Gentamicin Sulfate Topical Spray

Gentamicin Sulfate, USP with Betamethasone Valerate, USP

Rx

- **Approved by FDA under ANADA # 200-415**
- **Gentamicin Sulfate Topical Spray is approved by the FDA as equivalent to the pioneer product Gentocin® Topical Spray.[1]**
- **For topical use in dogs only.**
- **Broad-spectrum antibiotic that is effective for the treatment of bacterial infections of the skin.**
- **Betamethasone Valerate, USP provides anti-inflammatory and anti-pruritic activity.**
- **Spray allows "hands off" treatment.**
- **Provides rapid relief for bacterial infections and also relieves pain and itching.**
- **Odorless and colorless to prevent staining.**

For the treatment of infected superficial lesions in dogs caused by bacteria susceptible to gentamicin. Please consult package insert for full product information (see back page).

Size	Reorder No.	Lbs/Case	Case Pack
60 mL (2.0 fl oz)	TP410	3 lbs.	12 x 1
120 mL (4.0 fl oz)	TP411	5 lbs.	12 x 1
240 mL (8.0 fl oz)	TP412	8 lbs.	12 x 1

[1] Gentocin® is a registered trademark of Intervet Inc., Madison, NJ

For a complete list of Priority Care distributors, please call our Customer Service Department at: 1-800-650-4899, or visit our Website: www.prioritycare.com

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Gentamicin Sulfate Topical Spray

Gentamicin Sulfate, USP
With Betamethasone Valerate, USP

Veterinary

For Topical Use in Dogs Only
Not For Use in Humans

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

DESCRIPTION: Each mL contains: gentamicin sulfate, USP equivalent to 0.57 mg gentamicin base, betamethasone valerate, USP equivalent to 0.284 mg betamethasone, 163 mg isopropyl alcohol, propylene glycol, methylparaben and propylparaben as preservatives, purified water q.s. Hydrochloric acid may be added to adjust pH.

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

Gentamicin sulfate veterinary contains not less than 500 micrograms of gentamicin base per milligram.

Betamethasone valerate is a synthetic glucocorticoid.

PHARMACOLOGY: Gentamicin, a broad-spectrum antibiotic, is a highly effective topical treatment for bacterial infections of the skin. *In vitro*, gentamicin is bactericidal against a wide variety of gram-positive and gram-negative bacteria isolated from domestic animals.[1,2] Specifically, gentamicin is active against the following organisms isolated from canine skin: *Alcaligenes* sp., *Citrobacter* sp., *Klebsiella* sp., *Pseudomonas aeruginosa,* indole-positive and -negative *Proteus* sp., *Escherichia coli, Enterobacter* sp., *Staphylococcus* sp., and *Streptococcus* sp.

Betamethasone valerate emerged from intensive research as the most promising of some 50 newly synthesized corticosteroids in the experimental model described by McKenzie,[3] et al. This human bioassay technique has been found reliable for evaluating the vasoconstrictor properties of new topical corticosteroids and is useful in predicting clinical efficacy.

Betamethasone valerate in veterinary medicine has been shown to provide anti-inflammatory and antipruritic activity in the topical management of corticosteroid-responsive infected superficial lesions in dogs.

WARNING: Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have produced cleft palate. Other congenital anomalies including deformed forelegs, phocomelia, and anasarca have been reported in offspring of dogs that received corticosteroids during pregnancy.

INDICATIONS: For the treatment of infected superficial lesions in dogs caused by bacteria susceptible to gentamicin.

Keep Out of Reach of Children.

CONTRAINDICATIONS: If hypersensitivity to any of the components occurs, discontinue treatment and institute appropriate therapy.

DOSAGE AND ADMINISTRATION: Prior to treatment, remove excessive hair and clean the lesion and adjacent area. Hold bottle upright 3 to 6 inches from the lesion and depress the sprayer head twice. Administer 2 to 4 times daily for 7 days.

Each depression of the sprayer head delivers 0.7 mL of Gentamicin Sulfate Topical Spray.

TOXICITY: Gentamicin Sulfate Topical Spray was well-tolerated in an abraded skin study in dogs. No treatment-related toxicological changes in the skin were observed.

Systemic effects directly related to treatment were confined to histological changes in the adrenals, liver, and kidney and to organ-to-body weight ratios of adrenals. All were dose related, were typical for or not unexpected with corticosteroid therapy, and were considered reversible with cessation of treatment.

SIDE EFFECTS: Side effects such as SAP and SGPT enzyme elevations, weight loss, anorexia, polydipsia, and polyuria have occurred following parenteral or systemic use of synthetic corticosteroids in dogs. Vomiting and diarrhea (occasionally bloody) have been observed in dogs.

Cushing's syndrome in dogs has been reported in association with prolonged or repeated steroid therapy.

PRECAUTIONS: Antibiotic susceptibility of the pathogenic organism(s) should be determined prior to use of this preparation. Use of topical antibiotics may permit overgrowth of nonsusceptible bacteria, fungi, or yeasts. If this occurs, treatment should be instituted with other appropriate agents as indicated.

Administration of recommended dose beyond 7 days may result in delayed wound healing. Animals treated longer than 7 days should be monitored closely.

Avoid ingestion. Oral or parenteral use of corticosteroids, depending on dose, duration, and specific steroid may result in inhibition of endogenous steroid production following drug withdrawal.

In patients presently receiving or recently withdrawn from systemic corticosteroid treatments, therapy with a rapidly acting corticosteroid should be considered in especially stressful situations.

If ingestion should occur, patients should be closely observed for the usual signs of adrenocorticoid overdosage that include sodium retention, potassium loss, fluid retention, weight gains, polydipsia, and/or polyuria. Prolonged use or overdosage may produce adverse immunosuppressive effects.

CONTACT INFORMATION:

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact First Priority, Inc. at (800) 650-4899 or www.prioritycare.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae

HOW SUPPLIED: Plastic spray bottles containing 60 mL, 120 mL and 240 mL of Gentamicin Sulfate Topical Spray

Store upright between 2° and 30°C (36° and 86°F).

REFERENCES:

1. Hennessy PW, et al. *In vitro* activity of gentamicin against bacteria isolated from domestic animals.
   Veterinary Medicine/Small Animal Clinician.
   November 1971; 1118-1122.
2. Bachmann HJ, et al. Comparative *in vitro* activity of gentamicin and other antibiotics against bacteria isolated from clinical samples from dogs, cats, horses, and cattle.
   Veterinary Medicine/Small Animal Clinician.
   October 1975; 1218-1222.
3. McKenzie HW, Atkinson RM. Topical activities of betamethasone esters in man.
   Arch Derm.
   May 1964; 741-746.

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TAKE TIME  OBSERVE LABEL DIRECTIONS

Manufactured by:
First Priority, Inc.
Elgin, IL 60123

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