

MICONAZOLE NITRATE- miconazole nitrate cream
H2-Pharma, LLC

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 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

PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

Miconazole Nitrate Cream USP, 2%
Antifungal Cream

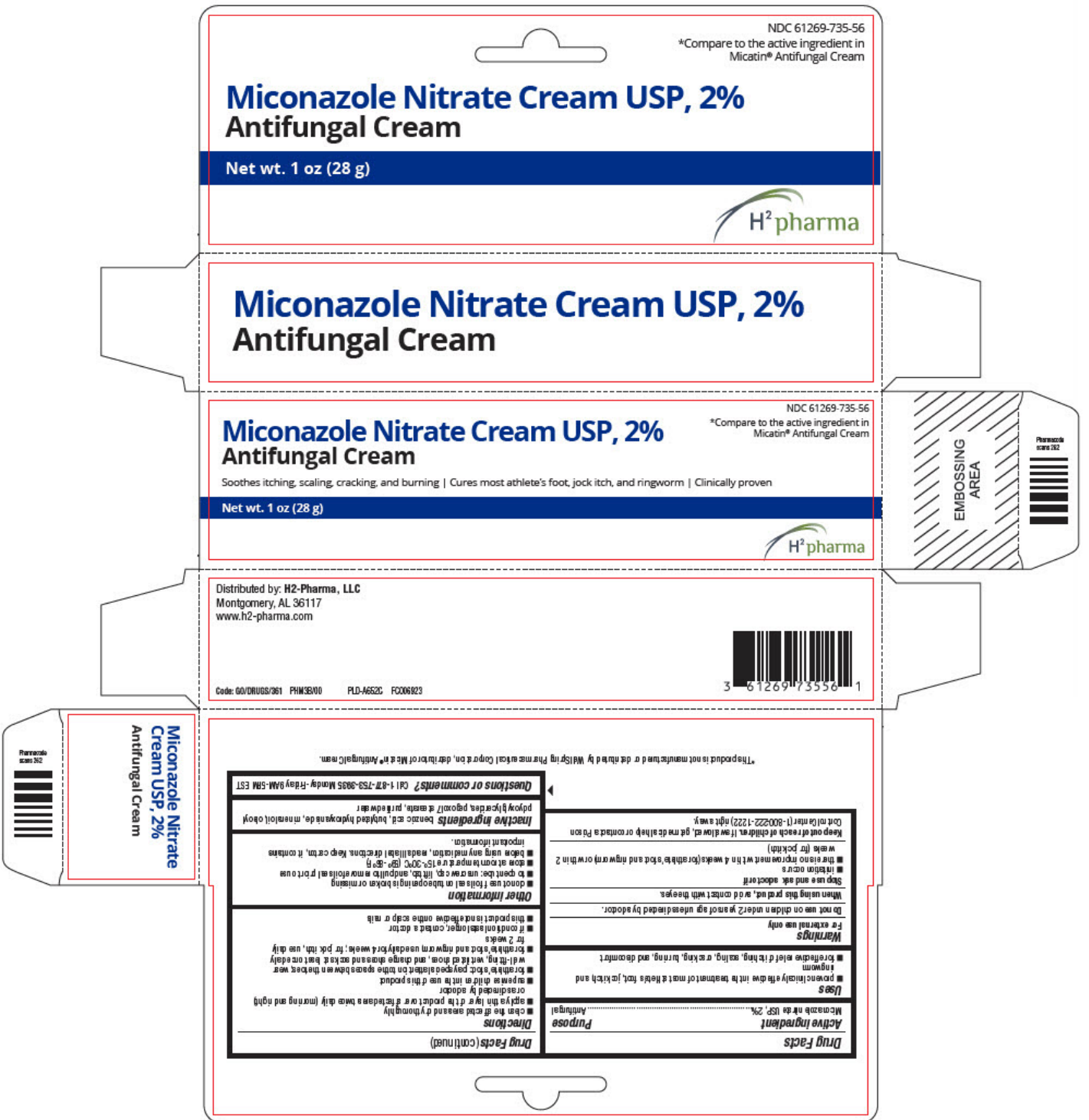
NDC 61269-735-56

*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



MICONAZOLE NITRATE			
miconazole nitrate cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	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 Date	Marketing End Date
1	NDC:61269-735-14	1 in 1 CARTON	06/29/2021	
1		14 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:61269-735-56	1 in 1 CARTON	06/29/2021	
2		28 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:61269-735-42	1 in 1 CARTON	06/29/2021	
3		42.5 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	06/29/2021		

Labeler - H2-Pharma, LLC (028473634)