

MICONAZOLE NITRATE- miconazole nitrate cream
H2-Pharma, LLC

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

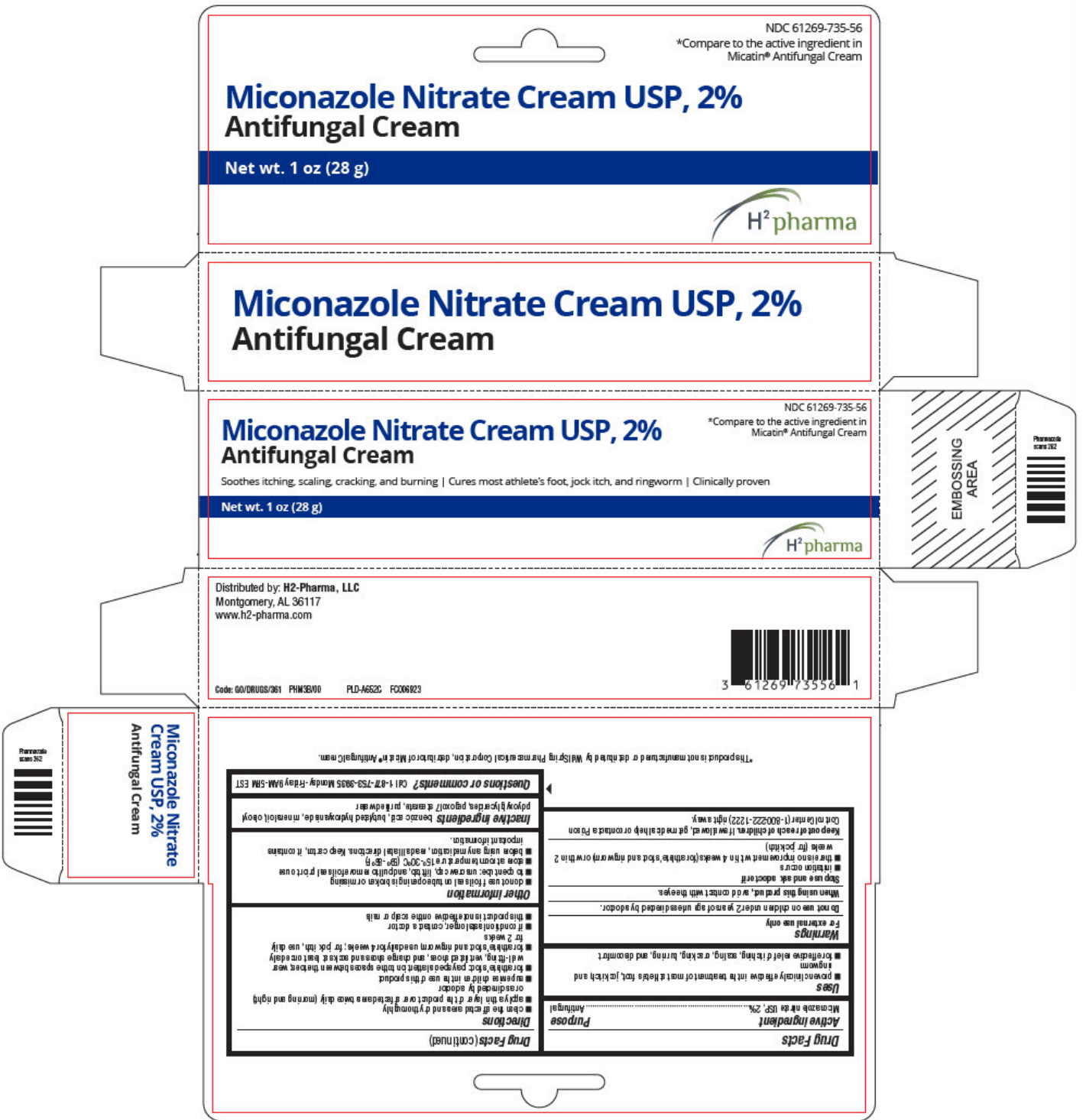
NDC 61269-735-56

*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	12/31/2025
1		14 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:61269-735-56	1 in 1 CARTON	06/29/2021	12/31/2025
2		28 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:61269-735-42	1 in 1 CARTON	06/29/2021	12/31/2025
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 Drug	M005	06/29/2021	12/31/2025	

Labeler - H2-Pharma, LLC (028473634)