

**GENTAVED- gentamicin sulfate spray**  
**Vedco, Inc.**

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**GentaVed Topical Spray Gentamicin Sulfate With Betamethasone Valerate**  
**TOPICAL SPRAY**

**GENTAMICIN SULFATE WITH BETAMETHASONE VALERATE TOPICAL SPRAY**

**ANADA 200-416, Approved by FDA**

**For Topical Use in Dogs Only**

**For Animal Use Only**

**Keep Out of Reach of Children**

**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 equivalent to 0.284 mg betamethasone, 163 mg isopropyl alcohol, 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 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 infections of the skin. *In vitro*, gentamicin is bactericidal against a wide variety of gram-positive and gram-negative bacteria isolated from domestic animals.<sup>1,2</sup> 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<sup>3</sup>, 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.

## **WARNINGS**

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 abnormalities including deformed forelegs, phocomelia, and anasarca have been reported in offspring of dogs which received corticosteroids during pregnancy.

## **INDICATIONS**

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

## **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 GentaVed Topical Spray.

## **TOXICITY**

Gentamicin Sulfate with betamethasone valerate topical spray was well tolerated in a 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 corticosteroids 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.

Cushings 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 the 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 parental 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 overdose which includes sodium retention, potassium loss, fluid retention, weight gains, polydipsia, and/or polyuria. Prolonged use or overdose 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 Sparhawk Laboratories Inc at 1-800-255-6388 or 1-913-888-7500. 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 bottle containing 60 mL, 120 mL, or 240 mL of GentaVed Topical Spray.

Store upright between 20°-25°C (68°-77°F), excursions permitted between 15° and 30° (between 59° and 86°F).

## **TAKE TIME OBSERVE LABEL DIRECTIONS.**

## **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



NDC 50989-433-19

# GentaVed® Topical Spray

Gentamicin Sulfate With Betamethasone Valerate

TOPICAL SPRAY  
NOT FOR USE IN HUMANS  
KEEP OUT OF REACH OF CHILDREN  
Net Contents: 60 mL



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

Approved by FDA under ANADA # 200-416

LOT NO.: EXP. DATE:

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.

**FOR TOPICAL USE IN DOGS ONLY**

**USUAL DOSE:** Two depressions of the sprayer head 2 to 4 times daily for 7 days. **Read accompanying directions carefully.** Store upright between 20°-25°C (68°-77°F), excursions permitted between 15° and 30°C (between 59° and 86°F).

Approved by FDA under ANADA # 200-416

TAKE TIME TO OBSERVE LABEL DIRECTIONS

Manufactured For **VEDCO, INC.** G-4357-01 Rev. 04-23  
St. Joseph, MO 64507

Manufactured by Spahawk Laboratories, Inc. Lenexa, KS 66215, USA

VINV-GENT-SPP3

OPEN HERE



**CONTACT INFORMATION:** To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Spahawk Laboratories, Inc. at 1-800-255-0388 or 1-913-885-7500. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanmae>

**HOW SUPPLIED:** Plastic spray bottle containing 60 mL, 120 mL or 240 mL of GentaVed® Topical Spray. Store upright between 20°-25°C (68°-77°F), excursions permitted between 15° and 30°C (between 59° and 86°F).

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3. McKenzie, HVJ, Atkinson, RM. Topical activities of betamethasone esters in man. *Arch. Derm.* May 1964; 741-746

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**GENTAMICIN SULFATE WITH BETAMETHASONE VALERATE TOPICAL SPRAY**

**Veterinary**

**For Topical Use in Dogs Only Not for Use in Humans**

**Keep Out of Reach of Children**

**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 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 is a mixture of sulfate salts of the antibiotics produced in this fermentation. The salts are weakly acidic and freely soluble in water.

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. <sup>1,2</sup> 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.

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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 abnormalities including deformed forelegs, phocomelia and anasarca have been reported in offspring of dogs which received corticosteroids during pregnancy.

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

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

**DOSE 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 GentaVed® Topical Spray.

**TOXICITY:** Gentamicin Sulfate with betamethasone valerate topical spray was well tolerated in an acute skin study in dogs. No treatment-related toxicological changes in the skin were observed. Systemic effects directly related to treatment were confined to neurologic changes in the strabismus,

liver and kidney and to organ-to-body weight ratios of adrenals. All these doses related, were typical for or not unexpected with corticosteroids therapy, and were considered reversible with cessation of treatment.

**SIDE EFFECTS:** Side effects such as SAP and SGPT enzyme elevations, weight loss, anorexia, polyuria and polyuria have occurred following parenteral or systemic use of synthetic corticosteroids in dogs. Vomiting and diarrhea (occasionally bloody) have been reported in dogs. Cushing's syndrome in dogs has been reported in association with prolonged or repeated steroid therapy.

**PRECAUTIONS:** Antibiotic susceptibility of the pathogenic organisms should be determined prior to the 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 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 adrenocortical overdose which include sodium retention, potassium loss, fluid retention, weight gains, polyuria, and/or polyuria. Prolonged use of overdose may produce adverse immunosuppressive effects.

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## GENTAVED® gentamicin sulfate spray

### Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:50989-433
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
GENTAMICIN SULFATE (UNII: 8X7386QLV) (GENTAMICIN - UNII:T6Z9V48IKG)		GENTAMICIN	0.57 mg in 1 mL	
BETAMETHASONE VALERATE (UNII: 9IFA5XM7R2) (BETAMETHASONE - UNII:9842X06Q6M)		BETAMETHASONE VALERATE	0.284 mg in 1 mL	
Inactive Ingredients				
Ingredient Name		Strength		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		163 mg in 1 mL		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50989-433-19	60 mL in 1 BOTTLE, PUMP		
2	NDC:50989-433-75	120 mL in 1 BOTTLE, PUMP		
3	NDC:50989-433-74	240 mL in 1 BOTTLE, PUMP		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANADA	ANADA200416	06/15/2013		

**Labeler** - Vedco, Inc. (021634266)

**Registrant** - Sparhawk Laboratories, Inc. (147979082)

Establishment			
Name	Address	ID/FEI	Business Operations
Sparhawk Laboratories, Inc.		147979082	manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
FUJIAN FUKANG PHARMACEUTICAL CO., LTD.		528180884	api manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
FARMABIOS S.p.A.		428680078	api manufacture