

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™

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-689
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
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: 059QF0KO0R)	

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)

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Strategic Sourcing Services LLC