for Patients

To avoid contamination, do not touch tip of container to the eye, eyelid or any surface.

Carcinogenesis, Mutagenesis, Impairment of Fertility

There are no published carcinogenicity or impairment of fertility studies on gentamicin. Aminoglycoside antibiotics have been found to be non-mutagenic.

Pregnancy

Gentamicin has been shown to depress body weights, kidney weights and median glomerular counts in newborn rats when administered systemically to pregnant rats in daily doses approximately 500 times the maximum recommended ophthalmic human dose. There are no adequate and well-controlled studies in pregnant women. Gentamicin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Bacterial and fungal corneal ulcers have developed during treatment with gentamicin ophthalmic preparations.

The most frequently reported adverse reactions are ocular burning and irritation upon drug instillation, non-specific conjunctivitis, conjunctival epithelial defects and conjunctival hyperemia.

Other adverse reactions which have occurred rarely are allergic reactions, thrombocytopenic purpura and hallucinations.

To report SUSPECTED ADVERSE REACTIONS, contact Bausch & Lomb Incorporated at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Instill one or two drops into the affected eye(s) every four hours. In severe infections dosage may be increased to as much as two drops every hour.

Gentamicin Sulfate Ophthalmic Solution, USP 0.3% is supplied in a plastic bottle with a controlled drop tip and a white polypropylene cap in the following sizes:

NDC 24208-580-60 - 5 mL

NOT FOR INJECTION INTO THE EYE

FOR OPHTHALMIC USE ONLY

DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.

Storage: Store between 2°-25°C (36°-77°F). Avoid exposure to excessive heat.

Keep out of reach of children.

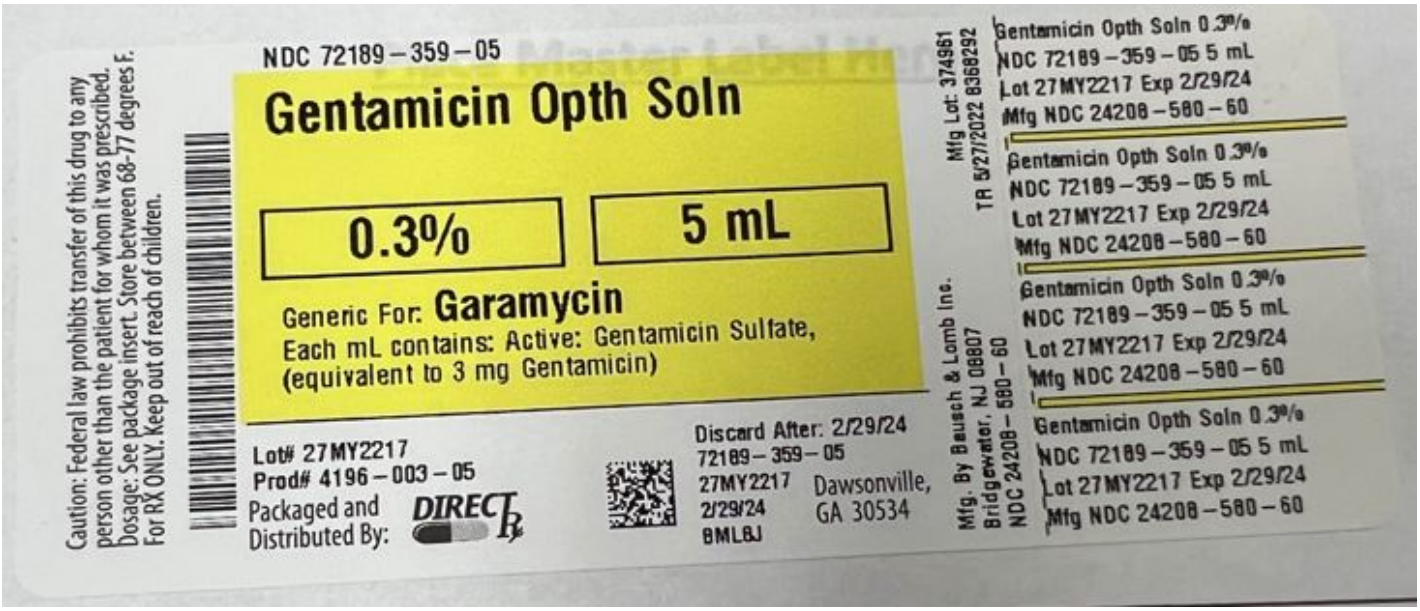
Distributed by:

Bausch + Lomb, a division of
Bausch Health US, LLC
Bridgewater, NJ 08807 USA

Manufactured by:
Bausch & Lomb Incorporated
Tampa, FL 33637 USA

Revised: February 2020

9116005 (Folded)
9116105 (Flat)



GENTAMICIN SULFATE OPTH SOLUTION

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Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72189-359(NDC:24208-580)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GENTAMICIN SULFATE (UNII: 8X7386QRLV) (GENTAMICIN - UNII:T6Z9V48IKG)	GENTAMICIN	3 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-359-05	5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	06/17/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064048	06/17/2022	

Labeler - Direct_Rx (079254320)

Registrant - Direct_Rx (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
Direct_Rx		079254320	repack(72189-359)

Revised: 6/2022 Direct_Rx