MICONAZOLE NITRATE- miconazole nitrate cream
NuCare Pharmaceuticals,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 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.

• 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

• 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.

• 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.

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 ™
101 NE Third Avenue Suite 1500
Ft. Lauderdale, FL 33301 USA
www.trifecta-pharma.com

Packaging

MICONAZOLE NITRATE

miconazole nitrate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-3429(NDC:69396-014)
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**
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)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68071-3429-3	1 in 1 BOX	06/06/2023	
1		30 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	03/22/2016	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-3429)

Revised: 6/2023 NuCare Pharmaceuticals,Inc.