

**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.*

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**CAREONE™**  
**Clotrimazole USP 1%**

***Drug Facts***

**Active ingredient**

Clotrimazole USP, 1%

**Purpose**

Antifungal

**Uses**

- cures most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)
- effectively relieves itching, cracking, burning and discomfort which can accompany these conditions

**Warnings**

**For external use only**

**When using this product**

- use only as directed
- avoid contact with the 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)

Do not use on children under 2 years of age except under the advice and supervision of a doctor.

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

**Directions**

- for best results, follow directions and continue treatment for length of time indicated
- to open, use pointed end on cap to puncture seal
- clean skin with soap and water and dry thoroughly
- apply a thin layer over affected area morning and evening
- for athlete's foot, pay special attention to spaces between the toes, wear well-fitted, ventilated shoes and change shoes and socks at least once daily
- best results in athlete's foot and ringworm are usually obtained with 4 weeks use, and in jock itch, with 2 weeks use. If satisfactory results have not occurred within these times, ask a doctor or pharmacist.
- children under 12 years of age should be supervised in the use of this product

- this product is not effective on the scalp or nails

**Other information**

- store between 2-30C (36-86F)
- do not use if seal on tube is broken or is not visible
- see box 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

DISTRIBUTED BY  
AMERICAN SALES COMPANY  
4201 WALDEN AVENUE  
LANCASTER, NY 14086

**PRINCIPAL DISPLAY PANEL - 30 g Tube Carton**

***ANTIFUNGAL  
CREAM***

**CURES MOST ATHLETE'S FOOT  
CLOTRIMAZOLE CREAM USP, 1%**

**Relieves Itching & Burning  
Greaseless, Nonstaining**

**NET WT 30 g (1 OZ)**

Compare to the Active Ingredient in Lotrimin® AF\*

CAREONE™

ANTIFUNGAL CREAM **CURES MOST ATHLETE'S FOOT**

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**CLOTRIMAZOLE CREAM USP, 1%**

Relieves Itching & Burning • Greaseless, Nonstaining

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Quality Guaranteed  
Or Your Money Back

This product has been tested by an Independent Laboratory to Ensure its Quality

Made in Canada.



**Drug Facts**

**Active Ingredient:** Clotrimazole USP, 1% (Antifungal)

**Uses:**  
• cures most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)  
• effectively relieves itching, crawling, burning and discomfort which can accompany these conditions

**Warnings:**  
For external use only.  
• use only as directed • 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)

**Directions:**  
• For best results, follow directions and continue treatment for length of time indicated.  
• To open, use pointed end on cap to puncture seal.  
• Clean skin with soap and water and dry thoroughly.  
• Apply a thin layer over affected areas morning and evening.  
• For athlete's foot, pay special attention to spaces between the toes, wear well-fitting, ventilated shoes and change shoes and socks at least once daily.  
• For athlete's foot and ringworm are usually obtained within 4 weeks use, and in jock itch, within 2 weeks use. If satisfactory results have not occurred within these times, ask a doctor or pharmacist.  
• Children under 12 years of age should be supervised in the use of this product.  
• This product is not effective on the scalp or nails.

**Other information:**  
• Do not use if seal on tube is broken or is not visible.  
• Store between 2-30°C (36-86°F) • do not use if seal on tube is broken or is not visible.  
• See box or tube for complete directions for use and expiration date.

**Inactive ingredients:** benzyl alcohol (1%), cetyl esters w/ax, 2-o-dihydro ethanol, poly sorbate 60, purified water, sorbitol monosebacate.

\*This product is not manufactured or distributed by Schering Corporation, registered trademark, Lotrimin® AF.

**CAREONE CLOTRIMAZOLE**

clotrimazole cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-305
<b>Route of Administration</b>	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:41520-305-02	1 in 1 CARTON		
1		30 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** - 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: 1/2013

American Sales Company