

Date of Approval: FEB 24 2000

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL OF NEW ANIMAL DRUG APPLICATION

ANADA 200-275

Triamcinolone Acetonide Cream

Medalone Cream

Sponsored by:

**Med-Pharmex, Inc.
2727 Thompson Creek Rd
Pomona, CA 91767-1861**

ANADA 200-275

FOIS 1

FREEDOM OF INFORMATION SUMMARY

1. **General Information:**

ANADA Number: 200-275.

Sponsor Name and Address:
Med-Pharmex, Inc.
2727 Thompson Creek Rd
Pomona, CA 91767-1861

Generic Name:
Triamcinolone Acetonide Cream

Trade Name:
Medalone Cream

Marketing Status: Rx.

2. **Indications for Use:**

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

3. **Dosage Form(s), Route(s) of Administration and Recommended Dosages and Contraindications:**

Dosage Form:
Medalone Cream is a cream which is topically applied to the infected area.

Route(s) of Administration and Recommended Dosages:
The Route of Administration is topical application of the cream.
The Recommended Dosage is that the cream is applied by rubbing into the affected areas two to four times daily for 4 to 10 days. Frequency of treatment may be decreased as improvement occurs.

Contraindications:
Medalone Cream should not be used ophthalmically.

Freedom of Information Summary (Cont'd):**4. TARGET ANIMAL SAFETY AND EFFECTIVENESS:**

Under the provisions of the Federal Food, Drug and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) 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 data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. Rather, approval of an ANADA relies on the ANADA sponsor showing that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (Fifth GADPTRA Policy Letter, 55 FR 24645, June 18, 1990; Bioequivalence Guidance, 1996, 61 FR 26182, May 24, 1996).

Based on the formulation characteristics of the generic product, Med-Pharmex, Inc., was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Medalone Cream (triamcinolone acetonide cream). The generic product is administered as a topical ointment and contains the same active and inactive ingredients in similar concentrations as the pioneer product.

5. Human Safety:

This drug is indicated for use only on dogs. It is not to be used for food-producing animals. Therefore, the issue of residues and human safety does not arise.

6. Agency Conclusions:

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

Attachment: Generic and pioneer labeling

Generic –

Pioneer –

(3) LABELING (CONT...)

DRAFT CARTON LABEL

7.5 gram

**MEDALONE
CREAM**

Triamcinolone
Acetonide
Cream USP
0.1%

Each gram provides: 1mg
triamcinolone acetonide (0.1%)
in a vanishing cream base
containing propylene glycol,
cetostearyl alcohol (and)
cetearth-20, white petrolatum,
sorbitol solution, glyceryl
monostearate, polyethylene
glycol monostearate,
simethicone, sorbic acid and
purified water.

Usual Dosage: Apply to
affected area 2 to 4 times daily
for 4 to 10 days.

See insert.

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

Manufactured by
Med-Pharmex Inc,
Pomona, CA 91767

**MEDALONE
CREAM**

Triamcinolone
Acetonide
Cream USP

0.1%

7.5 grams

SEE BOTTOM OR SIDE OF
CARTON FOR EXP. DATE
AND CONTROL NUMBER

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

DRAFT TUBE LABEL 7.5 gram

MEDALONE CREAM

Triamcinolone
Acetonide
Cream USP
0.1%
7.5 grams

FOR TOPICAL USE ON DOGS ONLY

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

Med-Pharmex Inc,

ANADA 200-275, .Approved by FDA

Each gram provides: 1mg
triamcinolone acetonide (0.1%) in a vanishing cream
base containing propylene glycol, cetostearyl alcohol
(and) cetareth-20, white petrolatum, sorbitol
solution, glyceryl monostearate, polyethylene glycol
monostearate, simethicone, sorbic acid and purified
water.

Usual Dosage: Apply to affected area 2 to 4 times
daily for 4 to 10 days- See insert.

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

Exp.Date and control number on crimp.

Manufactured by
Med-Pharmex Inc,
Pomona, CA 91767

(3) LABELING (CONT...)

DRAFT TUBE LABEL 15 gram

MEDALONE CREAM

Triamcinolone
Acetonide
Cream USP
0.1%
15 grams

FOR TOPICAL USE ON DOGS ONLY

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

Each gram provides: 1mg
triamcinolone acetonide (0.1%) in a vanishing cream
base containing propylene glycol, cetostearyl alcohol
(and) cetareth-20, white petrolatum, sorbitol
solution, glyceryl monostearate, polyethylene glycol
monostearate, simethicone, sorbic acid and purified
water.

Usual Dosage: Apply to affected area 2 to 4 times
daily for 4 to 10 days- See insert.

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

Exp. Date and control number on crimp.

Med-Pharmex Inc,

ANADA 200-275, Approved by FDA

Manufactured by
Med-Pharmex Inc,
Pomona, CA 91767

(3) LABELING (CONT...)

DRAFT CARTON LABEL

15 gram

**MEDALONE
CREAM**

Triamcinolone
Acetonide
Cream USP
0.1%

Each gram provides: 1mg
triamcinolone acetonide (0.1%)
in a vanishing cream base
containing propylene glycol,
cetostearyl alcohol (and)
ceteareth-20, white petrolatum,
sorbitol solution, glyceryl
monostearate, polyethylene
glycol monostearate,
simethicone, sorbic acid and
purified water.

Usual Dosage: Apply to
affected area 2 to 4 times daily
for 4 to 10 days.

See insert.

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

Manufactured by
Med-Pharmex Inc,
Pomona, CA 91767

**MEDALONE
CREAM**

Triamcinolone
Acetonide
Cream USP

0.1%

15 grams

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

SEE BOTTOM OR SIDE OF
CARTON FOR EXP. DATE
AND CONTROL NUMBER

(3) LABELING (CONT...)

DRAFT - PACKAGE INSERT

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
ANADA 200-275, Approved by FDA.

Medalone Cream

Triamcinolone Acetonide Cream USP
For Topical Use on Dogs Only

DESCRIPTION

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

ACTIONS

Medalone Cream 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

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

CONTRAINDICATIONS

Medalone Cream should not be used ophthalmically.

WARNINGS

Medalone Cream is indicated for use on dogs only. Do not use Medalone 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 Medalone 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.

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.

(3) LABELING (CONT...)

DRAFT – PACKAGE INSERT (continued)

PRECAUTIONS

If local infection exists, suitable concomitant antimicrobial therapy should be administered. If favorable response does not occur promptly, application of Medalone 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 Medalone Cream by rubbing into the affected areas two to four times daily for 4 to 10 days.

HOW SUPPLIED

Medalone Cream (Triamcinolone Acetonide Cream USP) is supplied in 7.5 gram and 15 gram tubes.

STORAGE

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

November 1999

Med-Pharmex Inc
Pomona, CA 91767

Each gram provides 1 mg triamcinolone acetonide (0.1%) in a vanishing cream base containing propylene glycol, cetylalcohol (and) ceteareth-20, white petrolatum, sorbitol solution, glyceryl monostearate, polyethylene glycol monostearate, simethicone, sorbic acid and purified water.

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

© 1990 Solvay Animal Health, Inc.
Manufactured by
E. R. Squibb & Sons, Inc.
Princeton, NJ 08543 for
SOLVAY Animal Health, Inc.
Mendota Heights, MN 55120-1129 USA
Made in USA 02516A / 98215

To open: Pierce sealed end with cap point

15 grams List 98215
**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

SOLVAY Animal Health, Inc.

Each gram provides 1 mg triamcinolone acetonide (0.1%) in a vanishing cream base containing propylene glycol, cetylalcohol (and) ceteareth-20, white petrolatum, sorbitol solution, glyceryl monostearate, polyethylene glycol monostearate, simethicone, sorbic acid and purified water.

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.

Manufactured by
E. R. Squibb & Sons, Inc.
Princeton, NJ 08543 for
SOLVAY Animal Health, Inc.
Mendota Heights, MN 55120 USA

Made in USA 025158 / 98215
44-002955-00

To open: Pierce sealed end with cap point

No. 98215
**VETALOG®
CREAM**

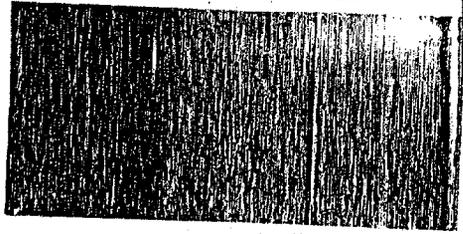
Triamcinolone
Acetonide
Cream USP
0.1%
15 grams



FOR TOPICAL USE
ON DOGS ONLY

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

SOLVAY Animal Health, Inc.



VETALOG
CREAM
Triamcinolone
Acetonide
Cream USP
15 grams

**VETALOG
CREAM**

Triamcinolone
Acetonide
Cream USP

0.1%

Each gram provides 1 mg triamcinolone acetonide (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.

Usual dosage: Apply to affected area 2 to 4 times daily for 4 to 10 days

See insert

Store at room temperature; avoid freezing

© 1990 Solvay Animal Health, Inc.

Manufactured by
E. R. Squibb & Sons, Inc.
Princeton, NJ 08540 for
SOLVAY Animal Health, Inc.
Mendota Heights, MN
55120-1139 USA Made in USA
L80260 / 98215



15 grams
List 98215
**VETALOG[®]
CREAM**

Triamcinolone
Acetonide
Cream USP

0.1%

SEE BOTTOM OR
SIDE OF CARTON
FOR EXP. DATE
AND CONTROL
NUMBER



**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

SOLVAY Animal Health, Inc.



L80260



VETALOG®
No. 98215
Triamcinolone
Acetonide Cream USP
15 grams

**VETALOG®
CREAM**

Triamcinolone
Acetonide
Cream USP

0.1%

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

Usual dosage: Apply
to affected area 2 to 4
times daily for 4 to 10
days.

See insert.

Store at room
temperature; avoid
freezing.

Manufactured by
E. R. Squibb & Sons, Inc.
Princeton, NJ 08543 for
SOLVAY Animal
Health, Inc.
Mendota Heights, MN
55120 USA
Made in USA

L8026E / 98215
36-002850-00



No. 98215

**VETALOG®
CREAM**

Triamcinolone
Acetonide
Cream USP

0.1%

15 grams

SEE BOTTOM OR SIDE
OF CARTON FOR EXP.
DATE AND CONTROL
NUMBER



NDC3-5350-1982-15-4



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

SOLVAY Animal Health, Inc.





SOLVAY Animal Health, Inc.

J4-054F
51-002849-00

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.

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 two to four 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

E. R. Squibb & Sons, Inc., Princeton, NJ 08543

for

SOLVAY Animal Health, Inc., Mendota Heights, MN 55120

Printed in USA

Revised June 1995

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