

HFA-305

Date of Approval:

SEP 4 2007

## FREEDOM OF INFORMATION SUMMARY

**ANADA 200-330**

**ANIMAX Cream**

**(nystatin-neomycin sulfate-thiostrepton-triamcinolone acetonide cream)**

**Dogs and Cats**

Indications: Topical dermatologic disorders characterized by inflammation and dry or exudative dermatitis, particularly associated with bacterial or candidal (*Candida albicans*) infections for use in cats and dogs only.

Sponsored by:  
Altana Inc.  
Melville, NY 11747

ANADA 200-<sup>330</sup>~~300~~

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## FREEDOM OF INFORMATION SUMMARY

### 1. GENERAL INFORMATION:

- a. File Number: ANADA 200-330
- b. Sponsor: Altana Inc.  
60 Baylis Road  
Melville, NY 11747  
  
Labeler Code: 025463
- c. Established Name: Nystatin, neomycin sulfate, thiostrepton, and triamcinolone acetonide
- d. Proprietary Name: ANIMAX Cream
- e. Dosage Form: Topical Cream
- f. How Supplied: 7.5 and 15 gram tubes
- g. How Dispensed: Rx
- h. Amount of Active Ingredients: Each gram contains: nystatin-100,000 units, neomycin sulfate-2.5 mg, thiostrepton-2,500 units, triamcinolone acetonide-1.0 mg
- i. Route of Administration: Topical
- j. Species/Class: Dogs and cats
- k. Recommended Dosage: Application may range from once daily to once a week. For severe condition, apply 2 to 3 times daily, if necessary.
- l. Pharmacological Category: Anti-inflammatory, antipruritic, antifungal, and antibacterial
- m. Indications: Topical dermatologic disorders characterized by inflammation and dry or exudative dermatitis, particularly associated with bacterial or candidal infections.

n. Pioneer Product: PANOLOG Cream; NADA 096-676; Fort Dodge Animal Health

## **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) 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 9, 2002).

Based upon the formulation characteristics of the generic product, Altana Inc. was granted a waiver on August 25, 1998, from the requirement for an *in vivo* bioequivalence study for ANIMAX Cream. The generic and pioneer products contain the same active and inactive ingredients in similar formulations. The pioneer product, PANOLOG, the subject of Fort Dodge Animal Health's NADA 96-676, was approved on July 11, 1978.

## **3. HUMAN SAFETY:**

This drug is indicated for use in dogs and cats, 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.

Human Warning is provided on the product label as follows:  
"Not for Ophthalmic Use"

## **4. 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 ANIMAX 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:

Pioneer Labeling for NADA 96-676:

PANOLOG-7.5 and 15 gram tubes

Insert

Generic Labeling for ANADA 200-330

ANIMAX Cream- 7.5 and 15 gram tubes

Insert



ANADA# 200-330 Approved by FDA

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

**animax<sup>®</sup> cream veterinary**

**nystatin - neomycin sulfate - thioestrepton - triamcinolone acetonide cream USP**

For Topical use on Dogs and Cats Only  
Not for Ophthalmic Use

**DESCRIPTION**

Animax Cream combines nystatin, neomycin sulfate, thioestrepton and triamcinolone acetonide.

Each gram contains:

nystatin	100,000 units
neomycin sulfate equivalent	
to neomycin base	2.5 mg
thioestrepton	2,500 units
triamcinolone acetonide	1.0 mg

in an aqueous nonirritating vanishing cream base of polyoxyethylene fatty alcohol ether, sorbitol solution, propylene glycol, white petrolatum, polyoxyl 40 stearate, glyceryl monostearate, titanium dioxide, citric acid, ethylenediamine, methylparaben, propylparaben.

**ACTIONS**

By virtue of its four active ingredients, Animax Cream (Nystatin-Neomycin Sulfate- Thioestrepton-Triamcinolone Acetonide Cream USP) provides four basic therapeutic effects: anti-inflammatory, antipruritic, antifungal and antibacterial. Triamcinolone acetonide is a potent synthetic corticosteroid providing rapid and prolonged symptomatic relief on topical administration. Inflammation, edema, and pruritis promptly subside, and lesions are permitted to heal. Nystatin is the first well-tolerated antifungal antibiotic of dependable efficacy for the treatment of cutaneous infections caused by *Candida albicans* (Monilia). Nystatin is fungistatic *in vitro* against a variety of yeast and yeastlike fungi including many fungi pathogenic to animals. No appreciable activity is exhibited against bacteria. Thioestrepton has a high order of activity against gram-positive organisms, including many which are resistant to other antibiotics; neomycin exerts antimicrobial action against a wide range of gram-positive and gram-negative bacteria. Together they provide comprehensive therapy against those organisms responsible for most superficial bacterial infections.

**INDICATIONS**

Animax Cream (Nystatin-Neomycin Sulfate-Thioestrepton-Triamcinolone Acetonide Cream USP) is indicated in the management of dermatologic disorders in dogs and cats, characterized by inflammation and dry or exudative dermatitis, particularly those caused, complicated, or threatened by bacterial or candidal (*Candida albicans*) infections. It is also of value in eczematous dermatitis, contact dermatitis, and seborrheic dermatitis; and as an adjunct in the treatment of dermatitis due to parasitic infestation.

**CONTRAINDICATIONS**

Animax Cream should not be used ophthalmically.

**WARNINGS**

Animax Cream is indicated for use in dogs and cats only. Not for use in animals which are raised for food.

(over)

<b>Animax Cream</b>	
I123 R11/01 Pharmacode # 288	
Dimension:SSI- 5 3.5"x 7"	
<b>ACTUAL CODE PLACED</b>	
Created	AA-10/2/00
Reg. Revs	AA-11/10/00
Dr Schafer & Reg revs	AA-12/20/00
Regulatory Revs	AA-12/27/00
Add ANADA Number/change Rdate	AA-11/26/01
change logo	AA-6/10/02

Absorption of triamcinolone acetonide through topical application and by licking may occur. Therefore animals should be observed closely for signs of polydipsia, polyuria and increased weight gain particularly when the preparation is 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**

Animax Cream (Nystatin-Neomycin Sulfate-Thiostrepton-Triamcinolone Acetonide Cream USP) is not intended for the treatment of deep abscesses or deep-seated infections such as inflammation of the lymphatic vessels. Parenteral antibiotic therapy is indicated in these infections.

Nystatin-Neomycin Sulfate-Thiostrepton-Triamcinolone Acetonide Cream USP has been extremely well tolerated. The occurrence of systemic reactions is rarely a problem with topical administration.

Sensitivity to neomycin may occur. If redness, irritation or swelling persists or increases, discontinue use. Do not use if pus is present since the drug may allow the infection to spread.

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**

Frequency of administration is dependent on the severity of the condition. For mild inflammations, application may range from once daily to once a week; for severe conditions Animax Cream may be applied as often as 2 to 3 times daily, if necessary. Frequency of treatment may be decreased as improvement occurs.

Clean affected areas, removing any encrusted discharge or exudate. Apply Animax Cream (Nystatin-Neomycin Sulfate-Thiostrepton-Triamcinolone Acetonide Cream USP) sparingly in a thin film.

**How supplied:** Animax Cream (Nystatin-Neomycin Sulfate-Thiostrepton-Triamcinolone Acetonide Cream USP) is supplied in tubes as follows:

7.5 gram tubes	NDC 0462-0123-75
15 gram tubes	NDC 0462-0123-15

TO OPEN: Use cap to puncture seal.

IMPORTANT: Do not use if seal has been punctured or is not visible.

Storage: Store at room temperature; avoid excessive heat (104°F).

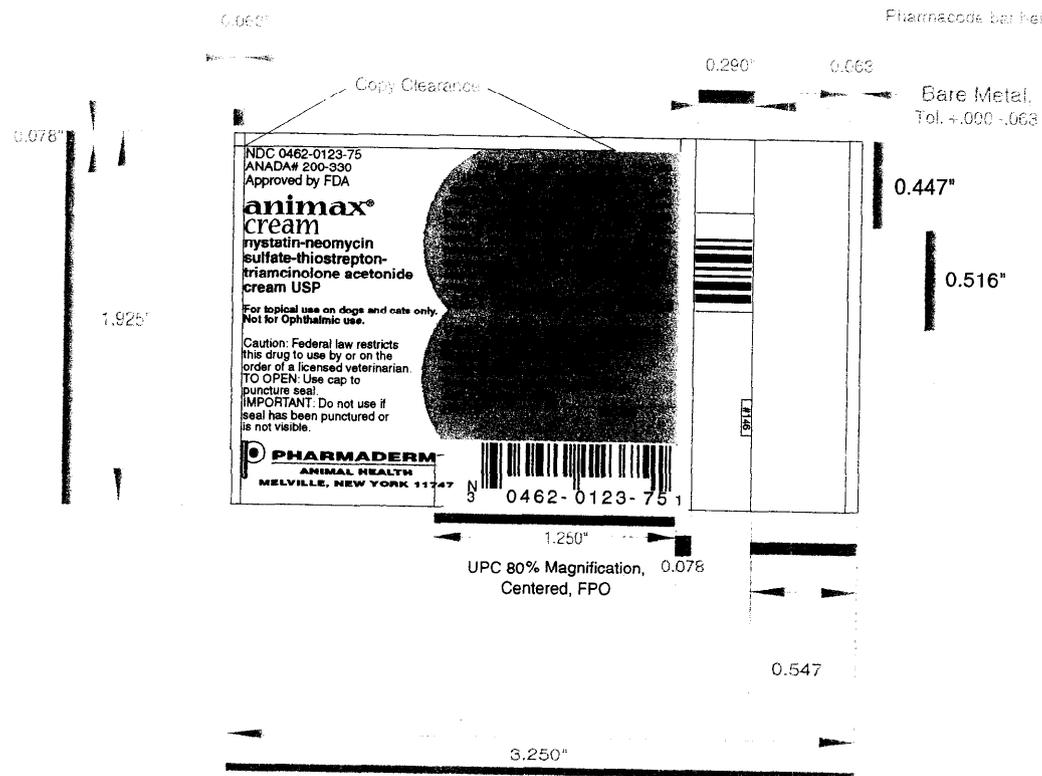
 **PHARMADERM**  
ANIMAL HEALTH  
MELVILLE, NEW YORK 11747

I123  
R6/02  
#288



Animax Cream  
I123 R6/02 Pharmacode # 288  
Dimension: SSI- 5 3.5"x 7"  
ACTUAL CODE PLACED

as stipulated, tolerance for all dimensions is +/- .005".  
 use UPC bar height when artwork allow. Max. height .625", Min. height .312"

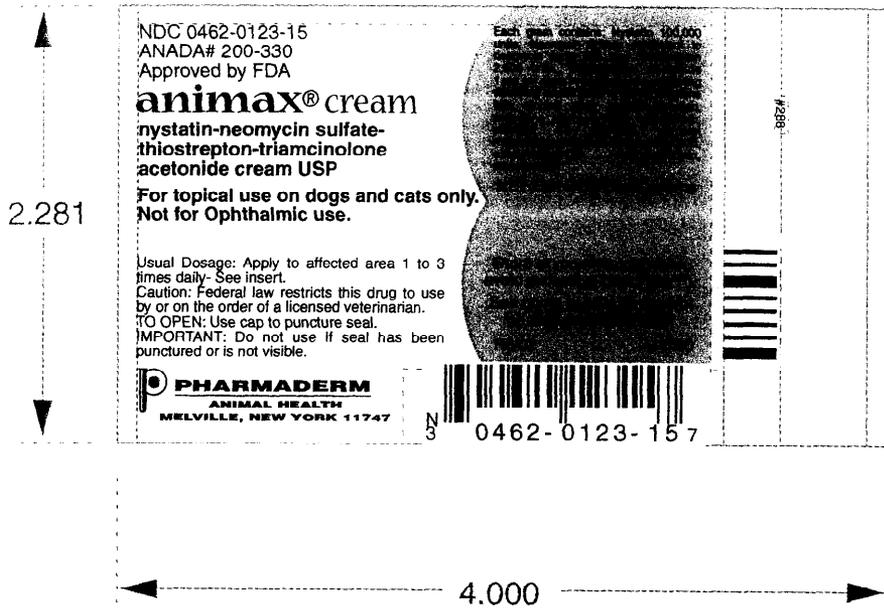


MINI PHARMACO  
 REQUESTED  
 BY PRODUCTION

ALTANA INC.		0.063	
MATERIAL:		SST93C -- 7.5 Grams Tube Base Template	
SCALE: 1:1	DRAWN BY: J. Scott	APPROVED BY:	DRAWING #: AD4JWS
	DATE: Aug.17, 2000	DATE:	

ANIMAX CREAM 7.5 g tube  
 U4779  
 ZE: SST-93C 3.250" x ??? Circ: 1.925"  
 795, 130 2X, Black  
 Nueva Roman  
 Nueva Roman Bold Extended  
 Helvetica Regular  
 Helvetica Bold

AA-10/2/00  
 AA-10/17/00- size revised  
 AA-11/10/00- Regulatory Revs  
 AA-12/20/00- Dr. Schafer/Reg Revisions  
 AA-12/27/00-Reg Revs  
 AA-11/26/01- Add ANADA #/Change R/date  
 AA-6/10/02 - Change logo

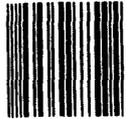


Item: Animax Cream 15 g tube  
 Item #:U4780  
 Die Size: SST-76A, 4 x .750" circ: 2.881"  
 PMS: 1795, 130 2X, Black  
 FONT- Nueva Roman  
       Nueva Roman Bold extended  
       Helvetica Regular  
       Helvetica Bold

Created -10/2/00-AA  
 Regulatory Revs - 11/10/00-AA  
 Dr. Schafer & Reg Revs - AA- 12/20/00  
 Regulatory Revs - AA-12/27/00  
 Add ANADA #/ Change Rdate - AA-11/26/01  
 change logo AA-6/10/02



J4-402C



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

# PANOLOG® CREAM VETERINARY

Nystatin-Neomycin Sulfate-Thiostrepton-Triamcinolone Acetonide Cream  
For Topical Use on Dogs and Cats

## DESCRIPTION

Panolog Cream combines nystatin, neomycin sulfate, thiostrepton and triamcinolone acetonide.

Each gram contains:

nystatin .....	100,000 units
neomycin sulfate equivalent to neomycin base.....	2.5 mg
thiostrepton .....	2,500 units
triamcinolone acetonide .....	1.0 mg

in an aqueous, nonirritating vanishing cream base with cetearyl alcohol (and) cetareth-20, ethylenediamine hydrochloride, methylparaben, propylparaben, propylene glycol, sorbitol solution, titanium dioxide, sodium citrate, citric acid, white petrolatum, glyceryl monostearate, polyethylene glycol monostearate, sorbic acid and simethicone.

## ACTIONS

By virtue of its four active ingredients, Panolog Cream (Nystatin-Neomycin Sulfate-Thiostrepton-Triamcinolone Acetonide Cream) provides four basic therapeutic effects: anti-inflammatory, antipruritic, antifungal and antibacterial. Triamcinolone acetonide is a potent synthetic corticosteroid providing rapid and prolonged symptomatic relief on topical administration. Inflammation, edema and pruritus promptly subside, and lesions are permitted to heal. Nystatin is the first well-tolerated antifungal antibiotic of dependable efficacy for

the treatment of cutaneous infections caused by *Candida albicans* (Monilia). Nystatin is fungistatic *in vitro* against a variety of yeast and yeastlike fungi including many fungi pathogenic to animals. No appreciable activity is exhibited against bacteria. Thiostrepton has a high order of activity against gram-positive organisms, including many which are resistant to other antibiotics; neomycin exerts antimicrobial action against a wide range of gram-positive and gram-negative bacteria. Together they provide comprehensive therapy against those organisms responsible for most superficial bacterial infections.

## INDICATIONS

Panolog Cream (Nystatin-Neomycin Sulfate-Thiostrepton-Triamcinolone Acetonide Cream) is indicated in the management of dermatologic disorders in dogs and cats, characterized by inflammation and dry or exudative dermatitis, particularly those caused, complicated or threatened by bacterial or candidal (*Candida albicans*) infections. It is also of value in eczematous dermatitis, contact dermatitis and seborrheic dermatitis; and as an adjunct in the treatment of dermatitis due to parasitic infestation.

## CONTRAINDICATIONS

Panolog Cream should not be used ophthalmically.

J4-402C

J4-402C

## WARNINGS

Panolog Cream is indicated for use in dogs and cats only. Not for use in animals which are raised for food.

Absorption of triamcinolone acetonide through topical application and by licking may occur. Therefore animals should be observed closely for signs of polydipsia, polyuria and increased weight gain particularly when the preparation is 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

Panolog Cream (Nystatin-Neomycin Sulfate-Thiostrepton-Triamcinolone Acetonide Cream) is not intended for the treatment of deep abscesses or deep-seated infections such as inflammation of the lymphatic vessels. Parenteral antibiotic therapy is indicated in these infections.

Panolog Cream has been extremely well tolerated. The occurrence of systemic reactions is rarely a problem with topical administration.



Manufactured by  
Bristol-Myers Squibb, Humacao, PR 00791 for  
**Fort Dodge Animal Health**  
Fort Dodge, Iowa 50501 U.S.A.

ER12830A

Revised March 1998

J4-402C

J4-402C

Sensitivity to neomycin may occur. If redness, irritation or swelling persists or increases, discontinue use. Do not use if pus is present since the drug may allow the infection to spread.

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

Frequency of administration is dependent on the severity of the condition. For mild inflammations, application may range from once daily to once a week; for severe conditions Panolog Cream may be applied as often as 2 to 3 times daily, if necessary. Frequency of treatment may be decreased as improvement occurs.

Clean affected areas, removing any encrusted discharge or exudate. Apply Panolog Cream sparingly in a thin film.

## HOW SUPPLIED

Panolog Cream (Nystatin-Neomycin Sulfate-Thiostrepton-Triamcinolone Acetonide Cream) is supplied in 7.5 gram and 15 gram tubes.

J4-402C



Exp. Date

Lot

CLIENT \_\_\_\_\_  
PATIENT \_\_\_\_\_  
DIRECTIONS \_\_\_\_\_

Nystatin... 100,000 units  
Neomycin Sulfate  
equivalent to  
neomycin base ... 2.5 mg  
Thiostrepton... 2,500 units  
Triamcinolone  
Acetonide ..... 1 mg  
per gram

in an aqueous vanishing  
cream base with cetearyl  
alcohol (and) cetearth-  
20, ethylenediamine hy-  
drochloride, methylpara-  
ben, propylparaben, pro-  
pylene glycol, sorbitol  
solution, titanium diox-  
ide, sodium citrate, citric  
acid, white petrolatum,

# Panolog<sup>®</sup> Cream

**NYSTATIN-  
NEOMYCIN  
SULFATE-  
THIOSTREPTON-  
TRIAMCINOLONE  
ACETONIDE  
CREAM**

**FORT DODGE<sup>®</sup>**

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

FOR TOPICAL USE ON  
DOGS AND CATS ONLY

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

Read all sides

## 15 g

glyceryl monostearate,  
polyethylene glycol  
monostearate, sorbic  
acid and simethicone.

**Usual dosage:** Apply to  
affected area 1 to 3 times  
daily—See insert

**Store at room tempera-  
ture; avoid excessive  
heat (104° F)**

Manufactured by  
Bristol-Myers Squibb  
Humacao, PR 00791 for  
**Fort Dodge  
Animal Health**  
Fort Dodge, Iowa 50501  
U.S.A.

90358 L8255C/ER12833A

# Panolog<sup>®</sup> Cream

**NYSTATIN-NEOMYCIN  
SULFATE-THIOSTREPTON-  
TRIAMCINOLONE  
ACETONIDE CREAM**

## 15 g



**Fj**  
094



**Panolog<sup>®</sup>  
Cream**

NYSTATIN-NEOMYCIN  
SULFATE-THIOSTREPTON-  
TRIAMCINOLONE  
ACETONIDE CREAM  
7.5 g

**Panolog<sup>®</sup>  
Cream**

NYSTATIN-  
NEOMYCIN  
SULFATE-  
THIOSTREPTON-  
TRIAMCINOLONE  
ACETONIDE  
CREAM

**FORT DODGE<sup>®</sup>**

FOR TOPICAL USE ON  
DOGS AND CATS ONLY

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

Read all sides

**7.5 g**

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

**Fj**  
094

Nystatin ..... 100,000 units  
Neomycin Sulfate  
equivalent to  
neomycin base ..... 2.5 mg  
Thiostrepton ..... 2,500 units  
Triamcinolone  
Acetonide ..... 1 mg  
per gram

in an aqueous vanishing  
cream base with cetearyl alco-  
hol (and) ceteareth-20, ethyl-  
enediamine hydrochloride,  
methylparaben, propylpara-  
ben, propylene glycol, sorbitol  
solution, titanium dioxide,  
sodium citrate, citric acid.

white petrolatum, glyceryl  
monostearate, polyethylene  
glycol monostearate, sorbic  
acid and simethicone.

**Usual dosage:** Apply to affect-  
ed area 1 to 3 times daily—See  
insert

**Store at room temperature;  
avoid excessive heat (104° F)**

Manufactured by  
Bristol-Myers Squibb  
Humacao, PR 00791 for

**Fort Dodge  
Animal Health  
Fort Dodge, Iowa 50501  
U.S.A.**

90358 L82568/ER12831A

