

MICONAZOLE NITRATE - miconazole nitrate cream
Physicians Total Care, 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.

Miconazole Nitrate Antifungal Cream

ACTIVE INGREDIENT

Miconazole nitrate 2%

PURPOSE

Antifungal

USES

- treats most athlete's foot, jock itch and ringworm
- relieves itching, scaling, burning, irritation and discomfort

WARNINGS

For external use only

WHEN USING THIS PRODUCT

- do not get into the eyes

STOP USE AND ASK A DOCTOR IF

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

Do not use on children under 2 years, unless directed by a doctor.

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center right away.

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
- this product does not work on the scalp or nails

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 every day
- For athlete's foot and ringworm

- use every day for 4 weeks
For jock itch
- use every day for 2 weeks. If condition lasts longer, contact a doctor.

OTHER INFORMATION

Store at room temperature 59° - 86°F (15° - 30°C).

IMPORTANT: The opening of this product is covered by a metal tamper-evident seal. If this seal has been punctured or is not visible, do not use and return product to place of purchase.

TO OPEN: To puncture the seal, reverse the cap and place the puncture-top onto the tube. Push firmly until seal is open. To close, screw the cap back onto the tube.

INACTIVE INGREDIENTS

Benzoic acid, BHA, mineral oil, peglicol 5 oleate, pegoxol 7 stearate, purified water

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 54868-2471-0



Compare to the active ingredient in Micatin® Antifungal Cream*

Actavis

Antifungal Cream

Miconazole Nitrate 2%

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

Net wt. 14 g tube cream

07350200D1 VC106266

Additional barcode labeling by:

Physicians Total Care, Inc.

Tulsa, Oklahoma 74146

MICONAZOLE NITRATE

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-2471(NDC:0472-0735)	
Route of Administration	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	
BENZOIC ACID (UNII: 8SKN0B0MIM)				
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)				
MINERAL OIL (UNII: T5L8T28FGP)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-2471-0	1 in 1 CARTON		
1		14 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part333C	03/20/2012		

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel(54868-2471)

Revised: 11/2012

Physicians Total Care, Inc.