GENTAMICIN SULFATE
ophthalmic solution, USP 0.3% sterile

DESCRIPTION
Gentamicin sulfate ophthalmic solution, USP is a sterile, topical anti-infective agent for ophthalmic use.

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 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:

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  NH2
O
CH3
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Each mL contains: Active: gentamicin sulfate equivalent to 3 mg (0.3%) gentamicin base. Preservative: benzalkonium chloride. Inactives: citrate disodium; polyvinyl alcohol 1.4%; purified water; sodium chloride; sodium phosphate, dibasic; and hydrochloric acid and/or sodium hydroxide may be added to adjust pH. The solution is an aqueous, buffered solution with a shelf life pH range of 6.5 to 7.5.

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
- Serratia marcescens

INDICATIONS AND USAGE

Gentamicin sulfate ophthalmic solution, USP 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
- Serratia marcescens

CONTRAINdications
Gentamicin sulfate ophthalmic solution, USP is contraindicated in patients with known hypersensitivity to any of its components.

WARNINGS

NOT FOR INJECTION INTO THE EYE.

Gentamicin sulfate ophthalmic solution, USP is not for injection. It should never be injected subconjunctivally, nor should it be directly introduced into the anterior chamber of the eye.

DOSE 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 sterile in white opaque LDPE plastic bottles and tips with white high impact polystyrene (HIPS) caps as follows:
- 5 mL in 10 mL bottle – NDC 60758-188-05

Storage: Store at or below 25°C (77°F). Avoid exposure to excessive heat (30°C/86°F or above).

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