GENTAMICIN SULFATE- gentamicin sulfate solution
Sparhawk Laboratories, Inc.

GENTAMICIN SULFATE SOLUTION Sterile Multi Dose Vial 100 mg/mL

Not For Use in Humans

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

DESCRIPTION

For intra-uterine use in horses only.
Each mL contains: Gentamicin sulfate veterinary equivalent to 100 mg gentamicin base; 2.4 mg sodium metabisulfite; 0.8 mg sodium sulfite, anhydrous; 0.1 mg edetate disodium; 10 mg benzyl alcohol as preservative; water for injection q.s.
Store between 2o and 30oC (36o and 86oF).
Protect from freezing.

TAKE TIME OBSERVE LABEL DIRECTIONS

CHEMISTRY: Gentamicin is a mixture of aminglycoside antibiotics derived from the fermentation of *Micromonospora purpurea*. Gentamicin sulfate is a mixture of sulfate salts of the antibiotics produced in this fermentation. The salts are weakly acidic, freely soluble in water, and stable in solution.

ANTIBACTERIAL ACTIVITY: *In Vitro* antibacterial activity has shown that gentamicin is active against most gram-negative and gram-positive bacteria isolated from domestic animals.[1] Gentamicin is active against *Pseudomonas aeruginosa*, indole-positive and -negative *Proteus* species, *Escherichia coli*, *Klebsiella* species, *Enterobacter* species, *Alcaligenes* species, *Staphylococcus* species, and *Streptococcus* species.

PHARMACOLOGY: Studies in man indicate that recommended doses of gentamicin produce serum concentrations bactericidal for most bacteria sensitive to gentamicin within an hour after intramuscular injection; these concentrations last for 6 to 12 hours.[2] Some 30% of the administered dose of gentamicin is bound by serum proteins and released as the drug is excreted.

Gentamicin is excreted almost entirely by glomerular filtration. High concentrations of the active form are found in the urine. Fifty to 100% of the gentamicin injected can be recovered unchanged within 24 hours from the urine of patients with normal renal function. A small amount is excreted into the bile.

TOXICITY STUDIES: No toxic effects were observed in rats given gentamicin sulfate 20 mg/kg/day for 24 days; in cats given 10 mg/kg/day for 40 days. Gentamicin sulfate given to dogs at 6 mg/lb/day, 6 days weekly for 3 weeks, caused no detectable kidney damage. At higher doses, impairment of equilibrium and renal function were observed in these species.

INDICATIONS

Gentamicin Sulfate Solution is recommended for the control of bacterial infections of the

uterus (metritis) in horses and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin. Bacteriologic studies should be conducted to identify the causative organism and to determine its sensitivity to gentamicin sulfate. Sensitivity discs of the drug are available for this purpose.

DOSAGE AND ADMINISTRATION

The recommended dose is 20 to 25 mL (2.0 - 2.5 grams) gentamicin sulfate solution per day for 3 to 5 days during estrus. Each dose should be diluted with 200-500 mL of sterile physiological saline before aseptic uterine infusion.

CONTRAINDICATIONS

There are no known contraindications to this drug when used as directed.

PRECAUTION

If hypersensitivity to any of the components develops, or if overgrowth of nonsusceptible bacteria, fungi, or yeasts occurs, treatment with Gentamicin Sulfate Solution should be discontinued and appropriate therapy instituted. Although Gentamicin Sulfate Solution is not spermicidal, treatment should not be given the day of breeding.

Warning: Do not use for horses intended for human consumption.

SIDE EFFECTS

There have been no reports of drug hypersensitivity or adverse side effects following the recommended intrauterine infusion of gentamicin sulfate solution combined with sterile physiological saline in mares.

HOW SUPPLIED

Gentamicin Sulfate Solution, 100 mg per mL for intrauterine use, is available in 100 mL and 250 mL multiple dose vials.

Store between 2ºand 30ºC (36º and 86ºF).

REFERENCES

1. Hennessey, PW, et al.*In vitro* activity of gentamicin against bacteria isolated from domestic animals.*Veterinary Medicine/Small Animal Clinician*, Nov. 1971; 1118-1122.

2. Black, J, et al. Pharmacology of gentamicin, a new broad spectrum antibiotic.*Antimicrob Agents and Chemother.* 1963, 138-147.

CONTACT INFORMATION: To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Sparhawk Laboratories, Inc. at 1-800-255-6368 or 1-913-888-7500. For additional information about adverse

drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae

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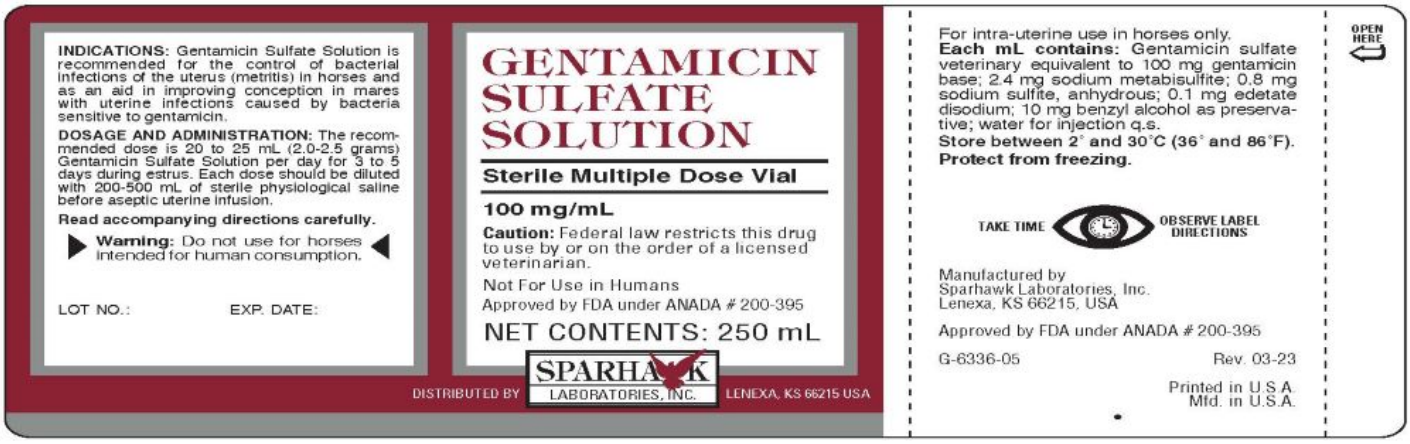
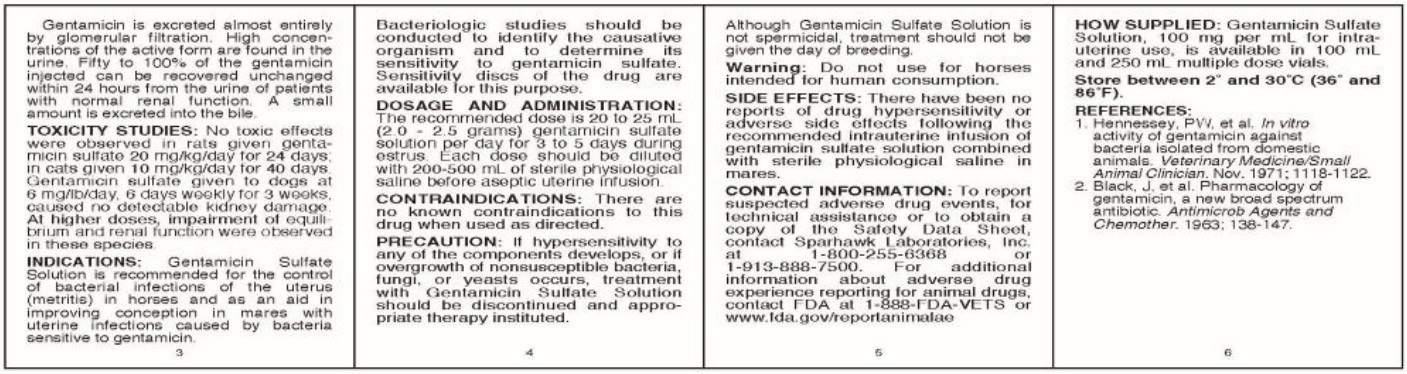
Approved by FDA under ANADA # 200-395





GENTAMICIN SULFATE

gentamicin sulfate solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:58005-633
Route of Administration	INTRAUTERINE		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GENTAMICIN SULFATE (UNII: 8X7386QRLV) (GENTAMICIN - UNII:T6Z9V48IKG)	GENTAMICIN	100 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58005-633-04	100 mL in 1 VIAL		
2	NDC:58005-633-05	250 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200395	08/21/2008	

Labeler - Sparhawk Laboratories, Inc. (147979082)

Revised: 6/2023 Sparhawk Laboratories, Inc.