GENTAMICIN SULFATE- gentamicin sulfate solution/ drops
Preferred Pharmaceuticals Inc.

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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 C₁, C₂, and C₁A. 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 68788-6342-5)

**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

GK00N

Rev. 06/16

**Relabeled By: Preferred Pharmaceuticals Inc.**

Principal Display Panel Text for Container Label:

NDC 68788-6342-5

Gentamicin
Sulfate Ophthalmic
Solution, USP

0.3%
(equivalent to 3 mg
gentamicin per mL)

Sterile
Rx only 5 mL
GENTAMICIN SULFATE
gentamicin sulfate solution/ drops

Product Information

Product Type: HUMAN PRESCRIPTION DRUG
Item Code (Source): NDC:68788-6342(NDC:17478-283)
Route of Administration: OPHTHALMIC

Active Ingredient/Active Moiety

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<th>Basis of Strength</th>
<th>Strength</th>
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<td>Gentamicin Sulfate (UNII: 8X7386QRLV) (Gentamicin - UNII:T6Z9V481KG)</td>
<td>Gentamicin</td>
<td>3 mg  in 1 mL</td>
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Inactive Ingredients

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<td>Sodium Chloride (UNII: 451W47IQ8X)</td>
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Packaging

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Marketing Information

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**Labeler** - Preferred Pharmaceuticals Inc. (791119022)

**Registrant** - Preferred Pharmaceuticals Inc. (791119022)

### Establishment

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Revised: 10/2019

Preferred Pharmaceuticals Inc.