

GENTACALM - gentamicin sulfate and betamethasone valerate spray
Dechra Veterinary Products

GENTACALM Topical Spray

Front Panel Label

GENTACALM
Topical Spray

(Gentamicin Sulfate With
Betamethasone Valerate)

Veterinary

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

ANADA 200-388, Approved by FDA

NDC 17033-335-12

Net Contents: 60 mL, 120 mL, or 240 mL Bottles

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.

For animal use only.

Keep out of Reach of Children.

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

Read accompanying directions carefully.

Store upright between 2⁰C and 30⁰C
(36⁰F and 86⁰F)

Manufactured For
Dechra Veterinary Products
Overland Park, KS 662211

Lot No.

Exp. Date

PRODUCT INFORMATION

ANADA 200-388, Approved by FDA

**GENTAMICIN SULFATE WITH BETAMETHASONE
VALERATE TOPICAL SPRAY**

(Gentamicin Sulfate, USP With Betamethasone
Valerate, USP Topical Spray)

Veterinary

For Topical Use in Dogs Only

For Animal Use Only

**CAUTION: Federal Law restricts this drug
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licensed veterinarian**

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: 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.

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: 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: 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**.

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.

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

Store upright between 2⁰C and 30⁰C (36⁰F and 86⁰F).

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 clincial samples from dogs, cats, horses and cattle. *Veterinary Medicine/Small Animal Clinician*. October 1975; 1218-1222.
3. McKenzie, HW and Atkinson, RM. Topical activities of betamethasone esters in Man. *Arch Derm*. May 1964;741-746.

June 2009

Manufactured For:

Dechra Veterinary Products

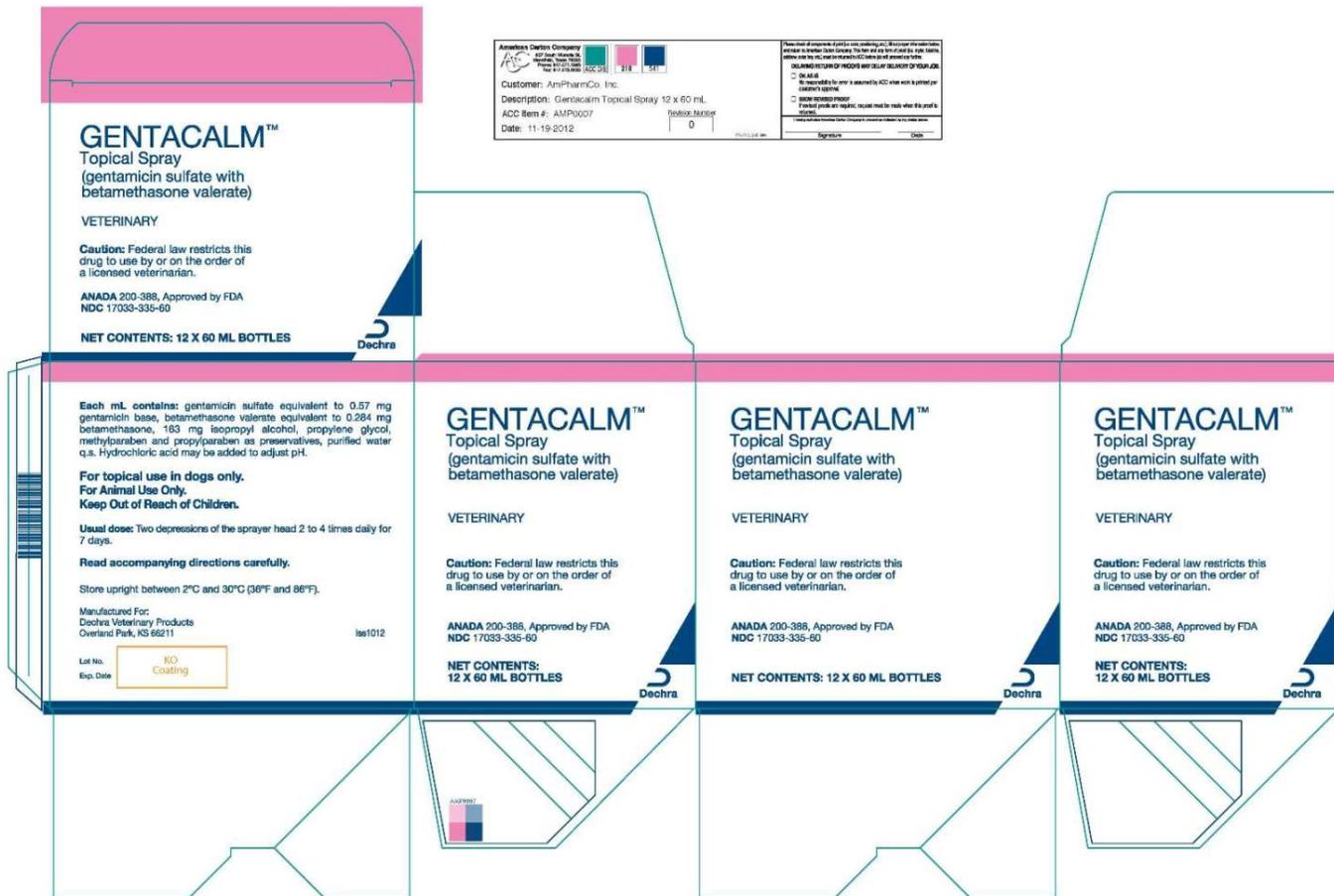
Overland Park, KS 66211

Gentacalm 60 mL Bottle Label

60 mL Bottle Label



60 mL box image



120 mL bottle label image

GENTACALM™

Topical Spray

(gentamicin sulfate with
betamethasone valerate)

VETERINARY

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

ANADA 200-388, Approved by FDA
NDC 17033-335-12

NET CONTENTS: 120 ML

Lot No.
Exp. Date



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.
For Animal Use Only.
Keep Out of Reach of Children.**

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

Read accompanying directions carefully.

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

Manufactured For:
Dechra Veterinary Products
Overland Park, KS 66211 Iss1012



120 mL box image

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

ANADA 200-388, Approved by FDA
NDC 17033-335-24

NET CONTENTS: 240 ML

Lot No.

Exp. Date



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.

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Manufactured For:
Dechra Veterinary Products
Overland Park, KS 66211 Iss1012



240 mL box image

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.

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June, 2009

Manufactured For:
Dechra Veterinary Products
Overland Park, KS 66211

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LIFT HERE



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Dechra Veterinary Products
Overland Park, KS 66211

Iss1012



Outcert Back Panel

Outcert back panel

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GENTACALM

gentamicin sulfate and betamethasone valerate spray

Product Information

| | | | |
|-------------------------|--------------------------|--------------------|---------------|
| Product Type | PRESCRIPTION ANIMAL DRUG | Item Code (Source) | NDC:17033-335 |
| Route of Administration | 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 |
| BETAMETHASONE VALERATE (UNII: 9IFA5XM7R2) (BETAMETHASONE - UNII:9842X06Q6M) | BETAMETHASONE VALERATE | 0.284 mg in 1 mL |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 163 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-------------------------------------|----------|
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| METHYLPARABEN (UNII: A2I8C7H9T) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------|----------------------|--------------------|
| 1 | NDC:17033-335-60 | 12 in 1 BOX | | |
| 1 | | 60 mL in 1 BOTTLE, SPRAY | | |
| 2 | NDC:17033-335-12 | 12 in 1 BOX | | |
| 2 | | 120 mL in 1 BOTTLE, SPRAY | | |
| 3 | NDC:17033-335-24 | 12 in 1 BOX | | |
| 3 | | 240 mL in 1 BOTTLE, SPRAY | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| ANADA | ANADA200388 | 01/24/2013 | |

Labeler - Dechra Veterinary Products (362142734)

Registrant - American Pharmaceuticals and Cosmetics, Inc. (038023805)

Revised: 2/2013

Dechra Veterinary Products