GENONE- gentamicin sulfate spray
MWI

GenOne™ Spray

(Gentamicin Sulfate, USP With Betamethasone Valerate, USP)

Topical

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.

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.[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 congential 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 GenOne™ Spray.

TOXICITY:

GenOne™ 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 nonsusceptible 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 adrenocorticoid overdosage that include sodium retention, potassium loss, fluid retension, weight gains, polydipsia, and/or polyuria. Prolonged use or overdosage 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 First Priority, Inc. at (800) 650-4899 or www.prioritycare.com. 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 bottles containing 60 mL, 120 mL and 240 mL of GenOne™ 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/SmallAnimal Clinician*. November 1971; 1118-1122.

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Distributed by: **MWI**

Boise, ID 83705

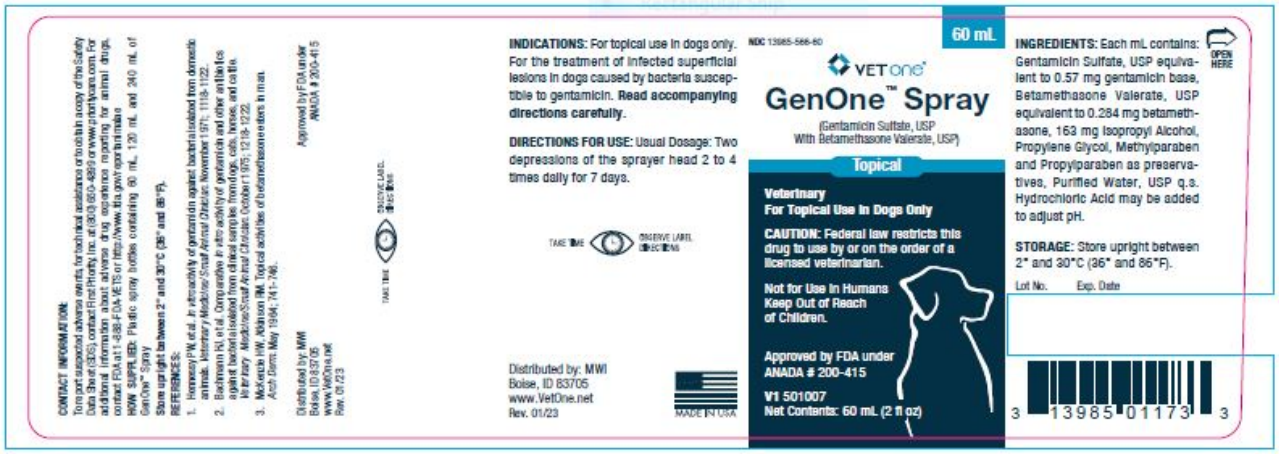
www.VetOne.net

Revision 01/23 (60 mL)

Revision 01/23 (120 mL & 240 mL)

Approved by FDA under ANADA# 200-415

V1 501007
Net Contents: 60 mL (2 fl oz)



BACK

GenOne™ Spray
Gentamicin Sulfate, USP
With Betamethasone Valerate, USP
Veterinary
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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.[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.

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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 GenOne™ Spray.

TOXICITY: GenOne™ 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 nonsusceptible 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.

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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.

VET one®

Quantity: **12** Bottles GenOne Topical Spray
(12 x 60 mL each)

V1 501007

10 3 13985 01173 0

Lot No. Exp. Date

NO VARNISH

Approved by FDA under
ANADA # 200-415
Rev. 01/23

VET one®

Quantity: **72** Bottles GenOne Topical Spray
(6 inner cases x 12 bottles, 60 mL each)

V1 501007

20 3 13985 01173 7

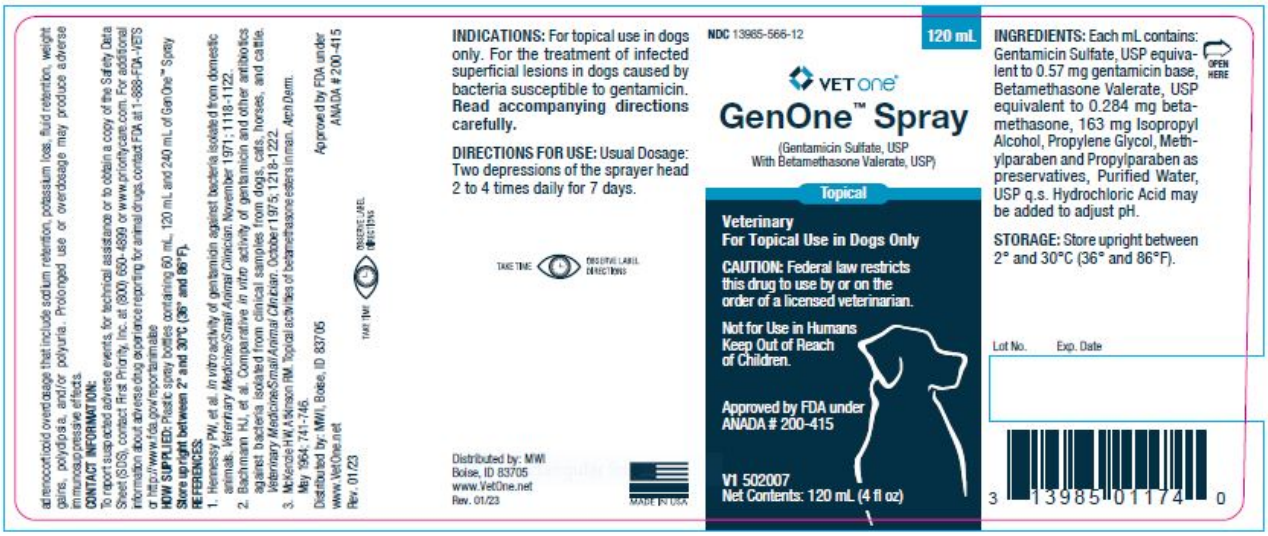
Lot No. Exp. Date

NO VARNISH

Approved by FDA under
ANADA # 200-415
Rev. 01/23

V1 502007
Net Contents: 120 mL (4 fl oz)

FRONT



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CONTACT INFORMATION:
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HOW SUPPLIED: Plastic spray bottles containing 60 mL, 120 mL and 240 mL of GenOne™ 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.
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3. McKenzie HW, Atkinson RM. Topical activities of betamethasone esters in man. *Arch Derm*. May 1964; 741-745.

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Rev. 01/23

Approved by FDA under
ANADA # 200-415

INSIDE LABEL DIRECTIONS

TAKE TIME

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.

TAKE TIME OUTSIDE LABEL DIRECTIONS

Distributed by: MWI
Boise, ID 83705
www.VetOne.net
Rev. 01/23

MADE IN USA

NDC 13985-566-12

120 mL

VETone

GenOne™ Spray

(Gentamicin Sulfate, USP
With Betamethasone Valerate, USP)

Topical

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

V1 502007
Net Contents: 120 mL (4 fl oz)

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.

OPEN HERE

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

Lot No. Exp. Date

3 13985 01174 0

BACK

GenOne™ Spray

Gentamicin Sulfate, USP With Betamethasone Valerate, USP
Veterinary
For Topical Use in Dogs Only
Not for Use in Humans

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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.[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.

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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 GenOne™ Spray.

TOXICITY: GenOne™ 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 nonsusceptible bacteria, fungi, or yeasts. If this occurs, treatment should be instituted with other appropriate agents as indicated.

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VET one®

Quantity: **12** Bottles GenOne Topical Spray
(12 x 120 mL each)

V1 502007

10 3 13985 01174 7

Lot No. Exp. Date

NO VARNISH

Approved by FDA under
ANADA # 200-415
Rev. 01/23

V1 503007
Net Contents: 240 mL (8 fl oz)

FRONT

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.
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Approved by FDA under
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TAKE TIME OBSERVE LABEL DIRECTIONS

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

TAKE TIME OBSERVE LABEL DIRECTIONS

Distributed by: MWI
Boise, ID 83705
www.VetOne.net
Rev. 01/23

MADE IN USA

NDC 13985-566-24

240 mL

VETone®

GenOne™ Spray

(Gentamicin Sulfate, USP
With Betamethasone Valerate, USP)

Topical

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
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Approved by FDA under
ANADA # 200-415

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OPEN HERE

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

Lot No. Exp. Date

NO VARNISH

3 13985 01175 7

BACK

GenOne™ Spray

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

VET one®

Quantity: **12** Bottles GenOne Topical Spray
(12 x 240 mL each)

V1 503007

10 3 13985 01175 4

Lot No. Exp. Date

NO VARNISH

Approved by FDA under
ANADA # 200-415
Rev. 01/23

VET one®

Quantity: **72** Bottles GenOne Topical Spray
(6 inner cases x 12 bottles, 240 mL each)

V1 503007

20 3 13985 01175 1

Lot No. Exp. Date

NO VARNISH

Approved by FDA under
ANADA # 200-415
Rev. 01/23

GENONE

gentamicin sulfate spray

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:13985-566
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GENTAMICIN SULFATE (UNII: 8X7386QRLV) (GENTAMICIN - UNII:T6Z9V48IKG)	GENTAMICIN	0.0599 g in 100 mL
BETAMETHASONE VALERATE (UNII: 9IFA5XM7R2) (BETAMETHASONE - UNII:9842X06Q6M)	BETAMETHASONE	0.0352 g in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:13985-566-60	12 in 1 CASE		
1		60 mL in 1 BOTTLE, SPRAY		
2	NDC:13985-566-12	12 in 1 CASE		
2		120 mL in 1 BOTTLE, SPRAY		
3	NDC:13985-566-24	12 in 1 CASE		
3		240 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200415	09/26/2023	

Labeler - MWI (019926120)

Establishment

Name	Address	ID/FEI	Business Operations
FIRST PRIORITY INCORPORATED		179925722	manufacture

Revised: 9/2023 MWI