MICONAZOLE- antifungal cream
Galentic Pharma (India) Priva Te Limited

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.

Antifungal

Active Ingredient

Miconazole Nitrate 2%

Uses - Antifungal

- For treatment of most athlete's foot (tinea pedis), jock itch (tinea crusis), Ringworm (tinea corporis).
- For the treatment of superficial skin infections caused by Yeast (Candida Albicans).
- Relieves itching, scaling, cracking, burning, redness, soreness, irritation discomfort and chafing associated with jock itch.

Warnings

Do not use:

- Do not use on children under 2 years of age unless directed by a doctor.
- Avoid contact with eyes.
- For athletes foot and ringworm - if irritation occurs, or if there is no improvement within 4 weeks, discontinue use and consult a doctor.
- For jock itch - if irritation occurs, or if there is no improvement within two weeks, discontinue use and consult a doctor.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Supervise children in the use of this product.
- If conditions persist longer, consult a doctor.
- This product is not effective on scalp or nails.

Other information.

Protect from freezing. Avoid excessive heat.

Directions

- Clean the affected area and dry thoroughly. Apply a layer of cream over affected area twice daily (morning and night) or as directed by a doctor.
- Foe athlete's foot and ringworm, use daily for 4 weeks.
- For jock itch, use daily for 2 weeks.
- For athlete's foot, pay special attention to spaces between toes: wear well fitting, ventilated shoes, and change shoes and socks at least once daily.

Inactive Ingredients

Inactive Ingredients: Cetomacrogol 1000, cetostearyl alcohol, chlorocresol, liquid paraffin, propylene glycol, purified water, white soft paraffin.

Keep Out of Reach of Children

- **KEEP OUT OF REACH OF CHILDREN**
- If swallowed get medical help or contact a Poison Control Center.

Principal Display Panel

Principal Display Panel

Miconazole Nitrate Cream USP 2%

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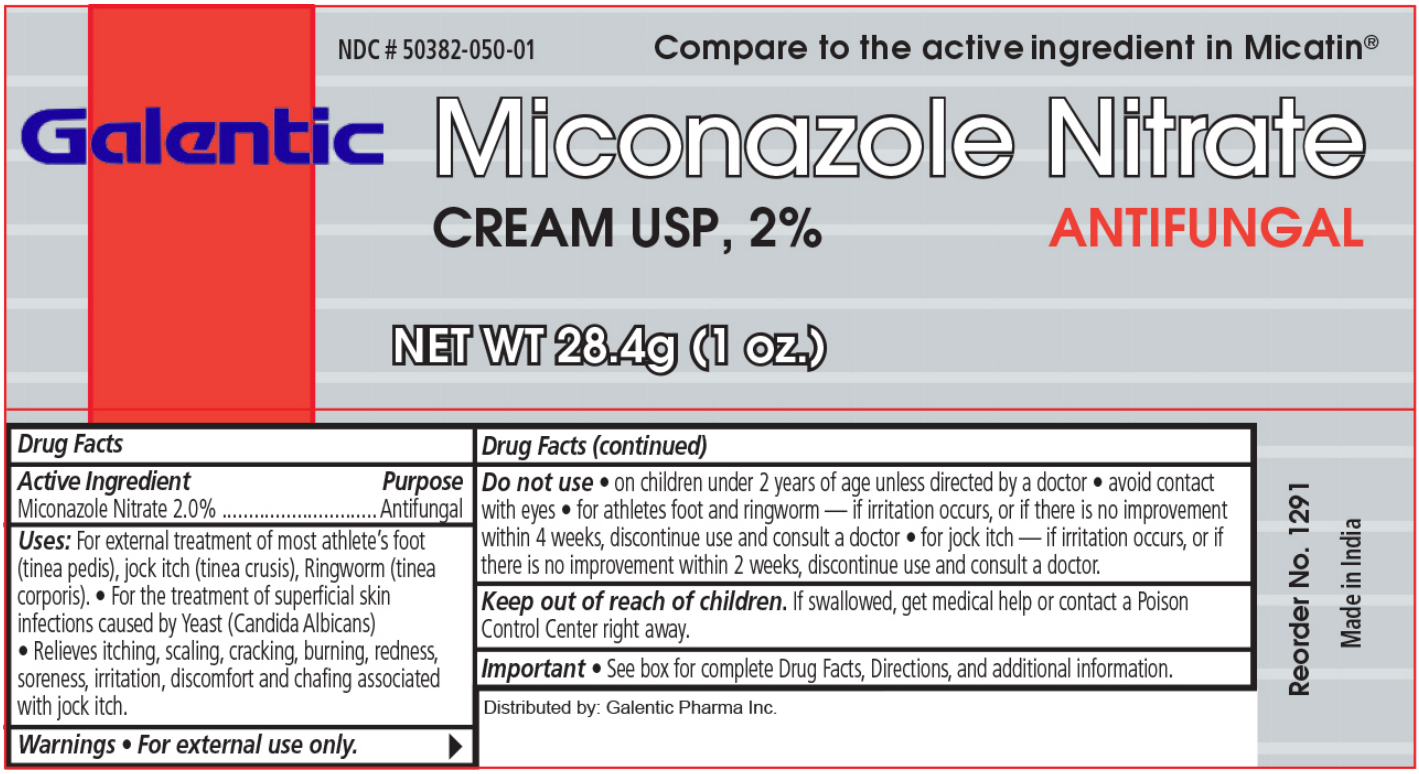

MICONAZOLE

antifungal cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50382-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETETH-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHLOROCRESOL (UNII: 36W53O7109)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50382-050-01	72 in 1 CASE		
1		1 in 1 BOX		
1		28.4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	07/18/2013	

Labeler - Galentic Pharma (India) Priva Te Limited (918531450)

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