

**GENTAMICIN SULFATE- gentamicin sulfate solution**  
**Asclemed USA, Inc.**

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**Gentamicin Sulfate**

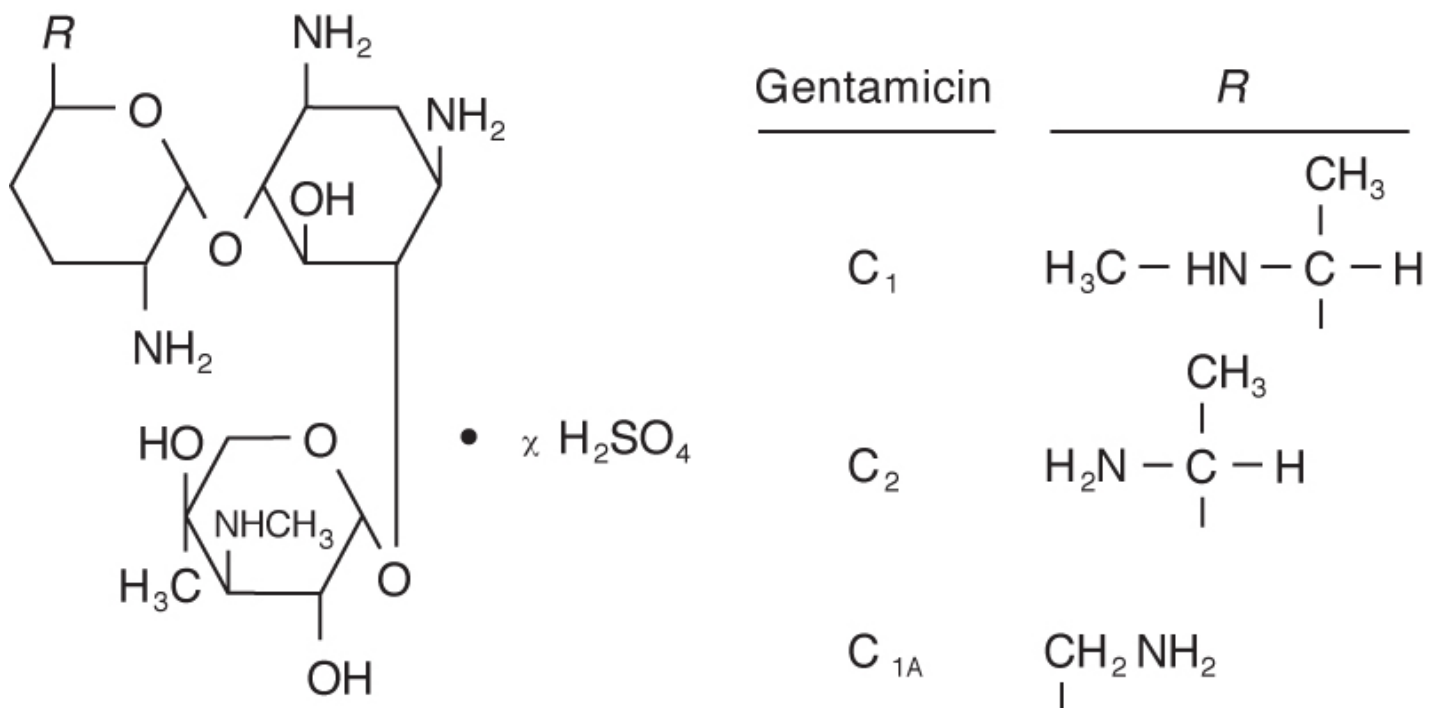
**Ophthalmic Solution USP**

**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<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.

**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).**

## **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** 76420-137-05 (relabelled from 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).

## **Relabeled by:**

Enovachem PHARMACEUTICALS  
Torrance, CA 90501

## **PRINCIPAL DISPLAY PANEL**

Relabeled By:



379 Van Ness Ave.  
Suite 1403-1406  
Torrance, CA 90501

Gentamicin Sulfate Ophthalmic Solution, USP 0.3%

NDC: 76420-137-05

Qty: 5



Manufactured By: Alcon Laboratories, Inc.  
Source NDC: 61314-633-05  
Description: 5mL solution in plastic dispenser  
Lot #: 00000000 Exp:  
Batch #: 00000000  
Drug Status: RX



(01) 0 0376420 13705 4  
(17)  
(10) 00000000  
(21)

Gentamicin Sulfate Ophthalmic Solution, USP 0.3%

NDC: 76420-137-05

S/N:

Qty: 5

Gentamicin Sulfate Ophthalmic Solution, USP 0.3%

NDC: 76420-137-05

S/N:

Qty: 5

Gentamicin Sulfate Ophthalmic Solution, USP 0.3%

NDC: 76420-137-05

S/N:

Qty: 5

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].

## GENTAMICIN SULFATE

gentamicin sulfate solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:76420-137(NDC:61314-633)
<b>Route of Administration</b>	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GENTAMICIN SULFATE</b> (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:76420-137-05	5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/04/2022	

### Marketing Information

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

**Labeler** - Asclemed USA, Inc. (059888437)

### **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ASCLEMED USA INC. DBA ENOVACHEM		059888437	relabel(76420-137)

Revised: 3/2022

Asclemed USA, Inc.