

## **CLOTRIMAZOLE- clotrimazole cream**

**Rebel Distributors Corp**

*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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### **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

Repackaged by:

**Rebel Distributors Corp**

Thousand Oaks, CA 91320

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

*Cures Most Athlete's Foot*

**Athlete's Foot**

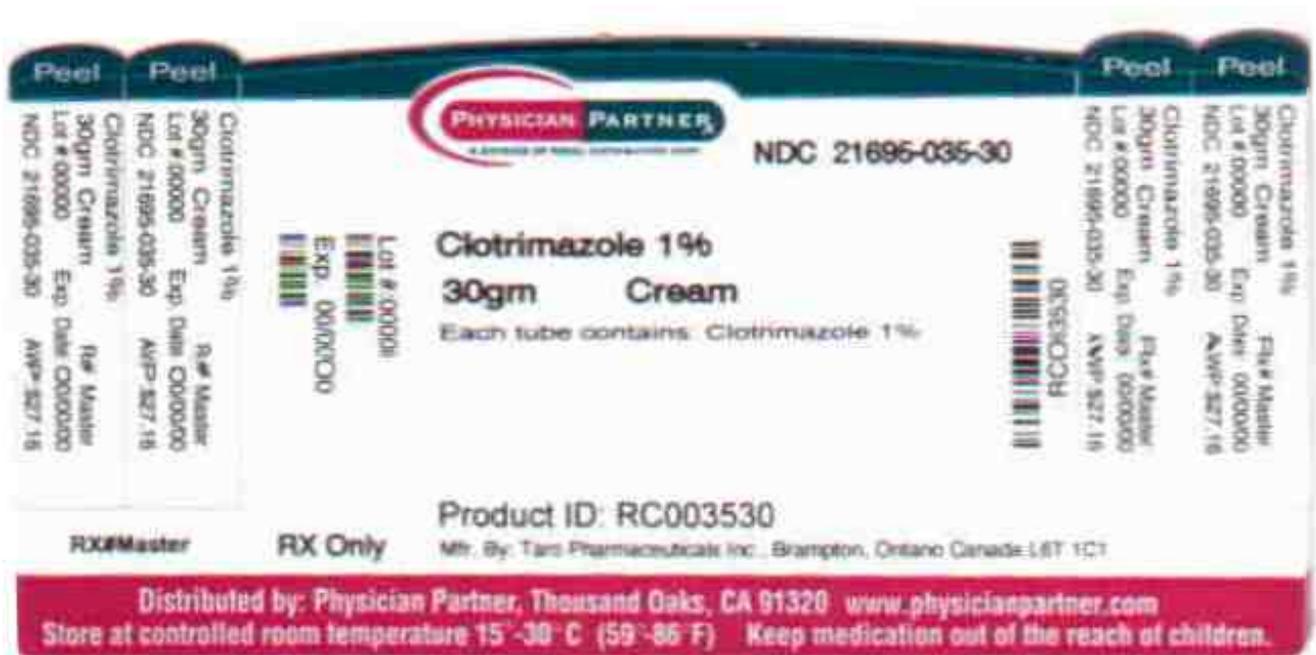
**Cream**

**Clotrimazole Cream USP, 1%**

**Antifungal Cream**

**Antifungal Cream**

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



## CLOTRIMAZOLE

clotrimazole cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:21695-035(NDC:51672-2002)
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Clotrimazole</b> (UNII: G07GZ97H65) (Clotrimazole - UNII:G07GZ97H65)	Clotrimazole	1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>benzyl alcohol</b> (UNII: LKG8494WBH)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>cetyl esters wax</b> (UNII: D072FFP9GU)	
<b>polysorbate 60</b> (UNII: CAL22UVI4M)	
<b>water</b> (UNII: 059QF0K00R)	
<b>sorbitan monostearate</b> (UNII: NVZ4I0H58X)	

### Product Characteristics

<b>Color</b>	WHITE (Smooth)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-035-15	1 in 1 CARTON		
1		15 g in 1 TUBE		
2	NDC:21695-035-30	1 in 1 CARTON		
2		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** - Rebel Distributors Corp (118802834)

## Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 2/2011

Rebel Distributors Corp