

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 54868-6745-1

15 mL - NDC 54868-6745-2

NOT FOR INJECTION

FOR OPHTHALMIC USE ONLY

DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.

Storage: Store between 2°- 30°C (36°- 86°F). Avoid exposure to excessive heat.

KEEP OUT OF REACH OF CHILDREN.

Revised August 2007

Bausch & Lomb Incorporated

Tampa, FL 33637

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Additional barcode labeling by:

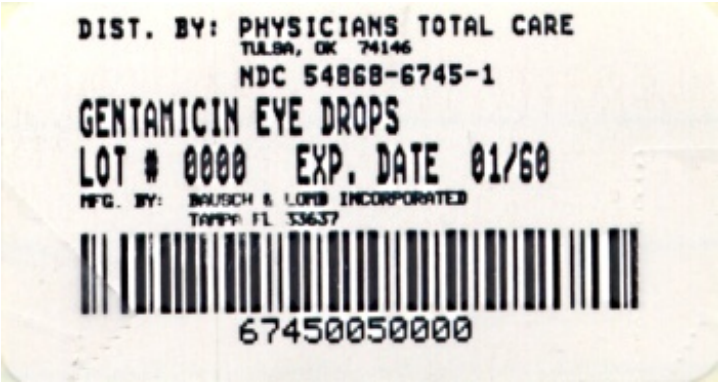
Physicians Total Care, Inc.

Tulsa, Oklahoma 74146

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

Gentamicin Sulfate Ophthalmic Solution USP, 0.3% (sterile)

Rx only



GENTAMICIN SULFATE

gentamicin sulfate solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:54868-6745(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: 059QF0K00R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-6745-1	1 in 1 CARTON		
1		5 mL in 1 BOTTLE, DROPPER		
2	NDC:54868-6745-2	1 in 1 CARTON		
2		15 mL in 1 BOTTLE, DROPPER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA064048	09/17/1993	
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Labeler - Physicians Total Care, Inc. (194123980)

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