

ANTIFUNGAL- miconazole nitrate cream
Cardinal Health, 110 dba LEADER

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.

Antifungal Cream

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

- **TAMPER EVIDENT: DO NOT USE IF THE SEAL ON THE TUBE IS PUNCTURED OR NOT VISIBLE**
- To open: unscrew cap, use pointed end on cap to puncture seal
- store at 20° to 25°C (68° to 77°F)
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

benzoic acid (0.20%) as a preservative, butylated hydroxytoluene, mineral oil, oleoyl polyoxyglyceride, PEG-6-32 stearate/glycol stearate, and purified water

Questions?

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

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017

PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

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

Antifungal Cream
Miconazole Nitrate Cream USP, 2% | Antifungal

COMPARE TO MICATIN®
active ingredient*

100% Money Back Guarantee

NET WT 1 OZ (30 g)

NDC 70000-0040-1

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CIN 5582036

REV. 2/20



DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myLeader.com 1-800-200-6313
Essential to Care[™] since 1979
Made in Canada

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✓ All LEADER[™] Brand Products Have A 100% Money Back Guarantee

Return to place of purchase if not satisfied.

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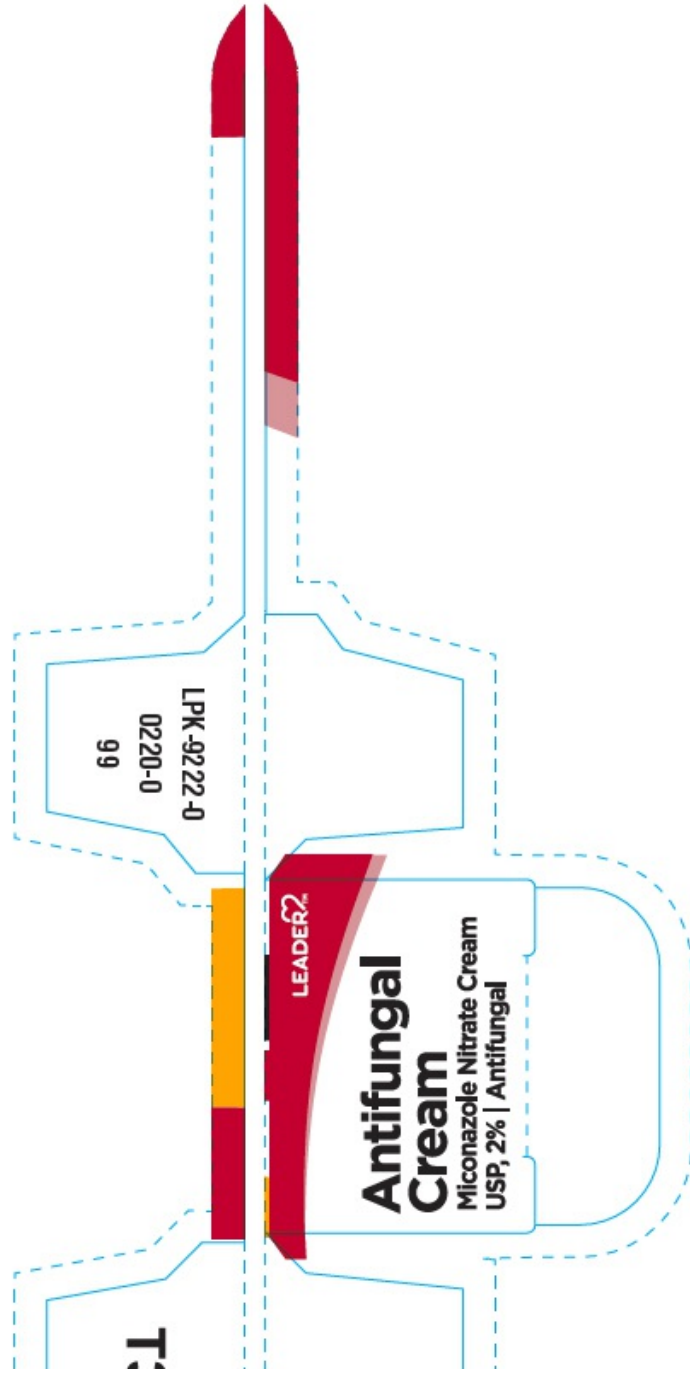
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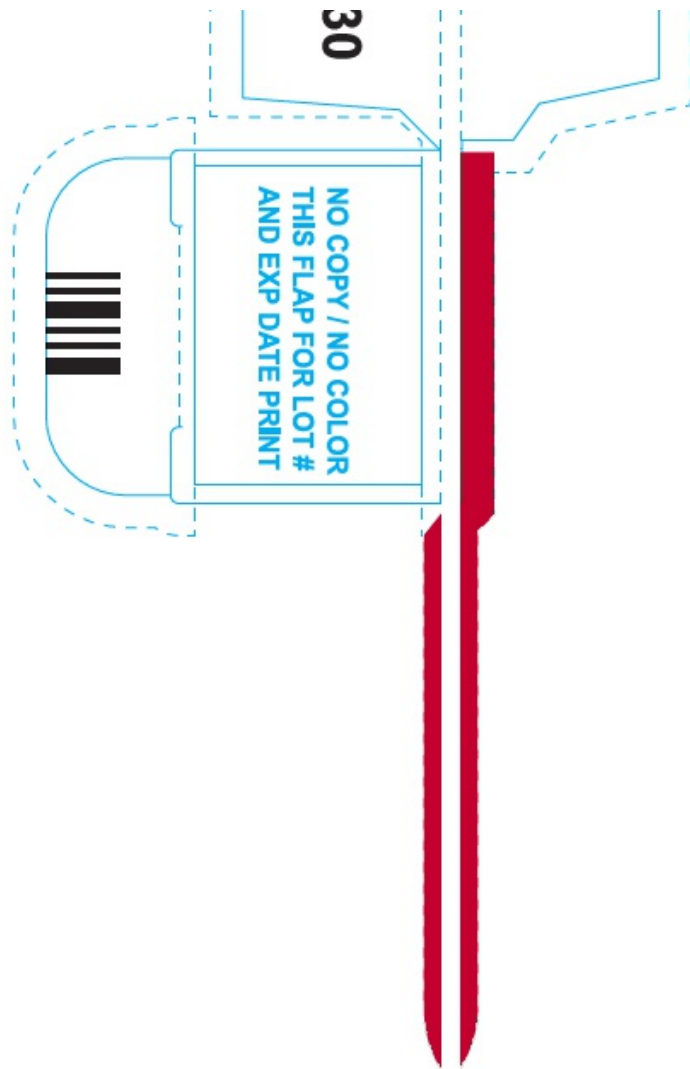
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LEADER²





ANTIFUNGAL

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0040
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
benzoic acid (UNII: 8SKN0B0MIM)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
glycol stearate (UNII: 0324G66D0E)	
mineral oil (UNII: T5L8T28FGP)	

water (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0040-1	1 in 1 CARTON	02/12/2020	04/30/2023
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	04/30/2023

Labeler - Cardinal Health, 110 dba LEADER (063997360)

Revised: 1/2023

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