CAREONE CLOTRIMAZOLE- clotrimazole cream American Sales Company

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.

CAREONE™ Clotrimazole 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 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 **1-866-923-4914**

DISTRIBUTED BY: FOODHOLD U.S.A. LLC LANDOVER, MD 20785

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

NDC 41520-305-02

 $CARE one^{\circledR}$

Compare to the active ingredient in Lotrimin® AF*

Antifungal Cream Clotrimazole Cream USP, 1% • Antifungal

Cures Most Athlete's Foot

OUR PHARMACISTS

RX

RECOMMEND

NET WT 1 OZ (28.4 g)

Relieves Itching, Burning, Cracking & Scaling •



CAREONE CLOTRIMAZOLE

clotrimazole cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-305	
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: 059QF0KO0R)			
sorbitan monostearate (UNII: NVZ4I0 H58 X)			

	Packaging				
Ш	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:41520-305-02	1 in 1 CARTON	08/31/1993		
	1	30 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 - American Sales Company (809183973)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(41520-305)	

Revised: 4/2019 American Sales Company