

BETAGEN- gentamicin sulfate with betamethasone valerate spray
Med-Pharmex, Inc

Betagen Topical Spray

For Topical Use in Dogs Only.

Approved by FDA under ANADA # 200-188

CAUTION: Federal law restricts this drug to use by or on the order of a 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 purpures*. 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.^{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, treatment with this product should be discontinued and appropriate therapy instituted.

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 Betagen™ 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.

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

CONTACT INFORMATION:

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Med-Pharmex at (800) 587-4306. 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>

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 include 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 bottle containing either 60 mL, 120 mL or 240 mL of Betagen™ Topical Spray.

STORAGE: Store upright between 2° and 30°C (36°F 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 and Atkinson, RM. Topical activities of betamethasone esters in man. *Arch Derm*. May 1964; 741-746.

Manufactured by:

Med-Pharmex, Inc.
Pomona, CA 91767

Rev. April 2023

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

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)

VETERINARY

NDC 54925-028-60

BETAGEN™ TOPICAL SPRAY

**(gentamicin sulfate, USP with
betamethasone valerate, USP)**

FOR TOPICAL USE IN DOGS ONLY

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

Net Contents: 60mL



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INCORPORATED
POMONA, CA 91767

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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)

VETERINARY

NDC 54925-028-12

BETAGEN™

TOPICAL SPRAY

(gentamicin sulfate, USP with betamethasone valerate, USP)

FOR TOPICAL USE IN DOGS ONLY

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

Net Contents: 120mL



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POMONA, CA 91767

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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)

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

VETERINARY

NDC 54925-028-24

BETAGEN™ TOPICAL SPRAY

(gentamicin sulfate, USP with betamethasone valerate, USP)

FOR TOPICAL USE IN DOGS ONLY

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

Net Contents: 240 mL



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BETAGEN

gentamicin sulfate with betamethasone valerate spray

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54925-028
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54925-028-06	60 mL in 1 BOTTLE, SPRAY		
2	NDC:54925-028-12	120 mL in 1 BOTTLE, SPRAY		
3	NDC:54925-028-24	240 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200188	04/01/1999	

Labeler - Med-Pharmex, Inc (025353699)

Revised: 4/2023

Med-Pharmex, Inc