

ANTIFUNGAL- miconazole nitrate cream

McKesson

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.

McKesson Antifungal Cream

Drug Facts

Active Ingredient

Miconazole Nitrate 2%

Purpose

Antifungal

Uses

Treats most jock itch, ringworm and athlete's foot

Warnings**Do not use**

- on children under 2 years of age
- for diaper rash. **For external use only.**

Avoid contact with eyes.

If irritation occurs or if there is no improvement within 4 weeks for athlete's foot or ringworm, or within 2 weeks for jock itch, discontinue use and consult 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 product over affected area twice daily (morning and night), or as directed by a physician.
- Supervise children in the use of this product.

Athlete's foot

- Pay special attention to the spaces between toes
- wear well-fitting, ventilated shoes and change shoes and socks at least once daily

Athlete's foot and ringworm

- use daily for 4 weeks

Jock Itch

- use daily for 2 weeks. If condition persists longer, consult a doctor.

This product is not effective on scalp or nails.

Other information Store at 59-86°F (15-30°C).

Inactive ingredients Purified Water, Isopropyl Palmitate, Glycerin, Glyceryl Stearate, PEG 100 Stearate, Cetearyl Alcohol, Cyclopentasiloxane, Propylene Glycol, Polyquaternium-37, Dicaprylate/Dicaprate, PPG-1 Trideceth-6, Aloe Barbados Leaf

Juice, DMDM Hydantoin, Iodopropynyl Butylcarbamate, (may contain Lactic Acid).

Questions? Call 1-800-777-4908

McKesson

Antifungal Cream

2% Miconazole Nitrate

Relieves itching, cracking, scaling and discomfort associated with most jock itch, ringworm and athlete's foot.

Net Contents

4 fl oz

(118.3mL)

MFR# 53-6391

NDC 68599-1470-4

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Distributed by McKesson Medical-Surgical Inc. Richmond, VA 23233 PVN C0617 Made in USA

MCKESSON

Antifungal Cream 2%
MICONAZOLE NITRATE

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(118.3 mL)

MFR # **53-6391**

ANTIFUNGAL

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68599-1470
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYQUATERNIUM-37 (10000 MPA.S) (UNII: 41QWS48DFN)	
PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA)	
PPG-1 TRIDECETH-6 (UNII: 1K7417JX6Q)	
ALOE (UNII: V5VD430YW9)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
WATER (UNII: 059QF0K00R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
GLYCINE (UNII: TE7660XO1C)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68599-1470-4	118 mL in 1 TUBE; Type 0: Not a Combination Product	05/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	05/26/2017	

Labeler - McKesson (023904428)

Establishment

Name	Address	ID/FEI	Business Operations
Central Solutions		007118524	manufacture(68599-1470)

Revised: 10/2017

McKesson