GENTAMICIN SULFATE- gentamicin sulfate solution/ drops
Medsource Pharmaceuticals

Gentamicin Sulfate

Ophthalmic Solution USP,

0.3% (Sterile)

Rx only

DESCRIPTION

Gentamicin Sulfate Ophthalmic Solution, is a sterile, aqueous solution buffered to approximately pH 7.0 and formulated for ophthalmic use.

EACH mL CONTAINS:

ACTIVE: Gentamicin Sulfate (equivalent to 3 mg gentamicin).

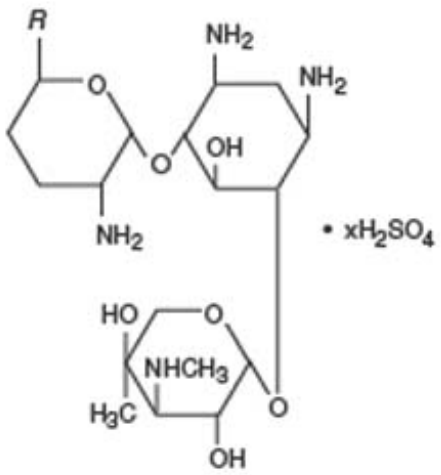
INACTIVES: Dibasic Sodium Phosphate, Sodium Chloride, Monobasic Sodium Phosphate, Purified Water. Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH (6.5 - 7.5).

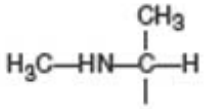
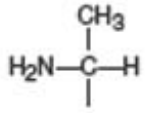
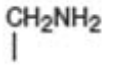
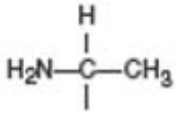
PRESERVATIVE ADDED: Benzalkonium Chloride 0.01%.

Gentamicin is an aminoglycoside antibiotic obtained from cultures of *Micromonospora purpurea*. It is a mixture of the sulfate salts of Gentamicin C_1, C_2, C_{1a} and C_{2a}. All three components appear to have similar antimicrobial activity.

Gentamicin sulfate occurs as a white to buff powder and is soluble in water and insoluble in alcohol.

The structural formula is as follows:



Gentamicin	R	Mol. Wt.
C_1		477.60
C_2		463.58
C_{1a}		449.55
C_{2a}		463.58

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 its 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.

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 every hour.

HOW SUPPLIED

Gentamicin Sulfate Ophthalmic Solution USP, 0.3% is supplied in a plastic bottle with a controlled drop tip in the following sizes:

5 mL - NDC 24208-580-60

15 mL - NDC 24208-580-64

NOT FOR INJECTION

FOR OPHTHALMIC USE ONLY

DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.

Storage: Store between 2°- 25°C (36°- 77°F). Avoid exposure to excessive heat.

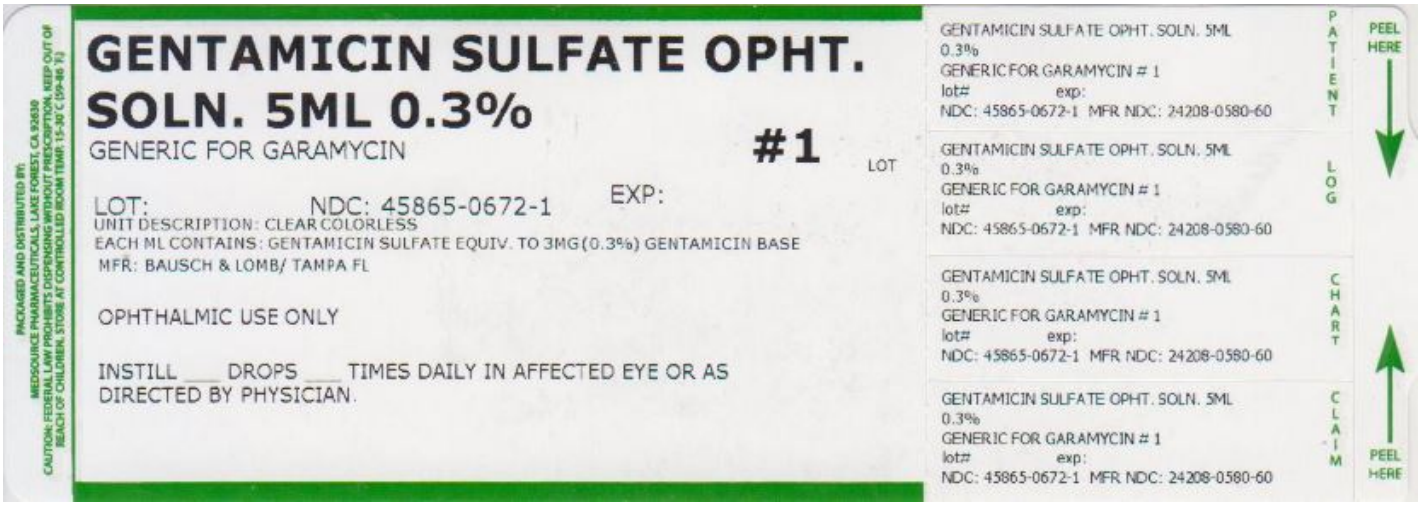
KEEP OUT OF REACH OF CHILDREN.

Revised: January 2013

Bausch & Lomb Incorporated
Tampa, FL 33637

9116002 **(Folded)**
9116102 **(Flat)**

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL



GENTAMICIN SULFATE

gentamicin sulfate solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:45865-672(NDC:24208-580)
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 PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:45865-672-01	1 in 1 CARTON	09/15/2015	
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	ANDA064048	05/11/1994	

Labeler - Medsource Pharmaceuticals (833685915)

Establishment

Name	Address	ID/FEI	Business Operations
Medsource Pharmaceuticals		833685915	relabel(45865-672)

Revised: 12/2019 Medsource Pharmaceuticals