SUNMARK MICONAZOLE NITRATE ANTIFUNGAL- miconazole nitrate cream Strategic Sourcing Services LLC

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.

sunmark™ antifungal

Drug Facts

Active ingredient

Miconazole nitrate 2%

Purpose

Antifungal

Uses

- cures most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis)
- for effective relief of
 - itching
 - scaling
 - cracking
 - burning
 - redness
 - soreness
 - irritation
 - discomfort

Warnings

For external use only

Ask a doctor before use

• on children under 2 years of age

When using this product

• avoid contact with eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot and ringworm) or within 2 weeks (for jock itch)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

This product is not effective on the scalp or nails.

For athlete's foot and ringworm: use daily for 4 weeks. For jock itch: use daily for 2 weeks.

- 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; change shoes and socks at least once daily

Other information

- To open: unscrew cap, use pointed end on cap to puncture seal
- store at room temperature
- 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 McKesson One Post Street San Francisco, CA 94104

PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

sunmark_{TM}

antifungal cream

Miconazole Nitrate 2% CURES MOST ATHLETE'S FOOT NET WT 1 OZ (30 g)



SUNMARK MICONAZOLE NITRATE ANTIFUNGAL

miconazole nitrate cream

Product Information	oduct Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-689			
Route of Administration	TOPICAL					

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

Inactive Ingredients			
Ingredient Name	Strength		
apricot kernel oil (UNII: 54JB35T06A)			
benzoic acid (UNII: 8 SKN0 B0 MIM)			
butylated hydroxytoluene (UNII: 1P9 D0 Z171K)			
glycol stearate (UNII: 0324G66D0E)			
mineral oil (UNII: T5L8T28FGP)			
polyethylene glycol 300 (UNII: 5655G9 Y8 AQ)			
water (UNII: 059QF0KO0R)			

1	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:49348-689-72	1 in 1 CARTON	10/01/1991			
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 - Strategic Sourcing Services LLC (116956644)

Revised: 11/2019 Strategic Sourcing Services LLC