# **GENTACALM-** gentamicin sulfate spray, metered Dechra Veterinary Products

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# **GENTACALM®** Topical Spray

Gentamicin Sulfate, USP With Betamethasone Valerate, USP

Veterinary
For Topical Use in Dogs Only

#### **CAUTION:**

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

## Not For Use in Humans Keep Out of Reach of Children

Approved by FDA under ANADA # 200-415

#### **INGREDIENTS:**

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, USP q.s. Hydrochloric Acid may be added to adjust pH.

#### STORAGE:

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

#### INDICATIONS:

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

Read accompanying directions carefully.

#### **DIRECTIONS FOR USE:**

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

Manufactured for: Dechra Veterinary Products

Overland Park, KS 66211 USA Rev. January 2023



GENTACALM is a registered trademark of Dechra Veterinary Products, LLC.

#### **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.<sup>1,2</sup> Specifically, gentamicin is active against the following organisms isolated from canine skin: *Alcaligenes* sp., *Citrobacter* sp., *Klebsiella* sp., *Pseudomonas aeruginosa*, indolepositive 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 antiinflammatory and antipruritic activity in the topical management of corticosteroidresponsive 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 GENTACALM® Topical Spray.

#### **TOXICITY:**

GENTACALM® 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.

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 veasts.

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 drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Dechra at (866) 933-2472. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/reportanimalae

#### **HOW SUPPLIED:**

Plastic spray bottles containing 60 mL and 120 mL of GENTACALM® 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.

GENTACALM is a registered trademark of Dechra Veterinary Products, LLC.

Rev. January 2023

Approved by FDA under ANADA # 200-415

Net Contents: 60 mL (2 fl oz)

PRECAUTIONS: Antibiolosasceptibility of the pathogenic organismis) should be determined prior use of this preparation. Lee of thispia anability cs. may permit overgrawing or rosassceptibe backets, trang, or years. If this cocus, resistant should be instituted with order spored as a land caled. Administration of recommended dose begond? days may result in delayed wound resting, Anima's treated longs than if days should be maintened observations and signal Anima's treated longs than if days should be maintened observations and signal Anima's treated longs than if days as a finite for the days and administration and signal Anima's treated longs than in this finite maniment observation and signal or administration of endogenous steroid production following out with every sould in highlight on the endogenous steroid scaled or should be considered in especially at east 1 situations. If ingestion should count, releasing should be considered in especially are set 1 situations. If no highlight on the cale in capacitation of adheric order and produces are endogenous steroid produces and produces are administration of adheric orders. Parket some appropriate result in the safety is a situation of technical assessment on the other is contine at high ylwaw, the safety line is set of CRINICALINF topical spirity and in an administration and out of CRINICALINF topical spirity and the safety is a situation of CRINICALINF topical spirity of gentamidia against hadden and all the safety and set of contine at high ylwaw, the spirity of gentamidia and days, calls there is an in withor activity of gentamidia against hadden and contine and calls.

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### NDC 17033-331-60 **GENTACALM°**

# Topical Spray Gentamicin Sulfate, USP

under AMA DA # 200-415

GBVR CAL Mis a registered trademark of Dectral Veterinary Products, LLC.

Approved by FDA

2023

January

Rev.

With Betamethasone Valerate, USP Veterinary

For Topical Use in Dogs Only CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Not For Use in Humans Keep Out of Reach of Children Approved by FDA under ANADA # 200-415





INGREDIENTS: Each mL contains: Gentamicin Suffate, USP equivalent to 0.57 mg gentamicin base, Betamethasone Valerate, USP equivalent to 0.284 mg betamethasone, 163 mg Isopropyl Alcohol, Propylene Glyod, Methylaraben and Propylparaben as preservatives, Purified Water, USP q.s. Hydrochloric Acid may be added to adjust pH. 9 STURACE: Store upright between 2° and 30°C (36° and 86°F).

INDICATIONS: For topical use in dogs only. For the treatment of infected superficial lesions in dogs caused by bacteria susceptible to pertameter. 331-60 in dogs caused by bacteria susceptione to gentamicin.
Read accompanying directions carefully.
DIRECTIONS FOR USE: Usual Dosage:
Two depressions of the sprayer head
2 to 4 times daily for 7 days. RETURNABL 17033-Manufactured for: Dechra Veterinary Products Zσ Overland Park, KS 66211 USA Lot No. Exp. Date

Rev. January 2023 **NO VARNISH** 

TAKE OBSTRUCTIONS OPECTIONS

GENTACALM is a registered trademark of Dechra Veterinary Products, LLC.

### **GENTACALM®**

**Topical Spray** Gentamicin Sulfate, USP With Betamethasone Valerate, USP

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 suffate, 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 aminophycoside antibiotics derived from the fermentation of Micromonospora purpurea. Gentamicin sulfate eterinary 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. 
Specifically, gentamicin is active against the following organisms isolated from canine sion: Abadgenes sp., Obrobacter sp., Kibbadla sp., Pseudomonas aeruginoss, indole-positive and -negative Proteurs sp., Escherichie 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 managem-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 dy stocia, 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 GENTACALM® Topical Spray. TOXICITY: GENTACALM® 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 onsidered reversible with cessation of treatment

SIDE EFFECTS: Side effects such as SAP and SGPT enzyme elevations, weight loss, ancrexia, polydipsia, and polyuria have occurred following parenteral or systemic use of synthetic conticosteroids 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.

**Net Contents:** 120 mL (4 fl oz) RECAUTIONS. Antitoic susceptibility of the pathogenic organismis) should be de termined prior to use of this preparation, ilse ord trick antitioids any permit overgooth of prior bused place. In this cozons, teatment should be instituted with other appropriate against a indicated, Administration of recommended dose begroat 7 days may result in debrid wound healing. Administration of recommended dose begroat 7 days may result in debrid wound healing, Administrated by toget than 7 days should be monitated dosely, Aveid ingestion and specific steroid may result in hithition of endogenous steroid production following drug with charact, in prefix presently correctly withdrawn from systemic corticoserrad isolated be considered in especially stressful situations. If ingestion should be decided be about the transfer of adventoration of reducing or endogenous should be decided be asserted by the size all spiral and adventor and specially at refer to a denen ordination of reducing or and ordinary and produce adverse introducing a corticoserrad should be related by the again any produce adverse immuniscuppressive effects.

CONTACT INFORMATION:

To report suspended adverse drug wents, for reduical assistance or to obtain a copy of the Selety Deta Stare (SLS), contact Dectra at (856) 933-3472. For additional information about adverse out scope incorrectoring for armed obtags, contact FDA at 1-888-F DA-VETS or ordine at http://www.tta.gov/teporterinalae

SUPPLIED: Plastic spray bottles containing 60 mL and 120 mL of GENTACALM® Topical Spray. Skire upright between 2° and 30°C (36° and 86°F).

REFBENCES

1. Hermossy PW, et al. in vitro activity of gentamicin against bacteria isolated from Monnestic animals.

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2. Bachmann Ly, et al. Comparative in with cashin by of partimicin and other ambinities against bacteria isolated from dincial samples from 0.5s, costs, nor ess, and ceitle. Welvinson Medicine/Smail Admart Common. October 1975: 1218-122.

3. Moderna HW, Akincon RM. Topical activities of be breatheacre esters in man.

4cb Remn. May 1964; 741-746.

January

GBITACALM is a registered trademark of Dechra Veterinary Products, LLC.

Approved by FDA under ANADA # 200-415

NDC 17033-331-12 **GENTACALM® Topical Spray** 

**Net Contents:** 

120 mL (4 fl oz)

Gentamicin Sulfate, USP With Betamethasone Valerate, USP

Veterinary For Topical Use in Dogs Only

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

Not For Use in Humans Keep Out of Reach of Children Approved by FDA under ANADA # 200-415

INGREDIENTS: 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, USP q.s. Hydrochloric Acid may be added to adjust pH.

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

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

Read accompanying directions carefully.

DIRECTIONS FOR USE: Usual Dosage: Two depressions of the sprayer head 2 to 4 times daily for 7 days.

Manufactured for: Dechra Veterinary Products Lat No. KS 66211 USA Rev. January 2023



**NO VARNISH** 

TAKE OBSERVE LABEL OBJECTIONS GENTACALM is a registered trademark of Dechra Veterinary Products, LLC.

### GENTACALM®

Topical Spray Gentamicin Sulfate, USP With Betamethasone Valerate, USP 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 Mcromonospora 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. 12

Specifically, gentamicin is active against the following organisms isolated from canine skin: Alcaligenes sp., Citrobacter sp., Rebsiella 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, 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 GENTACALM® Topical Spray.

TOXICITY: GENTACALM® 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,

anoraxia, polydipsia, and polydria have occurred following parenteral or systemic use of synthetic corticosteroids in dogs.

Vomitting and diarrhea (occasionally bloody) have been observed in dogs.

Cushings syndrome in dogs has been reported in association with prolonged or repeated steroid therapy.

#### **GENTACALM**

gentamicin sulfate spray, metered

#### **Product Information**

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Route	Λt	Λdmu	nictra	tion
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TOPICAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
GENTAMICIN SULFATE (UNII: 8X7386QRLV) (GENTAMICIN - UNII:T6Z9V48IKG)	GENTAMICIN	0.57 mg in 1 mL			
<b>BETAMETHASONE VALERATE</b> (UNII: 9IFA5XM7R2) (BETAMETHASONE - UNII:9842X06Q6M)	BETAMETHASONE	0.284 mg in 1 mL			

P	Packaging						
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date			
1	NDC:17033-331-60	72 in 1 CASE					
1		12 in 1 BOX					
1		60 mL in 1 BOTTLE, SPRAY					
2	NDC:17033-331-12	72 in 1 CASE					
2		12 in 1 BOX					
2		120 mL in 1 BOTTLE, SPRAY					

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANADA	ANADA200415	10/01/2022			

# **Labeler -** Dechra Veterinary Products (362142734)

Revised: 3/2024 Dechra Veterinary Products