TOPCARE ANTIFUNGAL- clotrimazole cream Topco Associates LLC

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.

TopCare_®
Antifungal Cream

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 eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot or 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.

Directions

- wash 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 spaces between the toes, wear well-fitting, ventilated shoes and change 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, ask a doctor
- this product is not effective on the scalp or nails

Other information

- To open: unscrew cap, use the pointed end of cap to puncture seal.
- store between 20° 25°C (68° 77°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 **1-888-423-0139**

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007

PRINCIPAL DISPLAY PANEL - 14.2 g Tube Carton

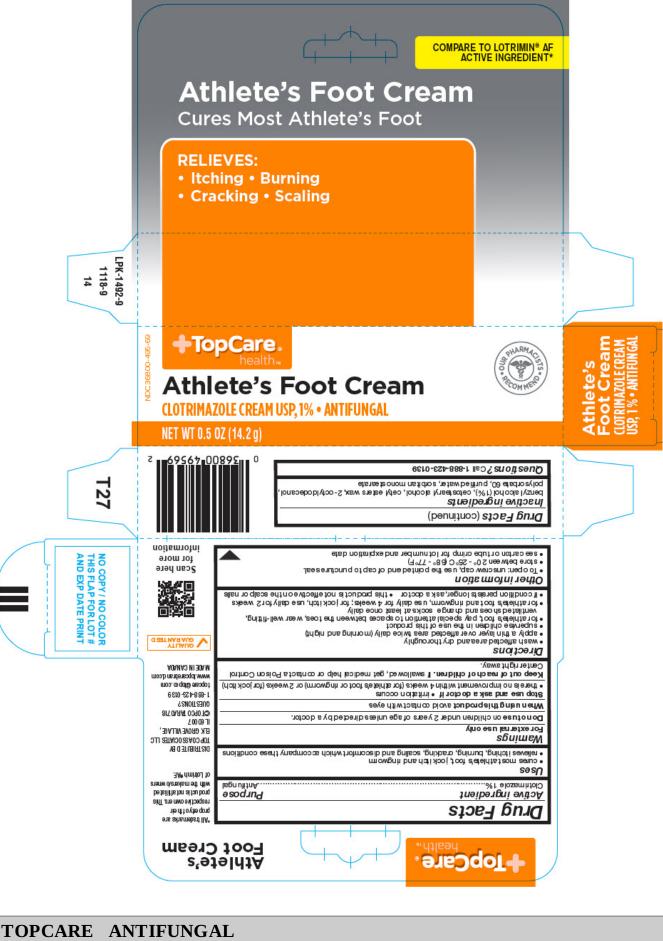
NDC 36800-495-69

 $TopCare_{\mathbb{R}}$ health $_{TM}$

Athlete's Foot Cream CLOTRIMAZOLE CREAM USP, 1% • ANTIFUNGAL

• OUR PHARMACISTS RECOMMEND •

NET WT 0.5 OZ (14.2 g)



Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-495 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: 059QF0KO0R)		
sorbitan monostearate (UNII: NVZ4I0H58X)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:36800-495-69	1 in 1 CARTON	08/31/1993		
1	14.2 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part333C	08/31/1993		

Labeler - Topco Associates LLC (006935977)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(36800-495)	

Revised: 3/2019 Topco Associates LLC