

Approval Date: _____

FREEDOM OF INFORMATION SUMMARY

**ORIGINAL ABBREVIATED NEW ANIMAL DRUG
APPLICATION**

ANADA 200-459

**VETAZINE Cream
(triamcinolone acetonide)**

For Topical Use in Dogs

**Indications: for topical treatment of allergic dermatitis and
summer eczema in dogs**

Sponsored by:

Modern Veterinary Therapeutics, LLC

2008-200-459

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FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-459
- b. Sponsor: Modern Veterinary Therapeutics, LLC
1550 Madruga Ave., suite 329
Coral Gables, FL 33146

Drug Labeler Code: 015914
- c. Established Name: Triamcinolone acetonide
- d. Proprietary Name: VETAZINE Cream
- e. Dosage Form: Cream
- f. How Supplied: 28.4 g and 85.2 g tubes
- g. How Dispensed: Rx
- h. Amount of Active Ingredients: 1 mg of triamcinolone acetonide per gram
- i. Route of Administration: Topical
- j. Species/Class: Dogs
- k. Recommended Dosage: Apply VETAZINE Cream by rubbing into the affected areas two to four times daily for 4 to 10 days.
- l. Pharmacological Category: Anti-inflammatory corticosteroid
- m. Indications: VETAZINE Cream is indicated for topical treatment of allergic dermatitis and summer eczema in dogs.
- n. Pioneer Product: VETALOG Cream; NADA 046-146; Fort Dodge Animal Health, Division of Wyeth Holdings Corp.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2002).

Based on the formulation characteristics of the generic product, Modern Veterinary Therapeutics, LLC was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product VETAZINE Cream (triamcinolone acetonide). The generic product is administered as topical cream, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, VETALOG Cream (triamcinolone acetonide), the subject of Fort Dodge Animal Health, Division of Wyeth Holdings Corp., NADA 046-146, was approved on March 27, 1975.

3. HUMAN SAFETY:

This drug is intended for use in dogs, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that VETAZINE Cream, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as indicated below:

Generic Labeling for ANADA 200-459

VETAZINE Cream (triamcinolone acetonide) - 28.4 g and 85.2 g container labeling, carton boxes labeling, and package insert labeling.

Pioneer Labeling for NADA 046-146:

VETALOG Cream (triamcinolone acetonide) - 15 g container labeling, carton boxes labeling, and package insert labeling.

Store at room temperature; avoid freezing.
Do not store above 30°C (86°F).
Exp. Date and control number on pump.

VETAZINE™ CREAM

Triamcinolone Acetonide Cream, USP 0.1%
28.4 gm

FOR TOPICAL USE ON DOGS ONLY
CAUTION: Federal law restricts this drug to use
by or on the order of a licensed veterinarian.

DESCRIPTION: VETAZINE™ Cream provides 1
mg triamcinolone acetonide per gram (0.1%) in a
vanishing cream base containing propylene glycol,
emulsifying wax, mineral oil, sorbitol, cetyl
palmitate, sorbic acid, potassium sorbate and purified
water.

DOSAGE AND ADMINISTRATION: Apply to
affected areas 2 to 4 times daily for 4 to 10 days --
See insert.

ANADA 200-459, Approved by FDA
Manufactured for
Modern Veterinary Therapeutics, LLC 
Coral Gables, FL 33146 - USA

File name: Container VETAZINE Cream 1 oz
Scale: The label is 100% of full size
Date: V01, 1008

Store at room temperature; avoid freezing.
Do not store above 30°C (86°F).
Exp. Date and control number on crimp.

VETAZINE™ CREAM

Triamcinolone Acetonide Cream, USP 0.1%
85.2 gm

FOR TOPICAL USE ON DOGS ONLY
CAUTION: Federal law restricts this drug to use
by or on the order of a licensed veterinarian.

DESCRIPTION: VETAZINE™ Cream provides 1
mg triamcinolone acetonide per gram (0.1%) in a
vanishing cream base containing propylene glycol,
emulsifying wax, mineral oil, sorbitol, cetyl
palmitate, sorbic acid, potassium sorbate and purified
water.

DOSAGE AND ADMINISTRATION: Apply to
affected areas 2 to 4 times daily for 4 to 10 days –
See insert.

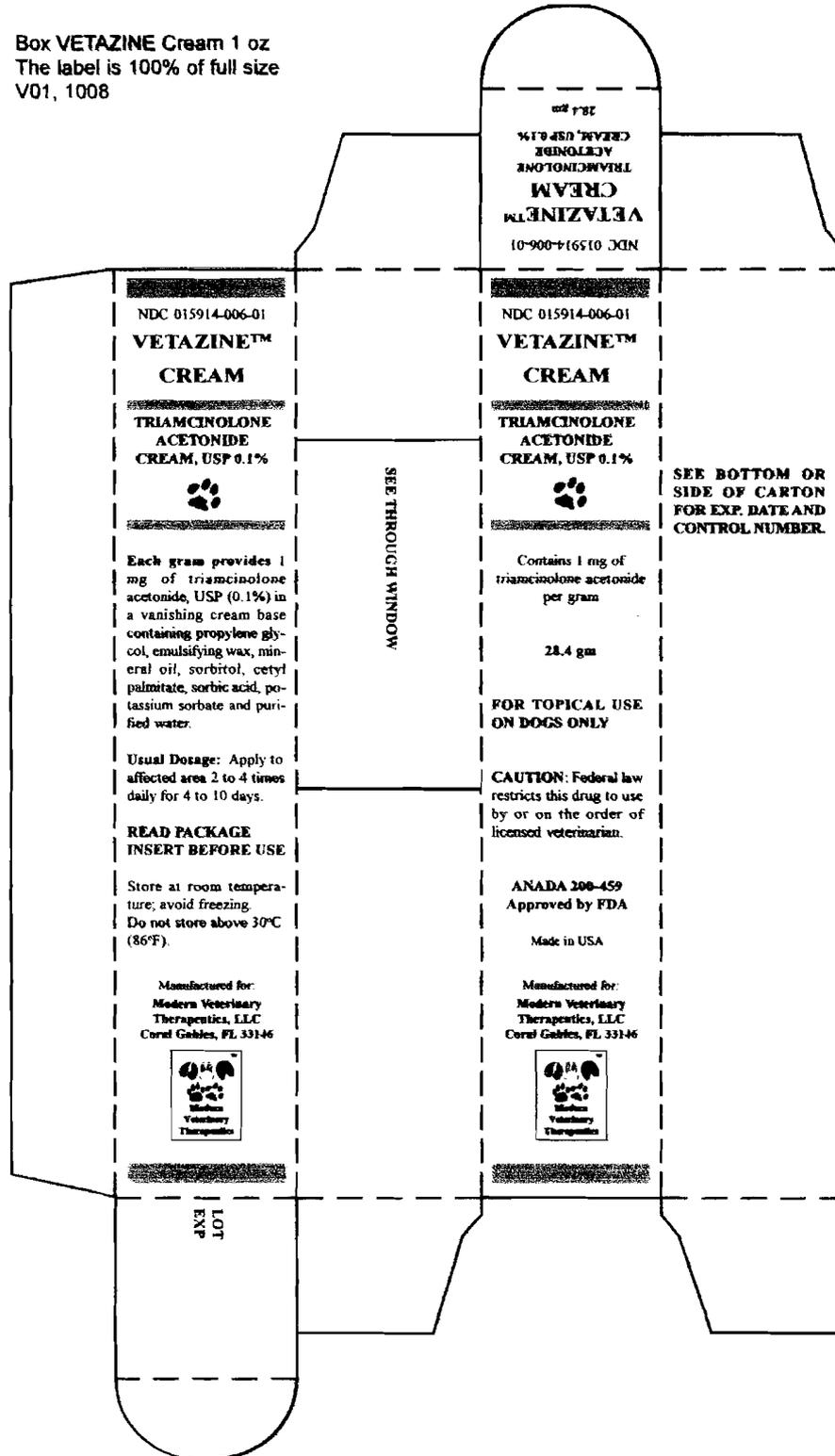
ANADA 200-459, Approved by FDA.
Manufactured for
Modern Veterinary Therapeutics, LLC 
Coral Gables, FL 33146 - USA

File name: Container VETAZINE Cream 3 oz

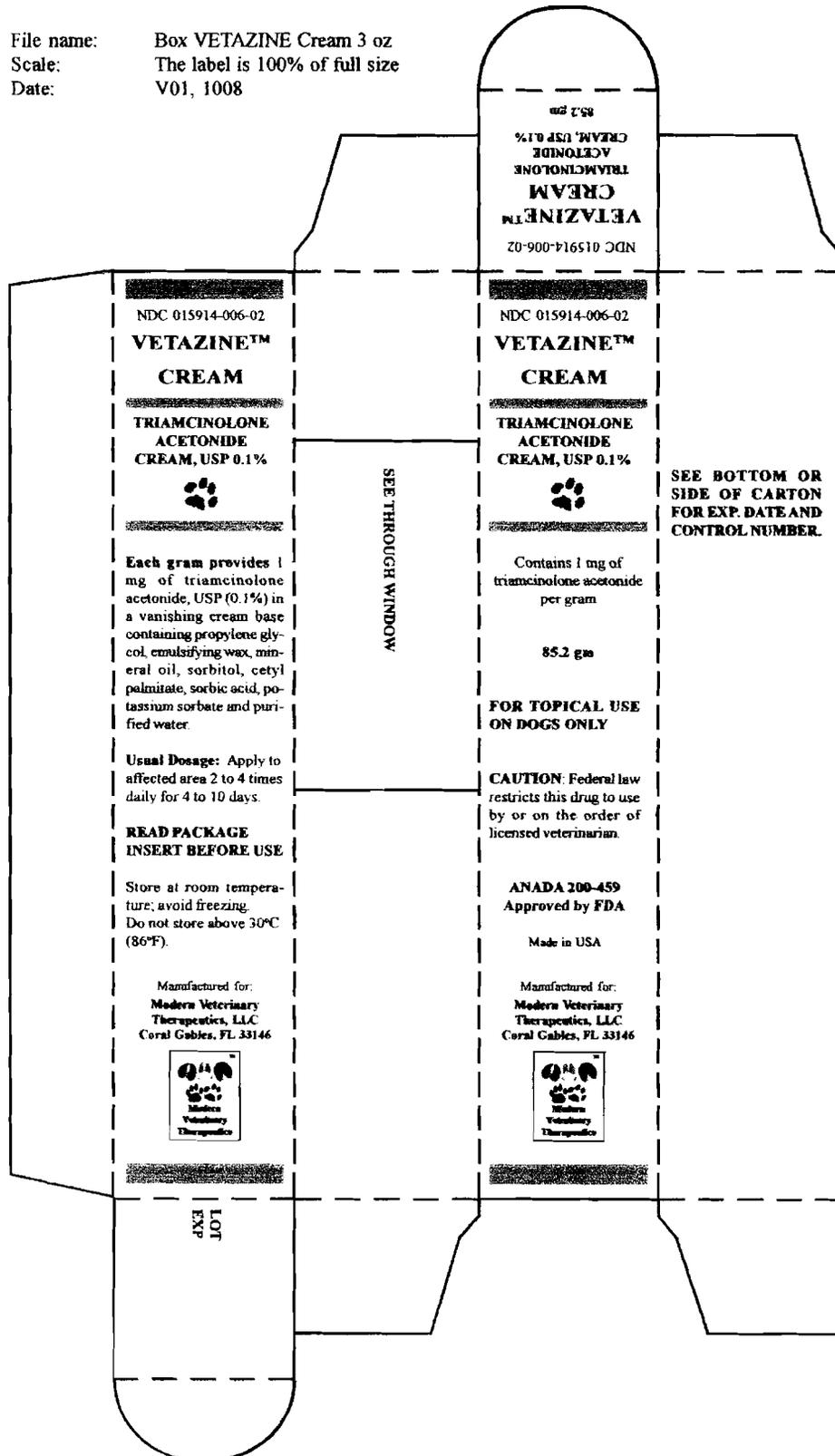
Scale: The label is 100% of full size

Date: V01. 1008

File name: Box VETAZINE Cream 1 oz
 Scale: The label is 100% of full size
 Date: V01, 1008



File name: Box VETAZINE Cream 3 oz
 Scale: The label is 100% of full size
 Date: V01, 1008



File name: Insert VETAZINE Cream
Scale: The label is 100% of full size
Date: V01, 1008

VETAZINE™ CREAM

Modern Veterinary Therapeutics, LLC
TRIAMCINOLONE ACETONIDE CREAM, USP 0.1%.
For Topical Use on Dogs Only

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

DESCRIPTION: VETAZINE™ Cream (triamcinolone acetonide) provides 1 mg triamcinolone acetonide per gram (0.1%) in a vanishing cream base containing propylene glycol, emulsifying wax, mineral oil, sorbitol, cetyl palmitate, sorbic acid, potassium sorbate and purified water.

ACTIONS: VETAZINE™ Cream contains a corticosteroid that provides prompt relief of itching, burning, inflamed skin lesions by virtue of its anti-inflammatory, antipruritic and anti-allergic effects.

INDICATIONS: VETAZINE™ Cream is indicated for topical treatment of allergic dermatitis and summer eczema in dogs.

CONTRAINDICATIONS: VETAZINE™ Cream should not be used ophthalmically.

WARNINGS: VETAZINE™ Cream is indicated for use on dogs only. Do not use VETAZINE™ Cream on animals which are raised for food production.

Absorption of triamcinolone acetonide through topical application on the skin and by licking does occur. Therefore, dogs receiving VETAZINE™ Cream therapy should be observed closely for signs of polydipsia, polyuria and increased weight gain, particularly when used over large areas or for extended periods of time.

Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used 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 resulted in cleft palate in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies including deformed forelegs, phocomelia and anasarca.

PRECAUTIONS: If local infection exists, suitable concomitant antimicrobial therapy should be administered. If favorable response does not occur promptly, application of VETAZINE™ Cream should be discontinued until the infection is adequately controlled by appropriate measures. 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.

SIDE EFFECTS: SAP and SGPT (ALT) enzyme elevations, 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.

DOSAGE AND ADMINISTRATION: Apply VETAZINE™ Cream by rubbing into the affected areas two to four times daily for 4 to 10 days.

HOW SUPPLIED: VETAZINE™ Cream is supplied in 28.4 & 85.2 gram tubes.

STORAGE: Store at room temperature; avoid freezing. Do not store above 30°C (86°F).

ANADA 200-459. Approved by FDA.

Manufactured for:
Modern Veterinary Therapeutics, LLC
Coral Gables, Florida 33146 - USA



Rev#1008

N 046-146

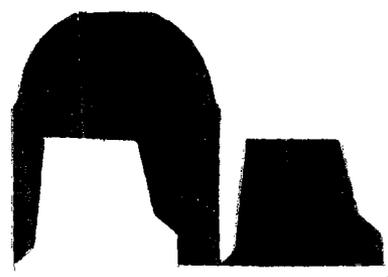
Base Coat 3"	<p>Each gram provides: 1 mg triamcinolone acetonide (0.1%) in a vanishing cream base containing propylene glycol, cetearyl alcohol (and) ceteareth-20, white petrolatum, sorbitol solution, glyceryl monostearate, polyethylene glycol monostearate, simethicone, sorbic acid and purified water.</p> <p style="text-align: center;">Vetalog[®] Cream TRIAMCINOLONE ACETONIDE CREAM USP 0.1%</p> <p style="text-align: center;">FORT DODGE[®]</p> <p>Usual dosage: Apply to affected area 2 to 4 times daily for 4 to 10 days - See insert. Store at room temperature; avoid freezing. Exp. Date and Control Number on crimp.</p> <p style="text-align: center;">FOR TOPICAL USE ON DOGS ONLY</p> <p>CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p>Manufactured by Bristol-Myers Squibb Humaco, PR 00791 for Fort Dodge Animal Health Fort Dodge, Iowa 50501 U.S.A. 91686 D0216C/ER12922A</p> <p style="text-align: right;">15 g</p> <p style="text-align: center;">SAMPLE</p> <p style="text-align: center;">FPO</p>	<p style="text-align: center;">FORT DODGE[®] FORT DODGE ANIMAL HEALTH LABEL CONTROL</p> <p>Revision: 3 Operator: Ish/hak Date: 08/03/98 Product I.D.#: ER12922A Product Name: Vetalog Cream Size: 2⁹/₃₂" x 4¹/₈" Product Type: Tube / 15 g File Location: V1/PF/ER12922A/ER12922A To Date: Rev. Level:</p> <p style="text-align: center;">■ PMS 287 ■ PMS 185</p> <p style="text-align: center;">FPO=PHARMACODE</p>
	<p style="text-align: center;">2⁹/₃₂"</p>	
Base Coat 1 ¹ / ₄ " (no imprint area)		

DER. Dated

07/18/02

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N 046-1215



**Vetalog[®]
Cream**

**TRIAMCINOLONE
ACETONIDE
CREAM USP**

0.1%

FOR TOPICAL USE
ON DOGS ONLY



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

Read all sides

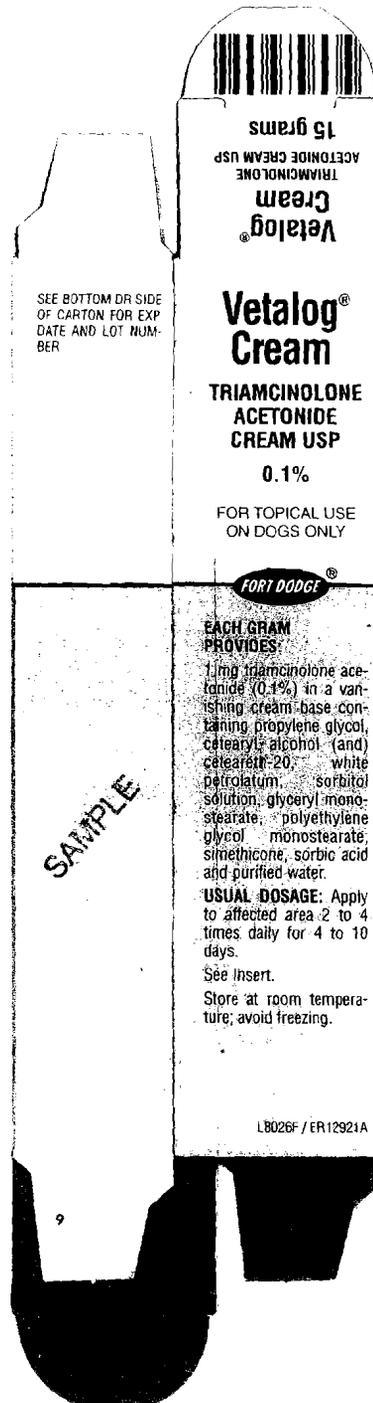
15 g

Manufactured by
Bristol-Myers Squibb
Humaco, PR 00791
for
**Fort Dodge
Animal Health**
Fort Dodge, Iowa 50501
USA



DER Dated 07/18/02

N 046-146



DEF Dated 07/18/02
11046-146



SAMPLE

J4-054G



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

VETALOG[®] CREAM

Triamcinolone Acetonide Cream, USP
For Topical Use on Dogs Only

DESCRIPTION

Vetalog Cream (Triamcinolone Acetonide Cream USP) provides 1 mg triamcinolone acetonide per gram (0.1%) in a vanishing cream base containing propylene glycol, cetearyl alcohol (and) cetareth-20, white petrolatum, sorbitol solution, glyceryl monostearate, polyethylene glycol monostearate, simethicone, sorbic acid and purified water.

ACTIONS

Vetalog is a corticosteroid that provides prompt relief of itching, burning, inflamed skin lesions by virtue of its anti-inflammatory, antipruritic and anti-allergic effects.

INDICATIONS

Vetalog Cream (Triamcinolone Acetonide Cream USP) is indicated for topical treatment of allergic dermatitis and summer eczema in dogs.

CONTRAINDICATIONS

Vetalog Cream should not be used ophthalmically.

WARNINGS

Vetalog Cream is indicated for use on dogs only. Do not use Vetalog Cream on animals which are raised for food production.

Absorption of triamcinolone acetonide through topical application on the skin and by licking does occur. Therefore, dogs receiving Vetalog Cream (Triamcinolone Acetonide Cream USP) therapy should be observed closely for signs of polydipsia, polyuria and increased weight gain, particularly when used over large areas or for extended periods of time.

Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta and metritis.

J4-054G

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Additionally, corticosteroids administered to dogs, rabbits and rodents during pregnancy have resulted in cleft palate in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies including deformed forelegs, phocomelia and anasarca.

PRECAUTIONS

If local infection exists, suitable concomitant antimicrobial therapy should be administered. If a favorable response does not occur promptly, application of Vetalog Cream should be discontinued until the infection is adequately controlled by appropriate measures.

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.

SIDE EFFECTS

SAP and SGPT (ALT) enzyme elevations, 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.

DOSAGE AND ADMINISTRATION

Apply Vetalog Cream by rubbing into the affected areas 2 to 4 times daily for 4 to 10 days.

HOW SUPPLIED

Vetalog Cream (Triamcinolone Acetonide Cream USP) is supplied in 15 gram tubes.

STORAGE

Store at room temperature; avoid freezing.



Manufactured by
Bristol-Myers Squibb, Humacao, PR 00791

for
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

ER12920A

Revised June 1998

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