

**MICONAZOLE NITRATE- miconazole nitrate cream**  
**Taro Pharmaceuticals U.S.A., 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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**Miconazole Nitrate**

***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, 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 persists
- 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

**Other information**

- To open: unscrew cap, use pointed end on cap to puncture seal
- store at 20° - 25°C (68° - 77°F)
- see carton or tube crimp for lot number and expiration date

**Inactive ingredients**

apricot kernel oil, benzoic acid, BHT, glycol stearate, mineral oil, PEG-6, PEG-6-32 stearate, purified water

**Questions?**

Call **1-866-923-4914**

Distributed by:

**Taro Pharmaceuticals**

**U.S.A., Inc.**

Hawthorne, NY 10532

**PRINCIPAL DISPLAY PANEL - 15 g Tube Carton**

*Cures Most Athlete's Foot*

**Antifungal Cream**

**Miconazole Nitrate**

**Cream USP, 2%**

**Antifungal Cream**

NET WT 1/2 oz (15 g)

Compare to the active ingredient in Micatin®\*

Cures Most Athlete's Foot

# Miconazole Nitrate

Cream USP, 2%

Antifungal Cream



- Cures Most Athlete's Foot
- Relieves Itching & Burning
- Also Cures Most Jock Itch and Ringworm

L PK-1067-8  
0611-8  
M295

Cures Most Athlete's Foot

Antifungal Cream

# Miconazole Nitrate

Cream USP, 2%

Antifungal Cream

NET WT 1/2 oz (15 g)

Miconazole Nitrate  
Cream USP, 2%  
Antifungal Cream

T27



**Drug Facts** (continued)

**Inactive ingredients:** apricot kernel oil, benzoic acid, BHT, glycol stearate, mineral oil, PEG-6, PEG-6-32 stearate, purified water

**Questions?** Call 1-866-923-4914

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THIS FLAP FOR LOT #  
AND EXP DATE PRINT

**TARO**  
Taro Pharmaceuticals U.S.A., Inc.  
Hawthorne, NY 10522  
U.S.A., Inc.  
Taro Pharmaceuticals  
Distributed by

**Drug Facts**

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**Purpose**  
Antifungal

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**Other information**  
• Taro is a registered trademark of Taro Pharmaceuticals U.S.A., Inc. Made in Canada.

This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the Miconazole registered trademark.

Miconazole Nitrate  
Cream USP, 2%  
Antifungal Cream

Cures Most Athlete's Foot  
Relieves Burning & Itching,  
Also Cures Most Jock Itch  
and Ringworm

## MICONAZOLE NITRATE

miconazole nitrate cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51672-2001
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
apricot kernel oil (UNII: 54JB35T06A)	
benzoic acid (UNII: 8SKN0B0MIM)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
glycol stearate (UNII: 0324G66D0E)	
mineral oil (UNII: T5L8T28FGP)	
polyethylene glycol 300 (UNII: 5655G9Y8AQ)	
water (UNII: 059QF0K00R)	
PEG-6 stearate (UNII: 8LQC57C6B0)	
PEG-32 stearate (UNII: 33GX5WQC0M)	

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:51672-2001-1	1 in 1 CARTON	10/01/1991	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51672-2001-2	1 in 1 CARTON	10/01/1991	
2		30 g in 1 TUBE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part333C	10/01/1991	

**Labeler** - Taro Pharmaceuticals U.S.A., Inc. (145186370)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-2001)