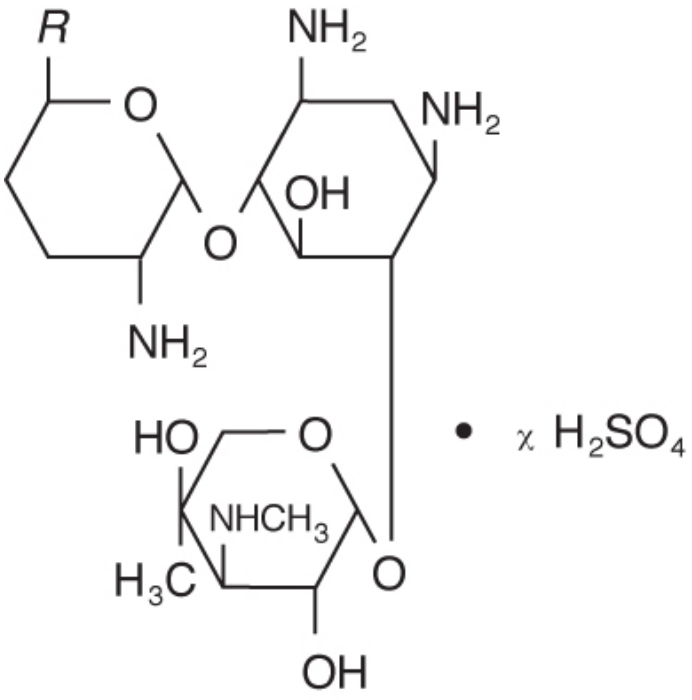
GENTAMICIN SULFATE- gentamicin sulfate solution
Sandoz Inc

Gentamicin Sulfate
Ophthalmic Solution USP
Sterile
Rx Only

DESCRIPTION

Gentamicin Sulfate is a water-soluble antibiotic of the aminoglycoside group. Gentamicin Sulfate Ophthalmic Solution is a sterile, aqueous solution buffered to approximately pH 7 for ophthalmic use. 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 white powder and is soluble in water and insoluble in alcohol. The structure is as follows:



Gentamicin	R
C_1	$H_3C-HN-\underset{\displaystyle CH_3}{\overset{\displaystyle CH_3}{C}}-H$
C_2	$H_2N-\underset{\displaystyle CH_3}{\overset{\displaystyle CH_3}{C}}-H$
C_{1A}	$\overset{\displaystyle CH_2NH_2}{CH}$

Established name: Gentamicin Sulfate

Chemical name: 0-3-Deoxy-4-C-methyl-3-(methylamino)-β-L-arabinopyranosyl-(1→6)-0-[2,6-diamino-2,3,4,6-tetradeoxy-α-D-erythro-hexopyranosyl-(1→4)]-2-deoxy-D-streptamine.

Ingredients: Each mL contains: Active: Gentamicin Sulfate USP (equivalent to 3 mg gentamicin). **Preservative:** Benzalkonium Chloride 0.1 mg (0.01%). **Inactives:** Sodium Chloride, Dried Sodium Phosphate, Tyloxapol, Sodium Hydroxide and/or Hydrochloric Acid (to adjust pH) and Purified Water.

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 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 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 non-susceptible 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.

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

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: 5 mL in plastic dispenser. **NDC** 61314-633-05

STORAGE

Protect from light and store away from heat. Store at controlled room temperature 15° to 25°C (59° to 77°F).

Manufactured by

Alcon Laboratories, Inc.

Fort Worth, Texas 76134 for

Sandoz Inc.

Princeton, NJ 08540

Rev. August 2021

300049859-0821

PRINCIPAL DISPLAY PANEL

NDC 61314-633-05

Gentamicin

Sulfate

Ophthalmic

Solution, USP

0.3%

Equivalent to 3 mg

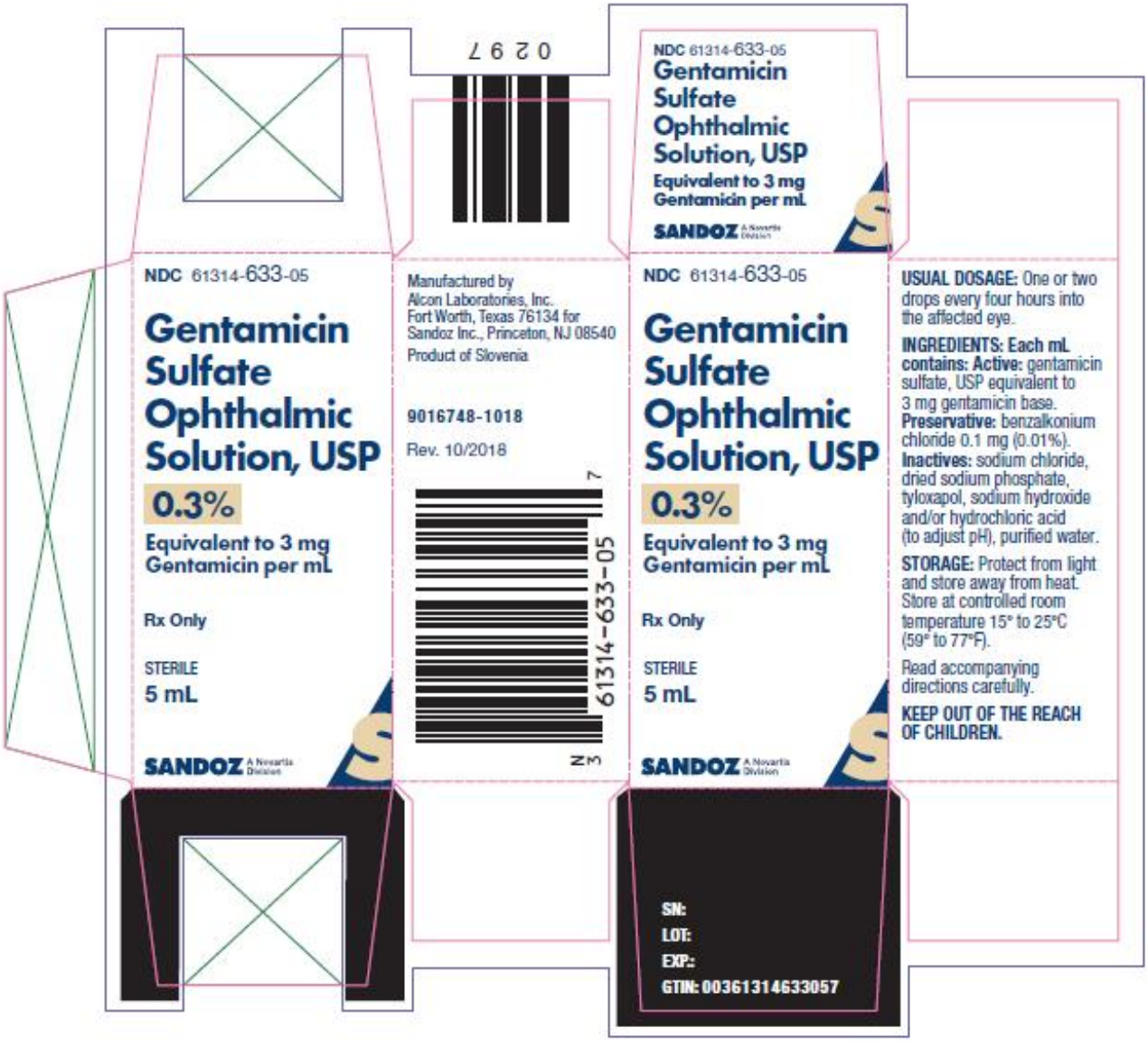
Gentamicin per mL

Rx Only

STERILE

5 mL

SANDOZ



GENTAMICIN SULFATE

gentamicin sulfate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61314-633
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**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
TYLOXAPOL (UNII: Y27PUL9H56)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61314-633-05	5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/05/1996	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062196	04/05/1996	

Labeler - Sandoz Inc (005387188)

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