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 C₁, C₂, C₁a, and C₂a. 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:

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 conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis, blepharoconjunctivitis, acute conjunctivitis, 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.

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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 Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC, at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION
Instil 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.
Gentamicin Sulfate Ophthalmic Solution, USP 0.3% is supplied in a plastic bottle with a controlled drop tip and a white polypropylene cap in the following sizes:
NDC 34280-580-60 - 5 mL
NDC 34280-580-64 - 15 mL

NOT FOR INJECTION INTO THE EYE
FOR OPHTHALMIC USE ONLY

DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.

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

KEEP OUT OF REACH OF CHILDREN.

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Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC
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