

**MICONAZOLE NITRATE- miconazole nitrate cream**  
**Rugby Laboratories, 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 Cream USP**

***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**

- do not use if the seal on tube is punctured or not visible
- 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: RUGBY LABORATORIES**

17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152

### **PRINCIPAL DISPLAY PANEL - 30 g Tube Carton**

*Rugby*

**Antifungal Cream**

*Cures Most Athlete's Foot*

**Miconazole Nitrate**

**Cream USP, 2%**

**Antifungal Cream**

**NET WT 1 oz (30 g)**



**Cures Most Athlete's Foot**

# Miconazole Nitrate

**Cream USP, 2%**

## Antifungal Cream

NDC 0536-1134-28

**Compare to the active ingredient in Micatin®\***



LPK-8512-0  
0517-0  
10

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



**Cures Most Athlete's Foot**

# Miconazole Nitrate

**Cream USP, 2%**      **Antifungal Cream**

**NET WT 1 oz (30 g)**

**Antifungal Cream**

**Miconazole Nitrate**  
Cream USP, 2%  
Antifungal Cream

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Micatin®.

**Distributed by: RUGBY LABORATORIES**  
17 177 N Laurel Park Dr., Suite 233, Livonia, MI 48152  
www.rugbylaboratories.com    Re-order No. 370548    Rev. 05/17    R-34  
Made in Canada



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T30  
B654  
ENG19.08

**NO VARNISH/NO AQ  
NO COPY / NO COLOR  
THIS FLAP FOR LOT #  
AND EXP DATE PRINT**

**Drug Facts**

**Active ingredient** Miconazole nitrate USP 2% Antifungal

**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: • 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 the product • for athlete's foot: pay special attention to spaces between 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** • do not use if the seal on tube is punctured or not visible • To open: unscrew cap, use pointed end on cap to puncture seal • see carton or tube crimp for lot number and expiration date

**Inactive ingredients** apocot hemal oil, benzoic acid, EHT, glycol stearate, mineral oil, PEG-9, PEG-D-32 stearate, purified water

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

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B654  
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**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:0536-1134
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4HICYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
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)	
stearyl alcohol (UNII: 2KR89I4HIY)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1134-28	1 in 1 CARTON	05/19/2017	
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	10/01/1991	

**Labeler** - Rugby Laboratories, Inc. (079246066)

Revised: 6/2017

Rugby Laboratories, Inc.