MICONAZOLE NITRATE- miconazole nitrate cream
NuCare Pharmaceuticals,Inc.

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: YRC528SWJY)	
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 Drug	M005	03/22/2016	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

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