MICONOSOL- miconazole nitrate lotion
Med-Pharmex, Inc

Miconosol Lotion 1% and Miconosol Spray 1%

(miconazole nitrate)

Approved by FDA under ANADA # 200-196

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

DESCRIPTION: Miconosol Lotion 1% and Miconosol Spray 1% are synthetic antifungal agents for use in dogs and cats. Both Miconosol Lotion 1% and Miconosol Spray 1% contain 1.15% miconazole nitrate (equivalent to 1% miconazole base by weight), polyethylene glycol 400 and ethyl alcohol 55%.

INDICATIONS:

Miconosol Lotion 1% and Miconosol Spay 1% are 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 Lotion 1% or Miconosol 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.

Miconosol Lotion 1%: 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.

Miconosol Spray 1%: 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.

CONTACT INFORMATION:
To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Med-Pharmex at (800) 587-4306.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/reportanimalae

HOW SUPPLIED:

Miconosol Lotion 1% is available in 60 mL containers.

Miconosol Spray 1% is available in 120 mL and 240 mL spray bottles.

Manufactured by:
Med-Pharmex, Inc.
Pomona, CA 91767

Rev. July 2023

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.

STORAGE: Store upright at room temperature between 15°-25°C (59°-77°F).

Rev. 05/2023
Lot No./Exp. Date

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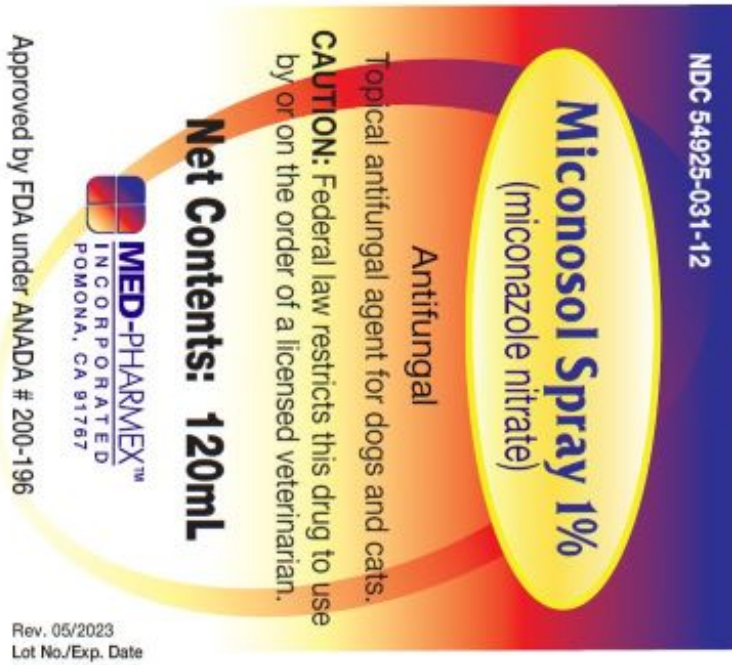

Rev. 05/2023
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MICONOSOL

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

Inactive Ingredients	
Ingredient Name	**Strength**
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	1 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)

Registrant - Med-Pharmex, Inc. (025353699)

Establishment

Name	Address	ID/FEI	Business Operations
Med-Pharmex, Inc.		025353699	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Erregierre		437721244	api manufacture

Revised: 7/2023 Med-Pharmex, Inc