MICONAZOLE NITRATE- miconazole nitrate cream Preferred Pharmaceuticals Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Miconazole Nitrate

Drug Facts

Active ingredient

Miconazole nitrate USP, 2%

Purpose

Antifungal

Uses

- proven clinically effective in the treatment of most athlete's foot, jock itch, and ringworm
- for effective relief of itching, scaling, cracking, burning, and discomfort

Warnings

For external use only

Do not use on children under 2 years of age unless directed by a doctor.

When using this product, avoid contact with the eyes.

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot and ringworm) or within 2 weeks (for jock itch)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- clean the affected area and dry thoroughly
- apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor
- supervise children in the use of this product

- for athlete's foot: pay special attention to the spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily
- for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks
- if condition lasts longer, contact a doctor
- this product is not effective on the scalp or nails

Other information

- do not use if foil seal on tube opening is broken or missing
- to open tube: unscrew cap, lift tab, and pull to remove foil seal prior to use
- store at room temperature 15°-30°C (59°-86°F)
- before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredients

benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl polyoxylglycerides, pegoxol 7 stearate, purified water

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Distributed by: **H2-Pharma, LLC**

Montgomery, AL 36117

Relabeled By: Preferred Pharmaceuticals Inc.

PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

Miconazole Nitrate Cream USP, 2% Antifungal Cream

NDC 68788-8107-2

*Compare to the active ingredient in

Micatin® Antifungal Cream

Soothes itching, scaling, cracking, and burning | Cures most athlete's foot, jock itch, and ringworm | Clinically proven

Net wt. 1 oz (28 g)

H² pharma

Relabeled By: Preferred Pharmaceuticals Inc.

Miconazole Nitrate 2% Cream

Generic for Monistat Active Ingredient Miconazole Nitrate, 2% ...

Antifungal Pkg Size: Exp Date:

Lot#: Batch#:

Ins: Mfg: H2-Pharma, LLC Prod#:

Warning use on children under 2 years of age unless by a doctor. When using this product, avoid or there is no improvement within 4 weeks (for of there is no improvement within 4 weeks (for oscillation). The constraint of the co

PREFERRED

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ackage,

as directed on

external use only.

For

doctor

CAUTION: Federal law PROHIBITS transfer of this drug to any person other thean the patient for whom it was prescribed

Jtilice como dirigido en Uso según lo dirigido por su doctor paquete.

Para exteramente

Miconazole Nitrate 2% Cream Qty: Ins: Lot#: Bat#:

Qty: Ins: Lot#: Bat#:

Prod# (NDC):

Miconazole Nitrate 2% Cream

Log

Chart

Patient

Miconazole Nitrate 2% Cream Insurance NDC:

Miconazole Nitrate 2% Cream Qty: Ins: Lot#: Bat#: Prod# (NDC):

MICONAZOLE NITRATE

miconazole nitrate cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68788-8107(NDC:61269-735) **Route of Administration TOPICAL**

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE -MICONAZOLE NITRATE 20 mg in 1 g UNII:7NNO0D7S5M)

Inactive Ingredients Strength **Ingredient Name** BENZOIC ACID (UNII: 85KN0B0MIM) **BUTYLATED HYDROXYANISOLE** (UNII: REK4960K2U) MINERAL OIL (UNII: T5L8T28FGP)

APRICOT KERNEL OIL PEG-6 ESTERS (UNII: DRG3KJZ1TJ)

PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)

WATER (UNII: 059QF0KO0R)

Product Characteristics

- round on a constant				
Color	WHITE	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

Packaging

Marketing Start Marketing End

1	#	item Code	Раскаде резсприон	Date	Date
		NDC:68788- 8107-2	1 in 1 CARTON	11/03/2021	
	1		28 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part333C	11/03/2021			

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment						
Name	Address	ID/FEI	Business Operations			
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-8107)			

Revised: 8/2023 Preferred Pharmaceuticals Inc.