GENTAMICIN SULFATE- gentamicin sulfate solution/ drops
Aidarex Pharmaceuticals LLC

Gentamicin Sulfate Ophthalmic Solution USP, 0.3%

Sterile

Rx only

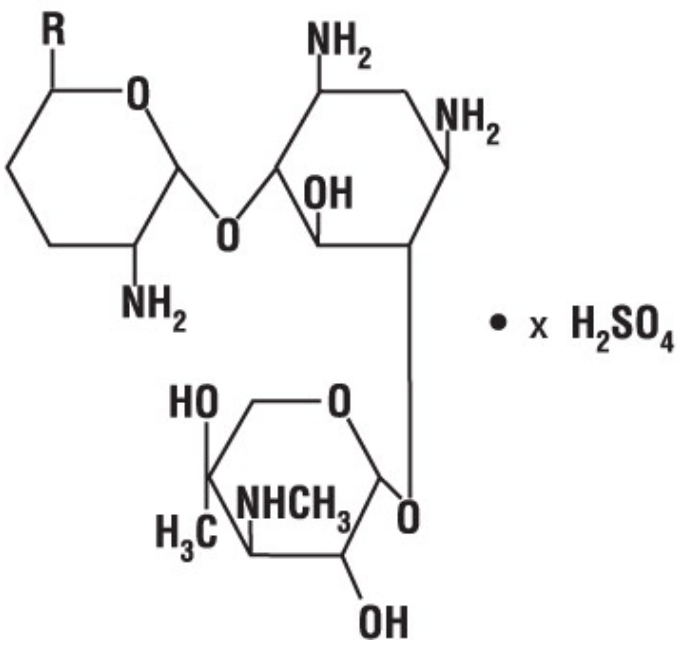
DESCRIPTION

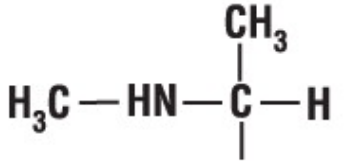
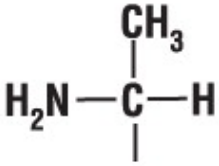
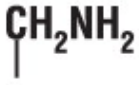
Gentamicin sulfate is a water-soluble antibiotic of the aminoglycoside group.

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 C_1, C_2, and C_{1A}. 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:



Gentamicin	R
C_1	
C_2	
C_{1A}	

CLINICAL PHARMACOLOGY

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 AND USAGE

Gentamicin Sulfate Sterile 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.*

CONTRAINDICATIONS

Gentamicin Sulfate Sterile Ophthalmic Solution is contraindicated in patients with known hypersensitivity to any of the components.

WARNINGS

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.

PRECAUTIONS

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

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

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 AND ADMINISTRATION

Gentamicin Sulfate sterile ophthalmic solution; 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 once every hour.

HOW SUPPLIED

Gentamicin Sulfate ophthalmic solution - Sterile, 5-mL plastic dropper bottle, box of one.

5 MILLILITER in a BOTTLE, DROPPER/1 BOTTLE in a CARTON (53217-229-01)

STORAGE: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Avoid exposure to excessive heat.

Repackaged By:

Aidarex Pharmaceuticals, LLC

Corona, CA 92880

PRINCIPAL DISPLAY PANEL

SPL Image

GENTAMICIN SULFATE

gentamicin sulfate solution/ drops

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53217-229(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, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53217-229-01	1 in 1 CARTON	12/13/2006	
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	ANDA064163	12/13/2006	

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 2/2017 Aidarex Pharmaceuticals LLC