

**CLOTRIMAZOLE- clotrimazole cream**  
**Padagis Israel Pharmaceuticals Ltd**

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**Clotrimazole Cream USP, 1% Drug Facts**

**Active ingredient**

Clotrimazole 1%

**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 unless directed by a doctor

**When using this product**

avoid contact with the 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 (for jock itch)

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

**Directions**

- wash the affected area and dry thoroughly
- apply a thin layer over affected area twice daily (morning and night)
- supervise children in the use of this product

- for athlete's foot pay special attention to the spaces between the toes, wear well-fitting ventilated shoes and change shoes and socks at least once daily
- for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks
- if condition persists longer, consult a doctor
- this product is not effective on the scalp or nails

### **Other information**

- store at 20°-25°C (68°-77°F)

### **Inactive ingredients**

benzyl alcohol, cetostearyl alcohol, cetyl esters wax, octyldodecanol, polysorbate 60, purified water, sorbitan monostearate

### **Questions or comments?**

**1-800-719-9260**

### **Principal Display Panel**

Cures Most Athlete's Foot

- Relieves Itching & Burning
- Greaseless, Non-Staining

Compare to Lotrimin® AF active ingredient

Clotrimazole Cream USP, 1%

Antifungal

NET WT 1 OZ (30 g)

Padagis™

NDC 45802-434-11

# Cures Most Athlete's Foot

- Relieves Itching & Burning
- Greaseless, Non-Staining

## OTC via Rx

If a prescription is written for this product it may be covered by your health plan.



NDC 45802-434-11

Compare to Lotrimin® AF active ingredient

# Clotrimazole Cream USP, 1%

Antifungal

NET WT 1 OZ (30 g)



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Distributed By  
  
 Allegan, MI 49010  
 www.padagis.com  
 85764 RT C4



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| <b>Drug Facts</b>  |
| <b>Active ingredient</b><br>Clotrimazole 1%<br>Antifungal  |
| <b>Purpose</b><br>Antifungal   |
| <b>Uses</b><br>■ cures most athlete's foot, jock itch and ringworm<br>■ relieves itching, burning, cracking, scaling and discomfort which accompany these conditions   |
| <b>Warnings</b><br>For external use only<br>Do not use on children under 2 years of age unless directed by a doctor<br>When using this product avoid contact with the eyes<br>Stop use and ask a doctor if<br>■ irritation occurs ■ there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch)<br>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)   |
| <b>Directions</b><br>■ wash the affected area and dry thoroughly<br>■ apply a thin layer over affected area twice daily (morning and night)<br>■ supervise children in the use of this product<br>■ for athlete's foot pay special attention to the spaces between the toes, wear well-fitting ventilated shoes and change shoes and socks at least once daily<br>■ for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks<br>■ if condition persists longer, consult a doctor ■ this product is not effective on the scalp or nails |
| <b>Other information</b><br>■ store at 20°-25°C (68°-77°F)   |
| <b>Inactive ingredients</b><br>benzyl alcohol, cetostearyl alcohol, cetyl esters wax, octyldodecanol, polysorbate 60, purified water, sorbitan monostearate  |
| <b>Questions or comments?</b> 1-800-719-9260   |

Clotrimazole Cream USP, 1% Antifungal



# CLOTRIMAZOLE

clotrimazole cream

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:45802-434 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>CLOTRIMAZOLE</b> (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65) | CLOTRIMAZOLE             | 1 g in 100 g    |

## Inactive Ingredients

| <b>Ingredient Name</b>                          | <b>Strength</b> |
|---|-----------------|
| <b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)        |                 |
| <b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)   |                 |
| <b>CETYL ESTERS WAX</b> (UNII: D072FFP9GU)      |                 |
| <b>OCTYLDODECANOL</b> (UNII: 461N1O614Y)        |                 |
| <b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)        |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)                 |                 |
| <b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X) |                 |

## Packaging

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                        | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|---|-----------------------------|---------------------------|
| 1        | NDC:45802-434-01 | 1 in 1 CARTON                                     | 06/03/2011                  | 01/31/2026                |
| 1        |                  | 15 g in 1 TUBE; Type 0: Not a Combination Product |                             |                           |
| 2        | NDC:45802-434-11 | 1 in 1 CARTON                                     | 06/09/2011                  | 04/30/2027                |
| 2        |                  | 28 g in 1 TUBE; Type 0: Not a Combination Product |                             |                           |

## Marketing Information

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC Monograph Drug        | M005  | 06/03/2011                  | 04/30/2027                |

**Labeler** - Padagis Israel Pharmaceuticals Ltd (600093611)