

Gentamicin Sulfate Ophthalmic Solution Sterile

ANADA 200-576, Approved by FDA

Veterinary

For Use in Dogs and Cats

DESCRIPTION: Gentamicin sulfate is a water soluble antibiotic of the aminoglycoside group active against a wide variety of pathogenic gram-negative and gram-positive bacteria.

Gentamicin Sulfate Ophthalmic Solution is a sterile aqueous solution for use in the eye. Each mL contains: Active: Gentamicin Sulfate USP (equivalent to 3 mg gentamicin base). Inactives: 2.9 mg Disodium Phosphate, 0.1 mg Monosodium Phosphate, and 7.40 mg Sodium Chloride. The pH range is from 6.8 to 7.3. Preservative: 0.1 mg Benzalkonium Chloride as preservative.

CHEMISTRY: Gentamicin is an aminoglycoside antibiotic mixture derived from *Micromonospora purpurea* of the Actinomycetes group. It is a powder, white to buff in color, readily soluble in water, and heat stable.

ACTION: Gentamicin sulfate, a broad spectrum antibiotic, is a highly effective topical treatment in primary and secondary bacterial infections of the eye and surrounding tissues. Gentamicin is bactericidal *in vitro* against a wide variety of gram-positive and gram-negative bacteria. Concentrations of gentamicin sulfate required to inhibit growth of gram-positive and gram-negative clinical and laboratory strains of bacteria tested were less than those of neomycin in most instances.^{1,2} Gentamicin is active against most gram-negative bacteria including *Pseudomonas aeruginosa*, indole positive and negative *Proteus* species, *Escherichia coli*, *Klebsiella* sp. and *Enterobacter* sp. Gentamicin is also active against strains of gram-positive bacteria including *Staphylococcus* species and *Streptococcus* species.

INDICATIONS: Gentamicin Sulfate Ophthalmic Solution is indicated for topical treatment of conjunctivitis caused by susceptible bacteria in dogs and cats.

DOSAGE AND ADMINISTRATION: Gentamicin Sulfate Ophthalmic Solution-1 or 2 drops instilled into the conjunctival sac 2 to 4 times a day.

PRECAUTIONS: Antibiotic susceptibility of infecting organisms should be determined prior to the use of these preparations. Prolonged use of topical antibiotics may give rise to overgrowth of nonsusceptible organisms such as fungi. Should this occur or if irritation or hypersensitivity to any component develops, discontinue use of the preparation and institute appropriate therapy.

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

HOW SUPPLIED:

Gentamicin Sulfate Ophthalmic Solution is supplied in a white low density polyethylene plastic squeeze bottle with a white controlled dropper tip and a white polypropylene cap in the following sizes:

NDC 59399-101-05 5 mL; box of one

Store solution at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

REFERENCES:

1. Weinstein MJ, Leudemann GM, Oden EM, Wagman GH. Gentamicin, a new broad spectrum antibiotic complex. *Antimicrob Agents and Chemother.* 1963:1-7.
2. Black J, et al. Pharmacology of Gentamicin: a new broad spectrum antibiotic. *Antimicrob Agents and Chemother.* 1964:138-147.



Manufactured by: **Akorn, Inc.**
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