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.

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

Repcaked 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

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.