ANTIFUNGAL- 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 Cream

Active Ingredient

Active Ingredient Purpose

Clotrimazole 1.0% Antifungal

Purpose

- 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.

Indications and Usage

- 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.
- Supervise children in the use of this product.
- 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.

Dosage and Administration

- Foe athlete's foot and ringworm, use daily for 4 weeks.
- For jock itch, use daily for 2 weeks. If conditions persist longer, consult a doctor.
- This product is not effective on scalp or nails.

Keep Out Of Reach Of Children

KEEP OUT OF REACH OF CHILDREN

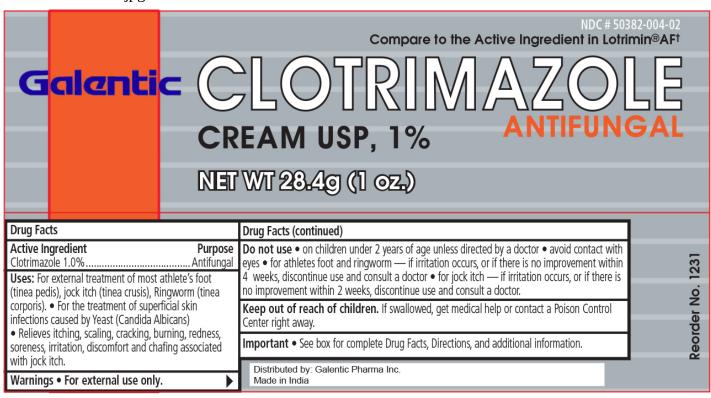
INACTIVE INGREDIENTS

Inactive Ingredients: Cetomicrogol 1000, Cetostearyl alcohol, Liquid paraffin, Methylparaben, Propylene glycol, Propylparaben, Purified water, White soft paraben

Principal Display Panel

Galentic Antifungal Cream

Gal Clotrimazole.jpg



ANTIFUNGAL

antifungal cream

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:50382-004

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
CETETH-20 (UNII: 1835H2IHHX)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
LIGHT MINERAL OIL (UNII: N6K5787QVP)			

METHYLPARABEN (UNII: A2I8 C7HI9 T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50382-004-01	28.25 g in 1 TUBE			
2	NDC:50382-004-02	113 g in 1 TUBE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	08/07/2013		

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

Revised: 8/2013 Galentic Pharma (India) Priva Te Limited