BETAGEN - gentamicin sulfate with betamethasone valerate spray
Clipper Distributing Company LLC

Betagen Topical Spray

ANADA #200-188, Approved by FDA
Veterinary

For Topical Use in Dogs Only.

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 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.[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 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 which received corticosteroids during pregnancy.

INDICATIONS: For the treatment of infected superficial lesions in dogs caused by bacteria sensitive 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 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.

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 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 60 mL, 120 mL and 240 mL of Gentamicin Sulfate with Betamethasone Valerate Topical Spray.

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 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*. 1964; 19:741-746.

April 1999
Manufactured by
Med-Pharmex, Inc
Pomona, CA 91767

VETERINARY

NDC 57319-551-70

ANADA #200-188
Approved by FDA

Betagen™
Topical Spray

(Gentamicin Sulfate with Betamethasone Valerate)

For topical use in dogs only.

Net Contents: 120 mL

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

PHOENIX
PHARMACEUTICAL, INC.

Manufactured For:
Clipper Distributing Company LLC
St. Joseph, MO USA

Lot No./Exp. Date

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

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.

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

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VETERINARY

NDC 57319-551-69

ANADA #200-188
Approved by FDA

Betagen™ Topical Spray

(Gentamicin Sulfate with Betamethasone Valerate)

For topical use in dogs only.

Net Contents: 240 mL

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

PHOENIX PHARMACEUTICAL, INC.

Manufactured For:
Clipper Distributing Company LLC
St. Joseph, MO USA

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

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.

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

Lot No./Exp. Date

BETAGEN

gentamicin sulfate with betamethasone valerate spray

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:57319-551
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	0.284 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57319-551-54	60 mL in 1 BOTTLE, SPRAY		
2	NDC:57319-551-70	120 mL in 1 BOTTLE, SPRAY		
3	NDC:57319-551-69	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 - Clipper Distributing Company LLC (150711039)

Registrant - Med-Pharmex, Inc (025353699)

Establishment

Name	Address	ID/FEI	Business Operations
Med-Pharmex, Inc		025353699	manufacture

Revised: 4/1999 Clipper Distributing Company LLC