

**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.*

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**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?**

1 844 500-2729 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**



ANTIFUNGAL CREAM

CURES MOST ATHLETE'S FOOT

MICONAZOLE NITRATE CREAM USP 2%

QPACK

NDC 70403-924-30


(30g) 1 OZ

QPACK Miconazole Nitrate Cream USP 2% Antifungal Cream

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NDC 70403-924-30

INNER LABEL

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<p style="text-align: right;">NDC 70403-924-30 Compare to other antifungal ingredient in Micatin</p> <p style="text-align: center;">MICONAZOLE NITRATE CREAM USP 2%</p> <p style="text-align: center;">CURES MOST ATHLETE'S FOOT</p> <p style="text-align: left;">ANTIFUNGAL CREAM</p> <p style="text-align: right;">1 OZ (30g)</p>		

## MICONAZOLE NITRATE

miconazole nitrate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70403-924
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>MICONAZOLE NITRATE</b> (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETETH-20</b> (UNII: I835H2IHHX)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>CHLOROCRESOL</b> (UNII: 36W53O7109)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Product Characteristics**

<b>Color</b>	white (white to off white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**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)