

## **CLOTRIMAZOLE - clotrimazole cream**

**H.J. Harkins Company, Inc.**

*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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### **Clotrimazole Cream USP, 1%**

#### **Antifungal Cream**

#### ***Drug Facts***

#### **Active ingredient**

Clotrimazole 1%

#### **Purpose**

Antifungal

#### **Uses**

- cures most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis)
- for effective relief of
- itching
- scaling
- cracking
- burning
- redness
- soreness
- irritation
- discomfort

#### **Warnings**

##### **For external use only**

##### **Ask a doctor before use**

- on children under 2 years of age

##### **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 within 2 weeks (for jock itch)

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

This product is not effective on the scalp or nails.

**For athlete's foot and ringworm:** use daily for 4 weeks. **For jock itch:** use daily for 2 weeks.

- clean the affected area and dry thoroughly
- apply a thin layer of the product 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; change shoes and socks at least once daily

#### **Other information**

- To open: unscrew cap, use the pointed end of cap to puncture seal.
- store between 2° - 30°C (36° - 86°F)
- see carton or tube crimp for lot number and expiration date

#### **Inactive ingredients**

benzyl alcohol (1%), cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate 60, purified water, sorbitan monostearate

#### **Questions?**

Call 1-866-923-4914

Distributed by:

**Taro Pharmaceuticals**

**U.S.A., Inc.**

Hawthorne, NY 10532

Repacked by:

**H.J. Harkins Company, Inc.**

**U.S.A., Inc.**

Nipomo, CA 93444

#### **PRINCIPAL DISPLAY PANEL - 15 g Carton**

*Cures Most Athlete's Foot*

**Athlete's Foot**

**Cream**

**Clotrimazole Cream USP, 1%**

**Antifungal Cream**

**Antifungal Cream**

**NET WT (1/2 oz) 15 g**

52959-088-03

RX Only: #XXXXXXXX

#XXX

CAUTION: Federal law PROHIBITS the transfer of this drug to anyone other than the person to whom prescribed and prohibits dispensing without a prescription unless OTC. See outsert for add'l RX info KEEP OUT OF REACH OF CHILDREN. Store in a cool dry place 68 to 77 degrees F.

CLOTRIMAZOLE 1% ANTI-FUNGAL CR

Lot #: CZL47TR

Mfg: TARO

Exp: 04/12

Mfg Hawthorne,

Loc.: NY

Compare to: Lotrimin AF

Mfg. NDC: 51672-2002-1

Pill ID: Cream

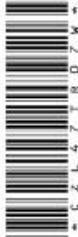
CLOTRIMAZOLE 1% ANTI-FUNGAL CR  
52959-088-03 Qty 15gm  
04/12 Lot CZL47TR  
Lotrimin AF 51672-2002-1

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CLOTRIMAZOLE 1% ANTI-FUNGAL CR  
52959-088-03 Qty 15gm  
04/12 Lot CZL47TR  
Lotrimin AF 51672-2002-1

Repack: HJ Harkins Co., Inc. Nipomo., CA 93444  
Dispense in tight, child & light-resistant container per USP



Take as directed by your Doctor or  
See outsert for usual dosage information



CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52959-088(NDC:51672-2002)
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
benzyl alcohol (UNII: LKG8494WBH)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetyl esters wax (UNII: D072FFP9GU)	
polysorbate 60 (UNII: CAL22UVI4M)	
water (UNII: 059QF0KO0R)	
sorbitan monostearate (UNII: NVZ4I0H58X)	

Product Characteristics

Color	WHITE (Smooth)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-088-03	15 g in 1 TUBE		
2	NDC:52959-088-05	30 g in 1 TUBE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333C	06/01/1995	

**Labeler** - H.J. Harkins Company, Inc. (147681894)

**Registrant** - Taro Pharmaceuticals U.S.A., Inc. (145186370)

**Establishment**

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE

Revised: 10/2011

H.J. Harkins Company, Inc.