

# GENTAMICIN SULFATE- gentamicin sulfate solution

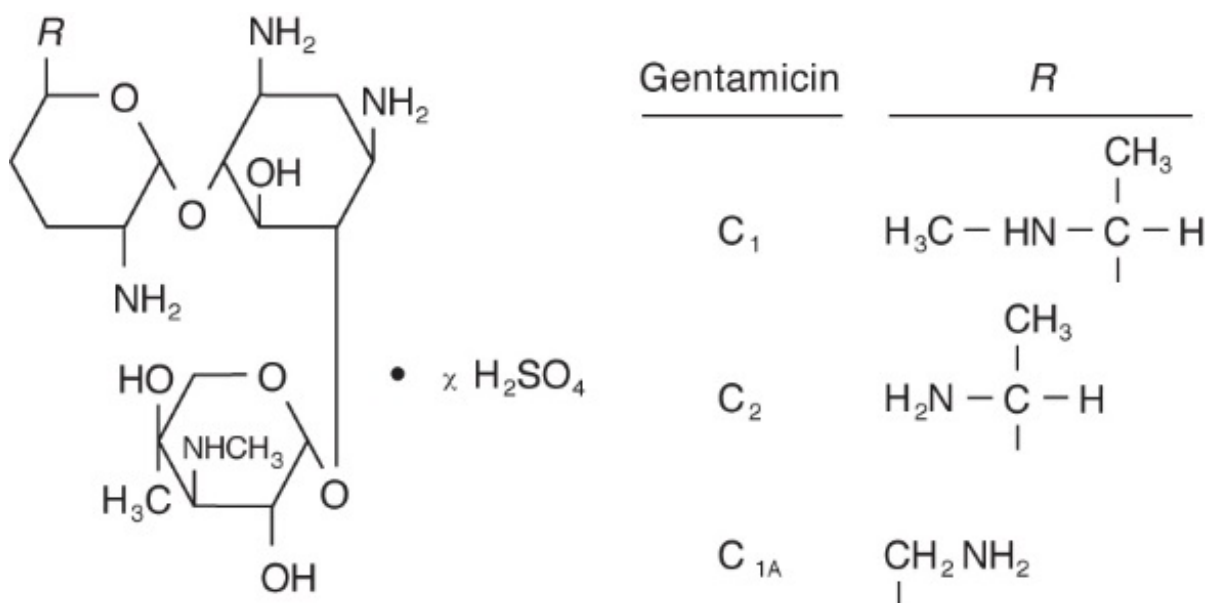
Preferred Pharmaceuticals Inc.

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## Gentamicin Sulfate Ophthalmic Solution USP

### 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<sub>1</sub>, C<sub>2</sub>, and C<sub>1A</sub>. 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:



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-tetrahydroxy-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.

### **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 DROP-TAINER\* dispenser.

**NDC** 68788-7336-5

**STORAGE:** Protect from light and store away from heat. Store at controlled room temperature 15°-30°C (59°-86°F).

**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](http://www.fda.gov/medwatch).**

\*DROP-TAINER is a registered trademark of Alcon Research, Ltd.

### **Rx Only**

**9007184-1011**

Manufactured By

Alcon Laboratories, Inc.

Fort Worth, Texas 76134 for

Sandoz Inc.,

Princeton, NJ 08540

Rev. December 2018

**Relabeled By: Preferred Pharmaceuticals Inc.**

### **PRINCIPAL DISPLAY PANEL**

NDC 68788-7336-5

**Gentamicin**

**Sulfate**

**Ophthalmic**

**Solution USP**

**Equivalent to 3 mg**

**Gentamicin per mL**



**Rx Only**

STERILE

**5 mL**

SANDOZ

**Relabeled By: Preferred Pharmaceuticals Inc.**

<p align="center"><b>Gentamicin Sulfate Ophth. Solution USP</b> <b>0.3%</b> Generic for Garamycin Each mL contains: Gentamicin Sulfate USP (eq. to 3mg gentamicin base) Pkg Size: Exp Date: Lot#: Batch#: Ins: Mfg: Sandoz Inc. Prod#: Warning <small>Store at 15°-25°C (59°-77°F). Protect from light and store away from heat. See USP Controlled Room Temperature. Keep this and all medications out of the reach of children. Rx Only. For ophthalmic use only. See package insert for dosage information.</small></p>	 <p>CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed</p>	<p>Gentamicin Sulfate Ophth. Solution USP 0.3% Qty: Ins: Lot#: Bat#:</p>	Log
<p>Directions English Instill _____ drops every _____ hours.</p>		<p>Prod# (NDC): Gentamicin Sulfate Ophth. Solution USP 0.3% Qty: Ins: Lot#: Bat#: Prod# (NDC):</p>	Chart
<p>Instrucciones Español: Póngase _____ gota(s) cada _____ horas.</p>	<p>Gentamicin Sulfate Ophth. Solution USP 0.3% Qty: Ins: Insurance NDC: Lot#: Bat#:</p>	Billing	Patient

GENTAMICIN SULFATE			
gentamicin sulfate solution			
Product Information			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:68788-7336(NDC:61314-633)
<b>Route of Administration</b>	OPHTHALMIC		
Active Ingredient/Active Moiety			
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
GENTAMICIN SULFATE (UNII: 8X7386QLV) (GENTAMICIN - UNII:T6Z9V48IKG)	GENTAMICIN	3 mg in 1 mL	

## Inactive Ingredients

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM PHOSPHATE</b> (UNII: SE337SVY37)	
<b>TYLOXAPOL</b> (UNII: Y27PUL9H56)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-7336-5	5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/12/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062196	03/12/2019	

**Labeler** - Preferred Pharmaceuticals Inc. (791119022)

**Registrant** - Preferred Pharmaceuticals Inc. (791119022)

## Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-7336)

Revised: 5/2021

Preferred Pharmaceuticals Inc.