ANTI-FUNGAL- miconazole nitrate cream
Universal Distribution Center LLC

Anti-Fungal Cream

Active Ingredient

Miconazole Nitrate 2%

Purpose

Antifungal

Uses

- cures most athlete's foot, jock itch, and ringworm.
- relieves itching, burning, cracking, scaling and discomfort which accompany these conditions.

Warnings

Do not use on children under 2 years of age except under the advice and supervision of a doctor.

For external use only.

When using this product avoid contact with eyes.

Stop using this product and ask a doctor

- irritation occurs
- there is no improvement within 4 weeks (for athlete’s foot and ringworm) or 2 weeks (for jock itch).
- do not use for diaper rash

Keep this and all drugs out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wash affected area and dry thoroughly
- Apply a thin layer over 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, pay special attention to spaces between the toes, wear well-fitting, ventilated shoes and change shoes and socks at least once a day
- for athlete's foot and ringworm use daily for 4 weeks, for jock itch use daily for 2 weeks
- if conditions persist longer, ask a doctor
- this product is not effective on the scalp or nails.

Other information

- Store between 20ºC to 25º C (68ºF to 77º F)
- Lot No. & Exp. Date: see crimp of tube.

Inactive Ingredients

Purified water, cetostearyl alcohol, cetomacrogol-1000, mineral oil, petrolatum, propyleneglycol, sodium phosphate, chlorocresol.

PRINCIPAL DISPLAY PANEL

Anti-Fungal Cream

NET WT 0.5 OZ (14 g)

ANTI-FUNGAL

miconazole nitrate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52000-061
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	0.02 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**

WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-20 (UNII: I835H2IHHX)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
CHLOROCRESOL (UNII: 36W53O7109)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-061-01	1 in 1 BOX	12/09/2020	
1		14 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	12/09/2020	

Labeler - Universal Distribution Center LLC (019180459)

Revised: 12/2024 Universal Distribution Center LLC