GENTAMICIN SULFATE- gentamicin sulfate solution/ drops
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DIRECT RX

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gentamicin sulfate

Gentamicin sulfate is a water-soluble antibiotic of the aminoglycoside group.

Gentamicin Sulfate Ophthalmic Solution is a sterile, aqueous solution for ophthalmic use.

Each mL contains:
Active: Gentamicin Sulfate USP (equivalent to 3 mg gentamicin base)
Preservative: Benzalkonium Chloride
Inactives: Disodium Phosphate, Monosodium Phosphate, and Sodium Chloride. The pH range is from 6.8 to 7.3.

Gentamicin is obtained from cultures of Micromonospora purpurea. It is a mixture of the sulfate salts of gentamicin C1, C2, and C1A. All three components appear to have similar antimicrobial activities. Gentamicin sulfate occurs as a white powder and is soluble in water and insoluble in alcohol. The structural formula is as follows:

CLINICAL PHARMACOLOGY SECTION

Microbiology

Gentamicin sulfate is active in vitro against 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.

INDICATIONS & USAGE SECTION

Gentamicin sulfate ophthalmic solution, USP 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.

CONTRAINDICATIONS SECTION

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

WARNINGS SECTION

NOT FOR INJECTION INTO THE EYE.

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

PRECAUTIONS SECTION

General

Prolonged use of topical antibiotics may give rise to overgrowth of nonsusceptible microorganisms, 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

Pregnancy Category C

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.

Pediatric Use

Safety and effectiveness in neonates have not been established

ADVERSE REACTIONS SECTION

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.

DOSAGE & ADMINISTRATION SECTION

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.

HOW SUPPLIED SECTION

Gentamicin sulfate ophthalmic solution, USP 0.3% is supplied sterile in white opaque LDPE plastic bottles and tips with white high impact polystyrene (HIPS) caps as follows:

5 mL in 10 mL bottle – NDC 60758-188-05

Storage: Store at or below 25°C (77°F). Avoid exposure to excessive heat (40°C/104°F or above).

Revised: 08/2013

Irvine, CA 92612, U.S.A.

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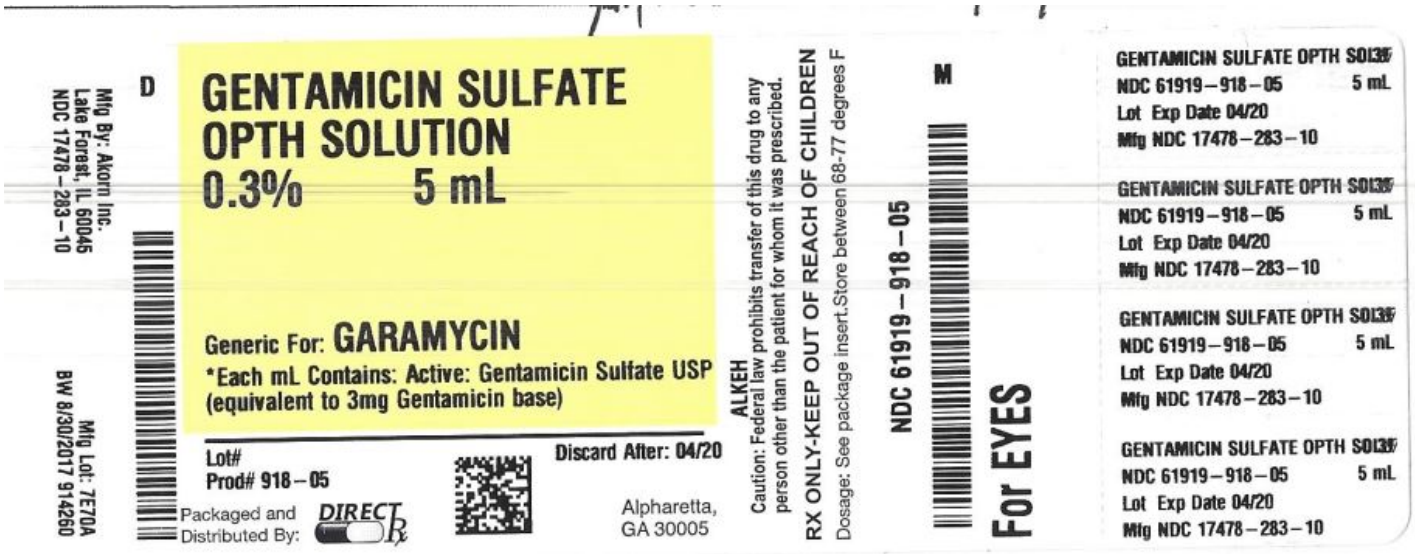
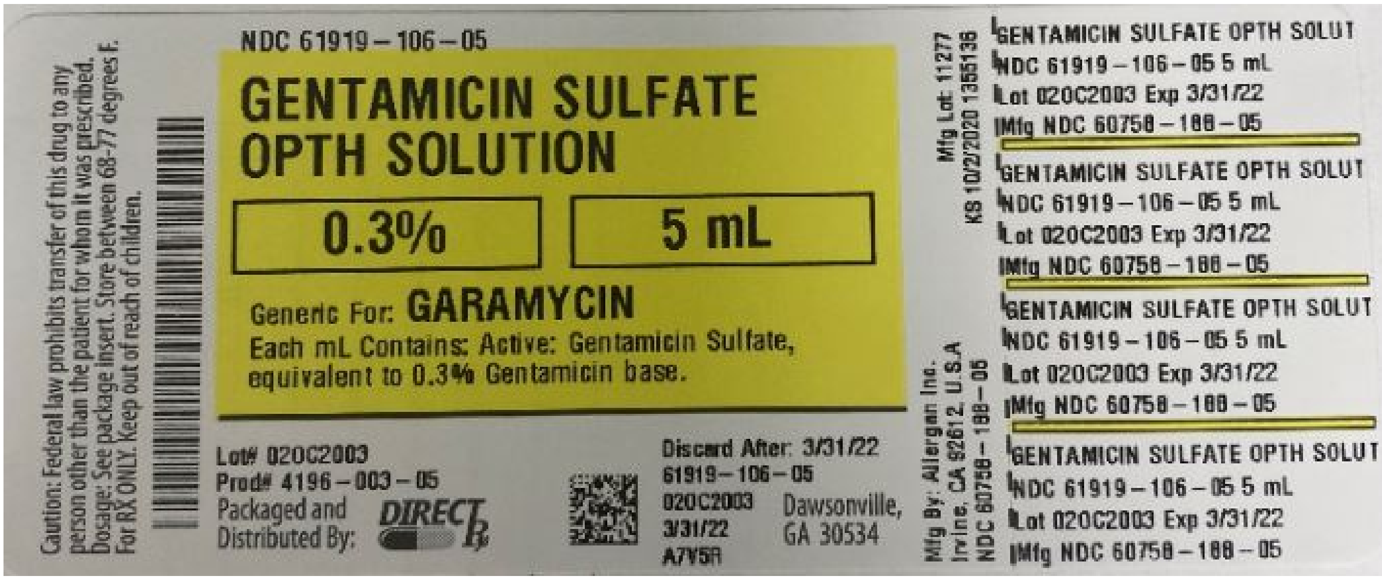
Made in the U.S.A.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





GENTAMICIN SULFATE

gentamicin sulfate solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61919-106(NDC:60758-188)
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**
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61919-106-05	5 mL in 1 CARTON; Type 0: Not a Combination Product	05/07/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062452	01/01/2014	

GENTAMICIN SULFATE

gentamicin sulfate solution/ drops

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61919-918(NDC:17478-283)
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
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-918-05	5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	03/19/2019	12/31/2023

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064163	03/19/2019	12/31/2023

Labeler - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations

DIRECT RX		079254320	relabel(61919-918, 61919-106)