

MAKESENSE - miconazole cream
Cherry Hill Sales Co

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.

Drug Facts

Active Ingredient

Miconazole 2.0%

Purpose

Antifungal

Uses

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

Warnings

For external use only.

Do not use

- on children under 2 years of age except under the advise and supervision of a doctor
- for diaper rash

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (jock itch)

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center immediately

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 at 59 to 86F (15 to 30C)

Inactive Ingredients

Cetearyl Alcohol, Glycerin, Glyceryl Stearate, Methylparaben, Mineral Oil, Petrolatum, Polysorbate 60, Propylene Glycol, Propylparaben, Purified Water, Sorbitan Stearate

Package Label



MAKESENSE
miconazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69020-208
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4HICYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69020-208-28	28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	07/15/2014	

Labeler - Cherry Hill Sales Co (145959768)