

**ANTIFUNGAL- antifungal cream**  
**Galentic Pharma (India) Private 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.*

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**Antifungal Cream**

**Active Ingredient**

Active Ingredient	Purpose
Clotrimazole 1.0%	Antifungal

**Purpose**

- For treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), 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 athlete's 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**

- For 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

Galentic

NDC # 50382-004-02

Compare to the Active Ingredient in Lotrimin®AF†

# CLOTRIMAZOLE

## CREAM USP, 1%

### ANTIFUNGAL

NET WT 28.4g (1 oz.)

Drug Facts	Drug Facts (continued)				
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 60%;">Active Ingredient</th> <th style="width: 40%;">Purpose</th> </tr> <tr> <td>Clotrimazole 1.0%.....</td> <td>Antifungal</td> </tr> </table> <p><b>Uses:</b> For external treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), Ringworm (tinea corporis). • For the treatment of superficial skin infections caused by Yeast (Candida Albicans)</p> <ul style="list-style-type: none"> <li>• Relieves itching, scaling, cracking, burning, redness, soreness, irritation, discomfort and chafing associated with jock itch.</li> </ul>	Active Ingredient	Purpose	Clotrimazole 1.0%.....	Antifungal	<p><b>Do not use</b> • 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 2 weeks, discontinue use and consult a doctor.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Important</b> • See box for complete Drug Facts, Directions, and additional information.</p>
Active Ingredient	Purpose				
Clotrimazole 1.0%.....	Antifungal				
<p><b>Warnings</b> • For external use only. ▶</p>	<p>Distributed by: Galentic Pharma Inc. Made in India</p>				

Reorder No. 1231

## ANTIFUNGAL

antifungal cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50382-004
<b>Route of Administration</b>	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: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

<b>METHYL PARABEN</b> (UNII: A2I8C7H9T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	

### 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) Private Limited (918531450)

Revised: 8/2013

Galentic Pharma (India) Private Limited