

WESTERN FAMILY ATHLETES FOOT- clotrimazole cream

Western Family Foods 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.

Western Family®

Athletes Foot

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
Western Family
Foods, Inc.
P.O. Box 4057
Portland, OR
97208 U.S.A.

PRINCIPAL DISPLAY PANEL - 15 g Tube Carton

Athlete's
Foot Cream

Clotrimazole Cream USP, 1%
ANTIFUNGAL CREAM

Relieves
Itching, Burning,
Scaling and Cracking

NET WT 1/2 OZ (15 g)



COMPARE TO THE ACTIVE INGREDIENT IN LOTRIMIN® AF*

Cures Most Athlete's Foot

Relieves Itching & Burning Greaseless, Nonstaining Cream

LPK-2864-4
0509-4
M289

Athlete's Foot Cream

Clotrimazole Cream USP, 1%
ANTIFUNGAL CREAM

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Athlete's Foot Cream

Clotrimazole Cream USP, 1%
ANTIFUNGAL CREAM

Relieves Itching, Burning, Scaling and Cracking

NET WT 1/2 OZ (15 g)



058894 8-1A80

Drug Facts (continued)
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 clamp for lot number and expiration date.
Inactive ingredients benzyl alcohol (1%), cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate 80, purified water, sorbitan monostearate.
Questions? Call 1-866-923-4914

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Drug Facts
Active ingredient Clotrimazole 1% Antifungal
Purpose
Uses
• cures most athlete's foot (thickened skin, blisters, and ringworm (thick scaly patches))
• for effective relief of itching, scaling, cracking, burning, redness, soreness
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 lock 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 lock 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.



Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-305	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	Clotrimazole (UNII: G07GZ97H65) (Clotrimazole - UNII:G07GZ97H65)	Clotrimazole	10 mg in 1 g	
Inactive Ingredients				
	Ingredient Name	Strength		
	BENZYL ALCOHOL (UNII: LKG8494WBH)			
	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
	CETYL ESTERS WAX (UNII: D072FFP9GU)			
	OCTYLDODECANOL (UNII: 461N1O614Y)			
	POLYSORBATE 60 (UNII: CAL22UVI4M)			
	WATER (UNII: 059QF0K00R)			
	SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-305-01	1 in 1 CARTON		
1		15 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	08/31/1993		

Labeler - Western Family Foods Inc (192166072)

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

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(55312-305)