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, peregal-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 TM

101 NE Third Avenue Suite 1500

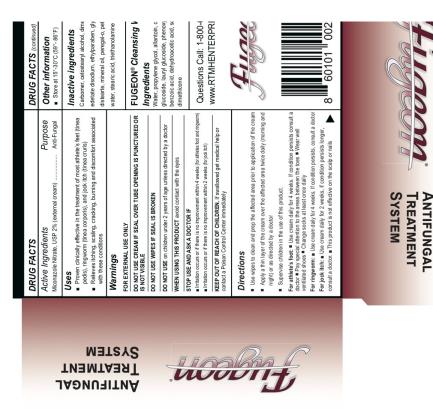
Ft. Lauderdale, FL 33301 USA

www.trifecta-pharma.com

Packaging



REVISED: 2019-04-26





C33 M100 Y75 K27

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

MICONAZOLE NITRATE 2% CREAM ANTIFUNGAL miconazole nitrate cream Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:72071-101

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: 4ELV7Z 65AP)				
TROLAMINE (UNII: 903K93S3TK)				

P	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)

Revised: 12/2022 RTMH Enterprises DBA Research Technology Medical Home