

MICONAZOLE NITRATE- antifungal 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.

Antifungal

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.

Consult a Doctor

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.

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.

Other Information

- This product is not effective on scalp or nails.
- Store at 59-86°F (15-30°C).

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, BHT, Cetyl Alcohol, Dimethicone, DMDM Hydantoin, Glycerin, Glyceryl Stearate, Isopropyl Palmitate, PEG 100 Stearate, Iodopropynyl Butylcarbamate,

Propylene Glycol, Purified Water, Stearic Acid, Triethanolamine (may contain Citric Acid).

NDC 68599-1471-4

McKesson

Antifungal Cream 2%

MICONAZOLE

NITRATE

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

4 fl oz

(118.3 mL)

MFR # 53-6391

NDC 68599-1471-4

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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.

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Questions? Call 1-800-777-4908

Distributed by McKesson Medical-Surgical Inc.
Richmond, VA 23233 PVN D0719 Made in USA



MCKESSON

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Cream 2%
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NITRATE**

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NET CONTENTS

4 fl oz

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MFR # **53-6391**

MICONAZOLE NITRATE

antifungal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68599-1471
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 mg

Inactive Ingredients

Ingredient Name	Strength
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
PEG-100 STEARATE (UNII: YD01N1999R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROLAMINE (UNII: 9O3K93S3TK)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68599-1471-4	118 mg in 1 TUBE; Type 0: Not a Combination Product	07/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	07/25/2019	

Labeler - McKesson (023904428)

Establishment

Name	Address	ID/FEI	Business Operations
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Central Solutions		007118524	manufacture(68599-1471)
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Revised: 9/2021

McKesson