

MICONAZOLE NITRATE- miconazole nitrate cream
Preferred Pharmaceuticals Inc.

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 polyoxyglycerides, 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

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 and ask doctor if irritation occurs or there is no improvement within 4 weeks (for athlete's foot and ringworm), irritation occurs or there is no improvement within 2 weeks (for jock itch). Store at room temperature (15° - 30°C (59° - 86°F)). Keep out of reach of children. Do not use if safety-sealed tube is punctured or damaged.



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

Miconazole Nitrate 2% Cream

Qty: Ins:
Lot#: Bat#:

Prod# (NDC):

Miconazole Nitrate 2% Cream

Qty: Ins:
Lot#: Bat#:
Prod# (NDC):

Miconazole Nitrate 2% Cream

Qty: Ins:
Insurance NDC:
Lot#: Bat#:

Miconazole Nitrate 2% Cream

Qty: Ins:
Lot#: Bat#:
Prod# (NDC):



Directions English

Use as directed on package.
Use as directed by your doctor
For external use only.



Instrucciones Espanol:

Utilice como dirigido en el paquete.
Uso según lo dirigido por su doctor
Para externamente aplique

Log

Chart

Billing

Patient

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 - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
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

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
---	-----------	---------------------	-----------------	---------------

#	Item Code	Package Description	Date	Date
1	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 Drug	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: 7/2024

Preferred Pharmaceuticals Inc.