MICONOSOL - miconazole nitrate lotion Med-Pharmex, Inc

Miconosol Lotion 1% and Spray 1% (Miconazole Nitrate)

ANADA #200-196, approved by FDA.

DESCRIPTION: Miconosol (Miconazole Nitrate) Lotion and Spray 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: Miconosol (Miconazole Nitrate) Lotion and Spray 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 Miconosol (Miconazole Nitrate) Lotion and Spray, 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 Miconosol (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 re-evaluated. Difficult cases may require treatment for 6 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. 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 re-evaluated. 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: Miconosol (Miconazole Nitrate) Lotion in 60 mL containers. Miconosol (Miconazole Nitrate) Spray in 120 mL and 240 mL containers.

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

August 1997

NDC 54925-031-06

MICONOSOL LOTION 1%

Antifungal

(Miconazole Nitrate)
Topical antifungal agent
for dogs and cats.

this drug to use by or on the order of a licensed veterinarian.

Net Contents: 60 mL



ANADA #200-196 Approved by FDA

Lot No. / Exp. Date

Avoid contact with eyes, since irritation may result. Wash hands thoroughly DOSAGE: Apply a light covering to affected areas, once daily, for 2 to 4 after administration to avoid spread of fungal infection weeks. See accompanying literature for full directions.

DOSAGE: Spray affected areas, from a distance of 2 to 4 inches to apply a light covering, once daily for 2 to 4 weeks. See accompanying literature for full directions.

Wash hands thoroughly after administration to avoid

spread of fungal infection.

Avoid contact with eyes, since irritation may result.

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

NDC 54925-031-12

MICONOSOL 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.

NET CONTENTS: 120 mL



ANADA # 200 - 196, Approved by FDA

Lot No. / Exp. Date

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

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

See accompanying literature for full directions.

Wash hands thoroughly after administration to avoid spread

of fungal infection.

Avoid contact with eyes, since irritation may result.

NDC 54925-031-24

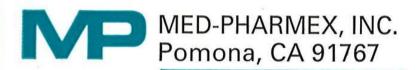
MICONOSOL Spray 1%

(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.

NET CONTENTS: 240 mL



ANADA # 200 - 196, Approved by FDA

Lot No. / Exp. Date

MICONOSOL

miconazole nitrate lotion

Product Information					
Product Type	PRESCRIPTION ANIMAL DRUG LABEL	Item Code (Source)	NDC:54925- 031		
Route of Administration	TOPICAL	DEA Schedule			

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
Miconazole Nitrate (Miconazole)	Miconazole Nitrate	1.0 g in 100 mL			

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:54925-031-06	60 mL in 1 BOTTLE				
2	NDC:54925-031-12	120 mL in 1 BOTTLE, SPRAY				
3	NDC:54925-031-24	240 mL in 1 BOTTLE, SPRAY				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANADA	ANADA200196	10/08/2012			

Labeler - Med-Pharmex, Inc (025353699)

Revised: 10/2012 Med-Pharmex, Inc