

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

DOSAGE: Apply a light covering 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.

NDC 54925-031-06

MICONOSOL LOTION 1%

Antifungal

(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: 60 mL



MED-PHARMEX™
INCORPORATED
POMONA, CA 91767

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.

Avoid contact with eyes, since irritation may result.

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

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



MED-PHARMEX, INC.
Pomona, CA 91767

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.

Avoid contact with eyes, since irritation may result.

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

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



MED-PHARMEX, INC.
Pomona, CA 91767

ANADA # 200 - 196, Approved by FDA

Lot No. / Exp. Date

MICONOSOL

miconazole nitrate lotion

Product Information

Product Type

PRESCRIPTION ANIMAL DRUG

Item Code (Source)

NDC:54925-031

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)		Miconazole Nitrate	1.0 g in 100 mL	
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