

**MICONAZOLE NITRATE 2% CREAM ANTIFUNGAL- miconazole nitrate cream
RTMH Enterprises DBA Research Technology Medical Home**

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 2% Cream ANTIFUNGAL

Drug Facts

Active ingredient

Miconazole Nitrate 2%

Purpose

Anti-Fungal

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

Uses

- proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea crurus), and ringworm (tinea capitis)
- relieves itching, scaling, cracking, burning and discomfort associated with these conditions.

Warnings

For external use only. Do not use if the safety-sealed tube is punctured or damaged.

Do not use on children under 2 years of age unless directed by a healthcare professional. When using this product avoid contact with the eyes.

Stop use and ask a healthcare professional if • irritation occurs or if there is no improvement within 4 weeks (for athlete's foot and ringworm) • Irritation occurs, or if there is no improvement within 2 weeks (for jock itch).

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 healthcare professional • Supervise children in the use of this product.

For athlete's foot: • Use daily for 4 weeks. If condition persists, consult a healthcare

professional. • Pay special attention to the spaces between the toes • Wear well fitting, ventilated shoes • Change socks atleast once daily.

For ringworm: Use daily for 4 weeks. If condition persists, consult a healthcare professional.

For jock itch: Use daily for 2 weeks. If condition persists longer, consult a healthcare professional.

This product is not effective on the scalp or nails.

Inactive ingredients Carbomer, cetostearyl alcohol, dimethyl sulfoxide, edetate disodium, ethylparaben, glycerol, glyceryl distearate, mineral oil, pereg-al-o, purified water, stearic acid, triethanolamine, petrolatum.

Other Information

• Store at 15° - 30° c (59° - 86° f) • Lot number and expiration date see crimp of tube or see box. • To open: Unscrew cap, tear safety seal off.

You may report serious side effects to: QC@trifecta-pharma.com

FAST RELIEF 100% GUARANTEED

Relieves Itching and Burning

Also Cures Athlete's Foot and Ringworm

Distributed by:

Trifecta Pharmaceuticals USA™

101 NE Third Avenue Suite 1500

Ft. Lauderdale, FL 33301 USA

www.trifecta-pharma.com

Packaging



MICONAZOLE NITRATE 2% CREAM ANTIFUNGAL

miconazole nitrate cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:72071-101







ANTIFUNGAL TREATMENT SYSTEM
using proven ingredients.


- Relieves Itching and Burning.
- Cures Athlete's Foot, Ringworm and Jock Itch

CONTAINS:
1 TUBE 15G. MICONAZOLE CREAM
1 PACKAGE, 25 CLEANSING WIPES
FUGEON NDC: 72071-101-21

DISTRIBUTED BY
RTMH ENTERPRISES, LLC
LITCHFIELD PARK, AZ 85340 USA
WWW.RTMHENTERPRISES.COM

C33 M100 Y75 K27

**Size: 127*127*51 mm
5*5*2 In**

<p>DRUG FACTS</p> <p>Active Ingredients Miconazole Nitrate, USP 2% (external cream) Anti-Fungal</p> <p>Uses Proven clinically effective in the treatment of most athlete's foot (tinea pedis), ringworm (tinea corporis), and jock itch (tinea cruris) Relieves itching, scaling, cracking, burning and discomfort associated with these conditions</p> <p>Warnings FOR EXTERNAL USE ONLY DO NOT USE CREAM IF SEAL OVER TUBE OPENING IS PUNCTURED OR IS NOT VISIBLE DO NOT USE WIPES IF SEAL IS BROKEN DO NOT USE on children under 2 years of age unless directed by a doctor WHEN USING THIS PRODUCT avoid contact with the eyes STOP USE AND ASK A DOCTOR IF Irritation occurs or if there is no improvement within 4 weeks (for athlete's foot and ringworm) Irritation occurs or if there is no improvement within 2 weeks (for jock itch)</p> <p>Directions Use wipes to clean and prep the affected area prior to application of the cream Apply a thin layer of the cream over the 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: Use cream daily for 4 weeks. If condition persists consult a doctor. Pay special attention to the areas between the toes. Wear well ventilated shoes. Change socks at least once daily For ringworm: Use cream daily for 4 weeks. If condition persists, consult a doctor For jock itch: Use cream daily for 2 weeks. If condition persists longer, consult a doctor. This product is not effective on the scalp or nails</p>	<p>DRUG FACTS (continued)</p> <p>Other information Store at 15°-30°C (59° - 86°F)</p> <p>Inactive ingredients Carbomer, cetostearyl alcohol, dimethyl edetate disodium, ethylparaben, glycol distearate, mineral oil, pentaerythrityl sesquisebacate, polyethylene glycol, polyethylene glycol, allantoin, c glucoside, lauryl glucoside, phenoxy benzoic acid, dehydroacetic acid, x dimethicone</p> <p>FUGEON® Cleansing Wipes Ingredients Water, propylene glycol, allantoin, c glucoside, lauryl glucoside, phenoxy benzoic acid, dehydroacetic acid, x dimethicone</p> <p>Questions Call: 1-800-H WWW.RTMHENTERPRISES.COM</p>   <p>8 60101 002</p>
--	---

ANTIFUNGAL TREATMENT SYSTEM



Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL DISTEARATE (UNII: 73071MW2KM)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72071-101-21	1 in 1 BOX	09/28/2018	
1		15 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	09/28/2018	

Labeler - RTMH Enterprises DBA Research Technology Medical Home (042580344)

Registrant - RTMH Enterprises DBA Research Technology Medical Home (042580344)