

## GENTAMICIN SULFATE- gentamicin sulfate solution/ drops Proficient Rx LP

### 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.

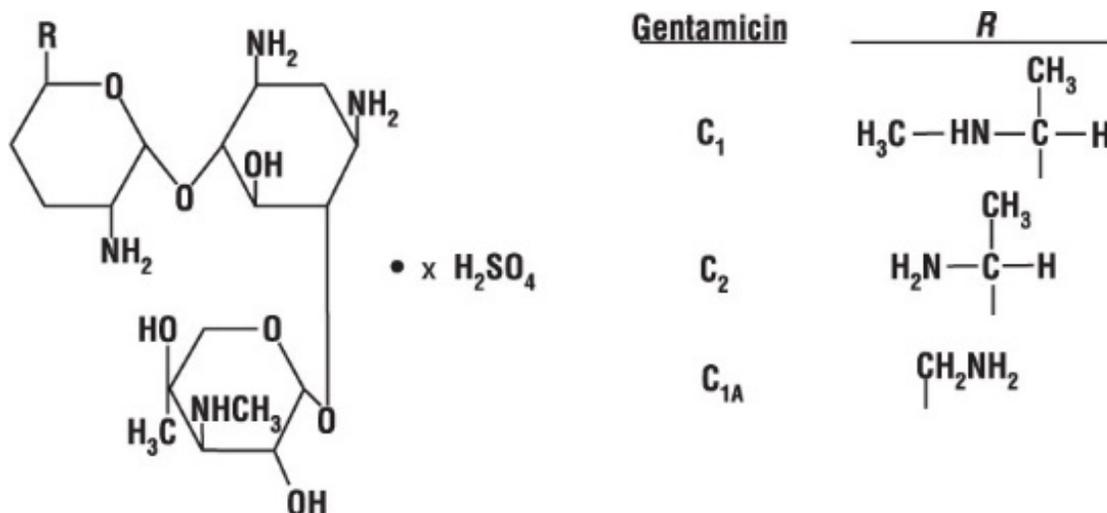
#### Each mL contains:

**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<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 a white powder and is soluble in water and insoluble in alcohol. The structural formula is as follows:



### 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. (NDC 63187-764-05)

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

Avoid exposure to excessive heat.

## **Akorn**

Manufactured by: **Akorn, Inc.**

Lake Forest, IL 60045

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320

GK00N

Rev. 11/11

Principal Display Panel Text for Container Label:

NDC 63187-764-05

Gentamicin

Sulfate Ophthalmic

Solution, USP

0.3%

(equivalent to 3 mg  
gentamicin per mL)

Sterile

Rx only 5 mL



NDC 63187-764-05

Lot #: 00000  
Exp. 00/00/00  
SN# MASTER

RX Only

**Gentamicin Sulfate 0.3%**

5mL Opth Solution

Each mL contains: Gentamicin Sulfate USP  
(equivalent to 3 mg gentamicin base)

See package insert.

Product ID: RG076405

Mfr: By Akorn, Inc. Lake Forest, IL 60045  
Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

Gentamicin Sulfate 0.3%  
5mL Opth Solution  
Lot #: 00000 SN# MASTER  
NDC 63187-764-05 Exp: 00/00/00Gentamicin Sulfate 0.3%  
5mL Opth Solution  
Lot #: 00000 SN# MASTER  
NDC 63187-764-05 Exp: 00/00/00Gentamicin Sulfate 0.3%  
5mL Opth Solution  
Lot #: 00000 SN# MASTER  
NDC 63187-764-05 Exp: 00/00/00Relabeled By: Proficient Rx LP  
Thousand Oaks, CA 91320**GENTAMICIN SULFATE**

gentamicin sulfate solution/ drops

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:63187-764(NDC:17478-283)
<b>Route of Administration</b>	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, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
Sodium Chloride (UNII: 451W47IQ8X)	
Benzalkonium Chloride (UNII: F5UM2KM3W7)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-764-05	1 in 1 CARTON	11/01/2016	
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** - Proficient Rx LP (079196022)

**Establishment**

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079 196022	RELABEL(63187-764)

Revised: 11/2019

Proficient Rx LP