

Approval Date: NOV 14 2005

FREEDOM OF INFORMATION SUMMARY
ORIGINAL ABBREVIATED NEW ANIMAL DRUG
APPLICATION
ANADA 200-362

PRICONAZOLE Lotion, 1% and Spray, 1%
(miconazole nitrate)

**Indications for use: for the topical treatment of fungal infections
in dogs and cats caused by *Microsporum canis*, *Microsporum*
gypseum, and *Trichophyton mentagrophytes*.**

Sponsored by:

First Priority, Inc.

2005-200-362

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FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-362
- b. Sponsor: First Priority, Inc.
1585 Todd Farm Dr.
Elgin, IL 60123

Drug Labeler Code: 058829
- c. Established Name: Miconazole nitrate
- d. Proprietary Name: PRICONAZOLE Lotion, 1%
PRICONAZOLE Spray, 1%
- e. Dosage Form: Liquid and Spray
- f. How Supplied: Lotion, 1%: 30 mL and 60 mL bottles
Spray, 1%: 120 mL and 240 mL bottles
- g. How Dispensed: Rx
- h. Amount of Active Ingredients: Lotion: 1.15% of miconazole nitrate
(equivalent to 1% of miconazole base by weight).
Spray: 1.15% of miconazole nitrate
(equivalent to 1% of miconazole base by weight).
- i. Route of Administration: Topical
- j. Species/Class: Dogs and cats
- k. Recommended Dosage: Apply a light covering to affected areas,
once daily for 2 to 4 weeks.
- l. Pharmacological Category: Antifungal
- m. Indications: PRICONAZOLE (miconazole nitrate)
Lotion, 1% and Spray, 1% is indicated for
the treatment of fungal infections in dogs
and cats caused by *Microsporum canis*,
Microsporum gypseum, and *Trichophyton*
mentagrophytes.

- n. Pioneer Product: CONOFITE Lotion 1% and Spray, 1%;
miconazole nitrate, NADA 095-184;
Schering-Plough Animal Health 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 shows 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 on the formulation characteristics of the generic product, First Priority, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product PRICONAZOLE (miconazole nitrate) Lotion, 1% and Spray, 1%. The generic product is administered as a topical spray or lotion, contains the same active ingredients 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, CONOFITE (miconazole nitrate) Lotion, 1% and Spray, 1%, the subject of Schering-Plough Animal Health Corp. (NADA 095-184), was approved on September 30, 1974.

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 statements are provided on the product labeling as follows: **“Keep out of the reach of children.**

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 PRICONAZOLE (miconazole nitrate) Lotion, 1% and Spray, 1%, when used under their proposed conditions of use, they are safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

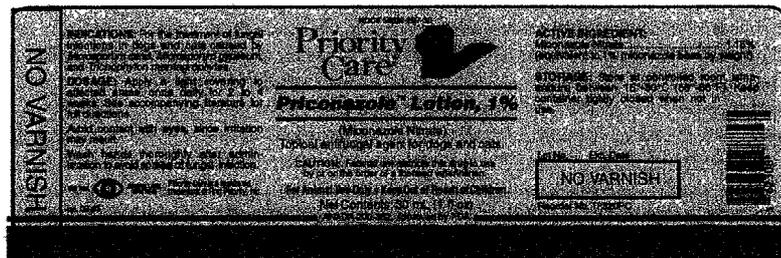
Generic Labeling for ANADA 200-362:

PRICONAZOLE Lotion, 1% (miconazole nitrate) 30 mL (1 fl. oz.) label
PRICONAZOLE Lotion, 1% (miconazole nitrate) 60 mL (2 fl. oz.) label
PRICONAZOLE Spray, 1% (miconazole nitrate) 120 mL (4 fl. oz.) label
PRICONAZOLE Spray, 1% (miconazole nitrate) 240 mL (16 fl. oz.) label
PRICONAZOLE Lotion, 1% and Spray, 1% (miconazole nitrate) Package Insert

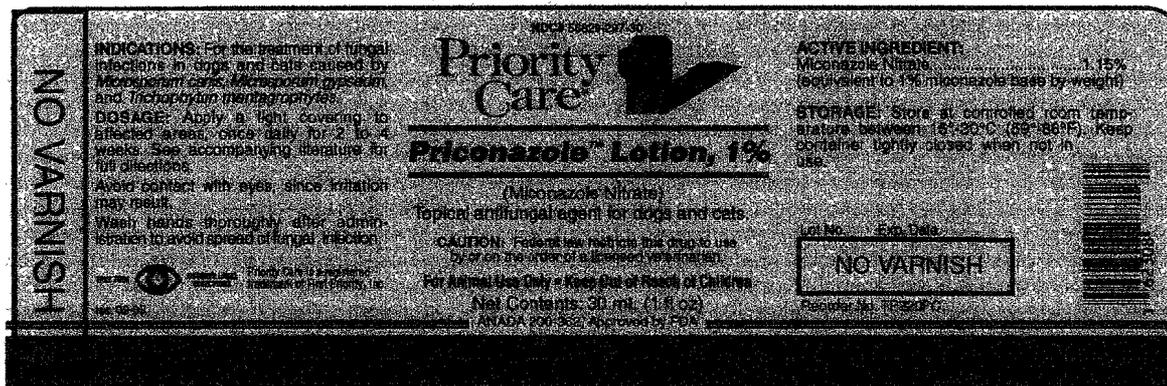
Pioneer Labeling for NADA 95-184:

CONOFITE Lotion, 1% (miconazole nitrate) 30 mL label
CONOFITE Spray, 1% (miconazole nitrate) 60 mL label
CONOFITE Lotion, 1% and Spray, 1% (miconazole nitrate) Package Insert

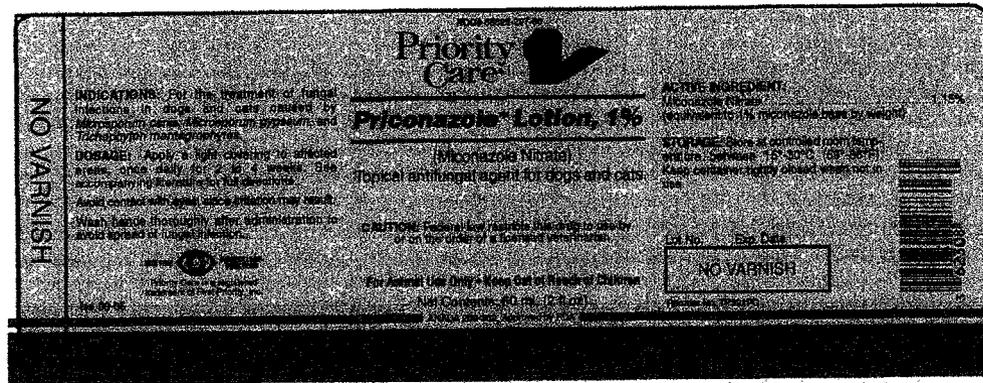
Actual Label Size
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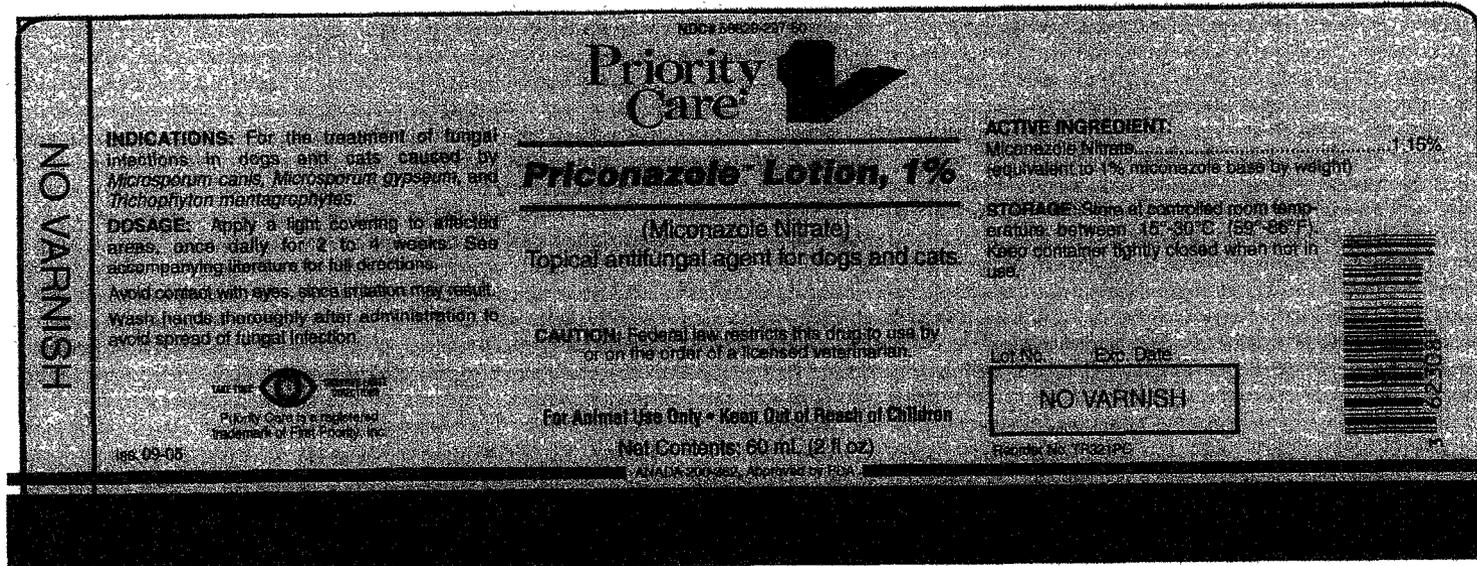
Enlargement



Actual Label Size
1.875 x 5



Enlargement



Actual Label Size
3 x 4.75

NDC# 54820-207-12

INDICATIONS: For the treatment of fungal infections in dogs and cats caused by *Microsporum canis*, *Microsporum gypseum*, and *Dichomyces dermatophytes*.

DOSEAGE: Apply a thin coating to affected areas once daily for 2 to 4 weeks. See accompanying literature for full directions.

Avoid contact with eyes. Since irritation may result.

Wash hands thoroughly after administration to avoid spread of fungal infection.

Priority Care



Priconazole™ Spray, 1%

(Miconazole Nitrate)

Topical antifungal agent for dogs and cats.

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

For Animal Use Only • Keep Out of Reach of Children

Net Contents: 120 mL (4 fl. oz.)

ANADA 200-562 Approved by FDA

ACTIVE INGREDIENT
Miconazole Nitrate .15%
(equivalent to 1% miconazole base by weight)

STORAGE: Store at controlled room temperature (20° to 25°C [68° to 77°F]) between 10° and 30°C (50° and 86°F). Keep container tightly closed when not in use.

Lot No.	Exp. Date
NO VARNISH	

Reader No. TP322PG

Priority Care is a registered trademark of First Priority, Inc.
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100-03-05

Actual Label Size
4.375 x 5.875

NDC 31223-207-04

INDICATIONS: For the treatment of fungal infections in dogs and cats caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes*.

DOSAGE: Apply a light coating to affected areas once daily for 2 to 4 weeks. See accompanying literature for full directions.

Avoid contact with eyes; some irritation may result.

Wash hands thoroughly after administration to avoid spread of fungal infection.

Priority Care



PriconazoleTM Spray, 1%

(Miconazole Nitrate)

Topical antifungal agent for dogs and cats.

ACTIVE INGREDIENT:
Miconazole Nitrate... 1.15%
(equivalent to 1% miconazole base by weight)

STORAGE: Store at controlled room temperature between 15°-30°C (59°-86°F). Keep container tightly closed when not in use.

 **Pfizer Inc.**
Priority Care is a registered trademark of Pfizer Inc., NY.

188 (2-05)

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

For Animal Use Only • Keep Out of Reach of Children

Net Contents: 240 mL (8 fl oz)

ANADA 200-362 / Approved by FDA

Lot No. Exp. Date

NO VARNISH

Product No. TP323PC

Priconazole™
Lotion, 1% & Spray, 1%

(Miconazole Nitrate)

DESCRIPTION: Priconazole™ (miconazole nitrate) Lotion, 1% & Spray, 1% is a synthetic antifungal agent for use in dogs and cats. It contains: 1.15% miconazole nitrate (equivalent to 1% miconazole base by weight), polyethylene glycol 400, and ethyl alcohol 55%.

INDICATIONS: Priconazole™ (miconazole nitrate) Lotion, 1% & Spray, 1% is indicated for the treatment of fungal infections in dogs and cats caused by *Microsporum canis*, *Microsporum gypsum*, and *Trichophyton mentagrophytes*.

PRECAUTIONS: In the event of sensitization or irritation due to Priconazole™ (miconazole nitrate) Lotion, 1% or Spray, 1%, treatment should be discontinued. Avoid contact with eyes, since irritation may result. Wash hands thoroughly after administration to avoid spread of fungal infection.

DOSAGE AND ADMINISTRATION: Accurate diagnosis of the infecting organism is essential. Identification should be made either by direct microscopic examination of a mounting of infected tissue in a solution of potassium hydroxide, or by culture on an appropriate medium.

Lotion: Apply a light covering of Priconazole™ (miconazole nitrate) Lotion, 1% or Spray, 1% to affected areas, once daily, for 2 to 4 weeks.

Spray: Spray affected areas from a distance of 2 to 4 inches to apply a light covering, once daily for 2 to 4 weeks.

Application is best accomplished using a gauze pad or cotton swab. Medication must be continued until the infecting organism is completely eradicated as indicated by appropriate clinical or laboratory examination. If no improvement is noticed within 2 weeks, diagnosis should be reevaluated. Difficult cases may require treatment for 6 weeks.

General measures in regard to hygiene should be observed to control sources of infection or reinfection. Clipping of hair around and over the sites of infection should be done at the start of treatment and again as necessary.

HOW SUPPLIED: Priconazole™ (miconazole nitrate) Lotion, 1% is available in 30 mL & 60 mL bottles with droppers, and Priconazole™ (miconazole nitrate) Spray, 1% is available in 120 mL & 240 mL bottles with spray misters.

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



Iss. 10-03

**Priority
Care** 

Manufactured By:
FIRST PRIORITY, INC.
Elgin, IL 60123-1146

ANADA# 200-362,
Approved by FDA



Topical antifungal agent for dogs and cats.

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

60 mL

sp Schering-Plough Animal Health

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CONCISE: Spray contains: 1.15% miconazole nitrate (equivalent to 1% miconazole base by weight), polyethylene glycol 400, and ethyl alcohol 55%.

DOSE AND ADMINISTRATION: Spray affected areas from a distance of 2 to 4 inches to apply a light covering, once daily for 2 to 4 weeks. Do not allow pet to contact finished wood surfaces until pet is thoroughly dried. See accompanying literature for full directions.

Avoid contact with eyes, since irritation may result.

Wash hands thoroughly after administration to avoid spread of fungal infection.

20504705 Rev. 10/97

F-21093807

Conofite[®] SPRAY, 1%
AND LOTION, 1%
(MICONAZOLE NITRATE)

DESCRIPTION: CONOFITE (miconazole nitrate) Spray or Lotion is a synthetic antifungal agent for use in dogs and cats. It contains: 1.15% miconazole nitrate (equivalent to 1% miconazole base by weight), polyethylene glycol 400, and ethyl alcohol 55%.

INDICATIONS: CONOFITE (miconazole nitrate) Spray or Lotion is indicated for the treatment of fungal infections in dogs and cats caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes*.

PRECAUTIONS: In the event of sensitization or irritation due to CONOFITE Spray or Lotion, treatment should be discontinued. Avoid contact with eyes, since irritation may result. Wash hands thoroughly after administration to avoid spread of fungal infection.

DOSAGE AND ADMINISTRATION: Accurate diagnosis of the infecting organism is essential. Identification should be made either by direct microscopic examination of a mounting of infected tissue in a solution of potassium hydroxide, or by culture on an appropriate medium.

Spray: Spray affected areas from a distance of 2 to 4 inches to apply a light covering, once daily for 2 to 4 weeks. Do not allow pet to contact finished wood surfaces until pet is thoroughly dried.

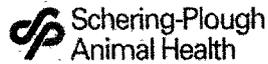
Lotion: Apply a light covering of CONOFITE (miconazole nitrate) Lotion to affected areas, once daily, for 2 to 4 weeks. Application is best accomplished using a gauze pad or cotton swab.

Medication must be continued until the infecting *organism is completely eradicated as indicated* by appropriate clinical or laboratory examination. If no improvement is noticed within 2 weeks, diagnosis should be reevaluated. Difficult cases may require treatment for 6 weeks.

General measures in regard to hygiene should be observed to control sources of infection or reinfection. Clipping of hair around and over the sites of infection should be done at the start of treatment and again as necessary.

HOW SUPPLIED: CONOFITE (miconazole nitrate) Spray, available in 60 mL containers (NDC 0061-5022-01) and CONOFITE (miconazole nitrate) Lotion available in 30 mL containers (NDC 0061-5031-01).

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



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B-21093807

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