MICONAZOLE NITRATE 2%- miconazole nitrate cream Pharmaceutica North America, Inc.

Active Ingredient

Miconazole Nitrate 2%

Purpose

Anti-Fungal

Uses

- proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis)
- relieves itching, scaling, cracking, burning and discomfort associated with these conditions.

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 or if there is no improvement within 4 weeks (for athlete's foot and ringworm)
- Irritation occurs, or if there is no improvement 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) immediately.

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 healthcare professional
- Supervise children in the use of this product.

For athlete's foot:

- Use daily for 4 weeks. If condition persists, consult a doctor
- Pay special attention to the spaces between the toes
- Wear well fitting, ventilated shoes
- Change socks at least once daily.

For ringworm: Use daily for 4 weeks. If condition persists, consult a doctor. **For jock itch**: Use daily for 2 weeks. If condition persists longer, consult a doctor. This product is not effective on the scalp or nails.

Other information

• store at 15° - 30°C (59 - 86°F)

Inactive Ingredients

Carbomer, alcohol, cetostearyl alcohol, dimethyl sulfoxide, edetate disodium, ethylparaben, glycerol, mineral oil, mono and di glycerides, polyoxyethylene lauryl ether, purified water, stearic acid, triethanolamine, petrolatum.

Questions or comments? (888)788-6472

Product label



NDC: 45861-078-03

Miconazole Nitrate 2%



Anti-fungal

30gm

Active Ingredient

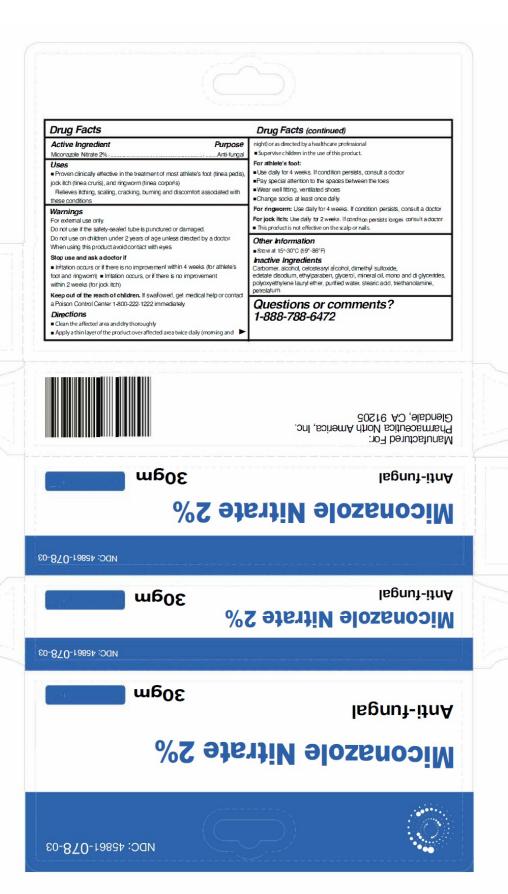
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MICONAZOLE NITRATE 2%

miconazole nitrate cream

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45861-078		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M) MICONAZOLE NITRATE 2 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
ETHYLPARABEN (UNII: 14255EXE39)			
GLYCERIN (UNII: PDC6A3C0OX)			
MINERAL OIL (UNII: T5L8T28FGP)			
LAURETH-30 (UNII: W9D845551A)			
WATER (UNII: 059QF0KO0R)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TROLAMINE (UNII: 903K93S3TK)			
PETROLATUM (UNII: 4T6H12BN9U)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			
GLYCERYL MONO AND DIPALMITOSTEARATE (UNII: KC98RO82HJ)			
ALCOHOL (UNII: 3K9958V90M)			

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:45861-078- 03	1 in 1 BOX	02/01/2025				
1		30 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	M017	02/01/2025			

Labeler - Pharmaceutica North America, Inc. (962739699)