

MICONAZOLE NITRATE 2% CREAM ANTIFUNGAL- miconazole nitrate cream Rugby

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.

Rugby Miconazole Nitrate 2%

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 (1-800-222-1222) immediately.

Uses

- proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis)
- 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 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).

Other information

Distributed by:

Rugby Laboratories

Indianapolis, IN. 46268

800-616-2471

www.majorpharmaceuticals.com

This product is not manufactured or distributed by Wellspring Pharmaceutical Corporation owner of the registered trademark Micatin.

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

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

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

This product is not effective on the scalp or nails.

Inactive ingredients Carbomer, alcohol, cetostearyl alcohol, dimethyl sulfoxide, edetate disodium, ethylparaben, glycerol, mineral oil, mono and di glycerides, polyoxyethylene lauryl ether, 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.

Packaging

OUTSIDE BOX





INNER TUBE



MICONAZOLE NITRATE 2% CREAM ANTIFUNGAL

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1375
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
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
MINERAL OIL (UNII: T5L8T28FGP)	
LAURETH-30 (UNII: W9D845551A)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
PETROLATUM (UNII: 4T6H12BN9U)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERYL MONO AND DIPALMITOSTEARATE (UNII: KC98RO82HJ)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1375-75	1 in 1 BOX	02/07/2023	
1		28.3 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	02/07/2023	

Labeler - Rugby (079246066)**Registrant** - Trifecta Pharmaceuticals USA (079424163)

