MICONAZOLE NITRATE- miconazole nitrate cream Aru Pharma 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.

QPACK MICONAZOLE NITRATE CREAM 2%

Drug Facts

Active ingredient

Miconazole Nitrate USP 2%

Purpose

Antifungal

Uses

- effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis)
- for effective relief of itching, scaling, cracking, burning and discomfort that can accompany these conditions.

Warnings

For external use only

Do not use on children less than 2 years of age unless directed by a doctor **When using this product** avoid contact with eyes

Stop use and ask a doctor if • irritation occurs • condition persist • there is no improvement of athlete's foot or ringworm within 4 weeks or jock itch within 2 weeks.

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

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 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

• not effective on the scalp or nails

Inactive ingredients

Cetostearyl alcohol, Cetomacrogol 1000, Paraffin wax, Micro crystalline wax, Light liquid paraffin, Polyethylene Glycol, Chlorocresol and purified water

Other information

- Do not use if seal is damaged or is not visible. To open, unscrew cap, pull tab to remove foil seal store at room temperature not exceeding 30°C (86°F). Do not freeze.
- see carton or tube crimp for lot number and expiration date

Questions or comments?

1844 500-2729 between 9 am and 4 pm EST, Monday to Friday.

CURES MOST ATHLETE'S FOOT

Relieves Itching and Burning Sensation Relieves from Cracking and scaling. Grease less and non-staining

Compared to the active ingredient in Micatin

Distributed by.

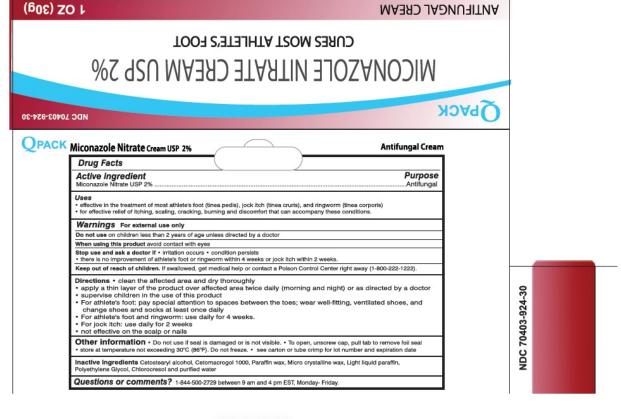
ARU PHARMA INC.

MOUNT VERNON, NY 10552

www.qpackrx.com

Packaging





INNER LABEL



MICONAZOLE NITRATE

miconazole nitrate cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70403-924	
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		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
CETETH-20 (UNII: 1835H2IHHX)			
PARAFFIN (UNII: 1900E3H2ZE)			
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)			
LIGHT MINERAL OIL (UNII: N6K5787QVP)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
CHLOROCRESOL (UNII: 36W53O7109)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics			
Color	white (white to off white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70403-924- 30	1 in 1 CARTON	01/01/2018	03/31/2025
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 final	part333C	01/01/2018	03/31/2025

Labeler - Aru Pharma Inc. (079736192)

Revised: 5/2023 Aru Pharma Inc.