GENTAVED TOPICAL SPRAY (gentamicin sulfate and betamethasone valerate) spray
[Vedco, Inc.]

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<td>PRESCRIPTION ANIMAL DRUG LABEL</td>
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<td>Abbreviated New Animal Drug Application</td>
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Front Panel

GentaVed
Topical Spray

(GENTAMICIN SULFATE WITH BETAMETHASONE VALERATE)

TOPICAL SPRAY
VETERINARY

Net Contents: 60 mL

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

ANADA 200-388, Approved by FDA

Each mL contains: gentamicin sulfate equivalent to 0.57 mg gentamicin base, betamethasone valerate 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.

For topical use in dogs only.

Usual dose: Two depressions of the sprayer head 2 to 4 times daily for 7 days.

Keep out of Reach of Children. For animal use only.

Read accompanying directions carefully.
Store upright between 2°C and 30°C (36°F and 86°F)

Manufactured For
VEDCO, INC.
St. Joseph, MO 64507

Description

DESCRIPTION: Each mL contains: gentamicin sulfate equivalent to 0.57 mg gentamicin base, betamethasone valerate 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, Pharmacology and Toxicity

CHEMISTRY: Gentamicin is a mixture of aminoglycoside 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 and freely soluble in water.

Gentamicin sulfate 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 infection 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 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.

TOXICITY: Gentamicin sulfate with betamethasone valerate 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.

Warning

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 which received corticosteroids during pregnancy.

Indications and contraindications

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

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

Dosage and Administration:

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 With Betamethasone Valerate Topical Spray.

Side Effects and Precautions

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 non-susceptible 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 corticosteroids 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, which includes sodium retention, potassium loss, fluid retention, weight gains, polydipsia and/or polyuria. Prolonged use or overdosage may produce adverse immunosuppressive effects.

How Supplied and Storage

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

Store upright between 20°C and 30°C (36°F and 86°F).

References

REFERENCES:


June 2009

Manufactured for: VEDCO INC.
St. Joseph, MO 64507
SIDE EFFECTS: Side effects such as SAP and SBE elevations, weight loss, anorexia, polydipsia and polyuria following parenteral or systemic use of synthetic corticosteroids. Vomiting and diarrhea (occasionally bloody) have been observed. Cushing’s syndrome in dogs has been reported in association with prolonged or repeated steroid therapy.

PRECAUTIONS: Antibiotic susceptibility of the pathogen should be determined prior to use of this preparation. Oral antibiotics may permit overgrowth of non-susceptible bacteria and yeasts. If this occurs, treatment should be instituted with 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 at higher dose, duration and specific steroid may result in inhibition of endogenous steroid production following drug withdrawal.

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

If ingestion should occur, patients should be closely observed for usual signs of adrenocorticoid overdosage, which include...
GENTAVED TOPICAL SPRAY
gentamicin sulfate and betamethasone valerate spray

Product Information

Product Type: PRESCRIPTION ANIMAL DRUG
NDC Product Code: 50989-712

Route of Administration: TOPICAL
DEA Schedule

Active Ingredient/Active Moiety

Ingredient Name: Basis of Strength
GENTAMICIN SULFATE (GENTAMICIN): GENTAMICIN 0.57 mg in 1 mL
BETAMETHASONE VALERATE (BETAMETHASONE): BETAMETHASONE 0.284 mg in 1 mL
ISOPROPYL ALCOHOL (ISOPROPYL ALCOHOL): ISOPROPYL ALCOHOL 163 mg in 1 mL

Inactive Ingredients

Ingredient Name
PROPYLENE GLYCOL
METHYLPARABEN
PROPYLPARABEN
WATER

Product Characteristics

Color: Score
Shape: Size
Flavor: Imprint Code
Contains

Packaging

# NDC Description Multilevel Packaging
1 50989-712-19 12 BOTTLE In 1 BOX contains a BOTTLE
1 60 mL In 1 BOTTLE This package is contained within the BOX (50989-712-19)
2 50989-712-19 12 BOTTLE In 1 BOTTLE contains a BOTTLE
This package is contained within the BOX (50989-712-75)

contains a BOTTLE

This package is contained within the BOX (50989-712-43)

Marketing Information

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<th>Marketing End Date</th>
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<td>ANADA</td>
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Labeler - Vedco, Inc. (021634266)
Registrant - American Animal Health, Inc. (102617875)

Establishment

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