

GENTAMICIN SULFATE - gentamicin sulfate ointment

Physicians Total Care, Inc.

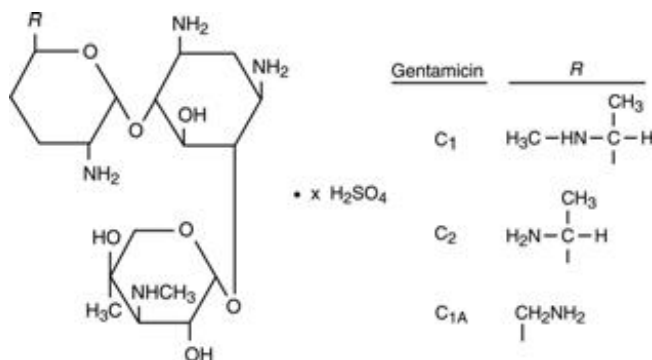
Rx only

DESCRIPTION

Gentamicin sulfate is a water soluble antibiotic of the aminoglycoside group.

Gentamicin Sulfate Ophthalmic Ointment USP is a sterile ointment for topical ophthalmic use. Each gram contains gentamicin sulfate (equivalent to 3 mg gentamicin) in a base of white petrolatum and mineral oil.

Gentamicin is obtained from cultures of *Micromonospora purpurea*. Gentamicin sulfate is a mixture of the sulfate salts of gentamicin C₁, C₂ and C_{1A}. 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 Ophthalmic Ointment 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 Ointment is contraindicated in patients with known hypersensitivity to any of the components.

WARNINGS

NOT FOR INJECTION INTO THE EYE. Gentamicin Sulfate Ophthalmic Ointment 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.

Ophthalmic ointments may retard corneal healing.

Information For Patients: To avoid contamination, do not touch tip of container to the eye, eyelid, or any surface.

Carcinogenesis, Mutagenesis and 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:Teratogenic effects - *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

Apply a small amount (about ½ inch) to the affected eye(s) two to three times a day.

HOW SUPPLIED

Gentamicin Sulfate Ophthalmic Ointment USP (equivalent to 3 mg gentamicin) is supplied as follows:
NDC 54868-1040-1 3.5 gram tubes

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F)

[see USP Controlled Room Temperature].

E. FOUGERA & CO.

a division of Altana Inc.

MELVILLE, NEW YORK 11747

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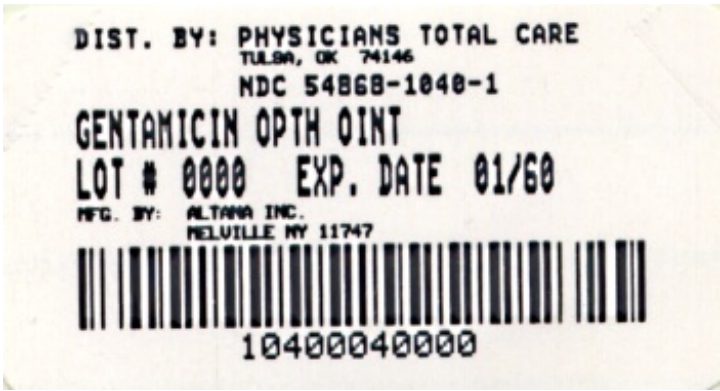
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Relabeling of "Additional Barcode" by:
Physicians Total Care, Inc.
Tulsa, OK 74146

PRINCIPAL DISPLAY PANEL

Gentamicin Sulfate Ophthalmic Ointment USP



GENTAMICIN SULFATE			
gentamicin sulfate ointment			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:54868-1040(NDC:0168-0044)
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 g
Inactive Ingredients			
Ingredient Name		Strength	
PETROLATUM (UNII: 4T6H12BN9U)			
MINERAL OIL (UNII: T5L8T28FGP)			
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-1040-1	3.5 g in 1 TUBE		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA065024	09/21/1994	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment			
Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel