VETADERM MICONITRATE- miconazole nitrate lotion Patterson Veterinary

VetaDerm MicoNitrate Lotion 1% and Spray 1% (Miconazole Nitrate)

TOPICAL ANITFUNGAL AGENT FOR DOGS AND CATS.

ANADA #200-196, approved by FDA.

DESCRIPTION: 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: 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 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 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: Miconazole Nitrate Lotion in 60 mL containers. 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: Spray affected areas, from a distance of 2 to 4 inches to apply a light Avoid contact with eyes, since irritation Wash hands thoroughly after adminiscovering, once daily for 2 to 4 weeks. See accompanying literature for full tration to avoid spread of fungal may result. directions. contains: 1.15% miconazole miconazole base by weight), VetaDermTM MicoNitrateTM nitrate (equivalent to 1% Polyethylene glycol 400, and ethyl alcohol 55%.

PV185MPH Rev. 11/17

infection.

PATTERSON° VETERINARY

NDC #14043-604-13

TM VetaDerm **MicoNitrate** TM 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.

ANADA 200-196, Approved by FDA

Net Contents: 120 mL



miconazole nitrate lotion

Product Information				
Product T ype	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:14043-604	
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
MICONAZOTE MILTALE (UMI: VW4HICYWIK) (MICONAZOTE - UMI:/MMOUD/S5M)	MICONAZOIE INITALE	1.0 g III 100 IIIL

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:14043-604-62	60 mL in 1 BOTTLE			
2	NDC:14043-604-13	120 mL in 1 BOTTLE, SPRAY			
3	NDC:14043-604-09	240 mL in 1 BOTTLE, SPRAY			

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
NADA200196	0 1/0 1/20 18			
	Application Number or Monograph Citation	Application Number or Monograph Citation Marketing Start Date		

Labeler - Patterson Veterinary (006962500)

Registrant - Med-Pharmex, Inc (025353699)

Establishment

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

Revised: 6/2018

Patterson Veterinary