

## **CLOTRIMAZOLE ANTIFUNGAL- clotrimazole cream**

**Actavis Pharma, 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.*

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### **Clotrimazole Cream-Antifungal**

#### **Drug Facts**

##### **Active ingredient**

Clotrimazole, USP 1%

##### **Purpose**

Antifungal

##### **Uses**

• cures most athlete's foot, jock itch, and ringworm • relieves itching, burning, cracking, scaling, and discomfort

##### **Warnings**

**For external use only**

##### **Do not use**

on children under 2 years, unless directed by a doctor.

##### **When using this product**

• 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 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**

- wash 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, and change shoes and 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 last longer, contact a doctor
- this product is not effective on the scalp or nails

### **Other information**

• Store between 2°-30°C (36° – 86°F). • Before using any medication, read all label directions. Keep carton, it contains important information.

### **Inactive ingredients**

benzyl alcohol, cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate 60, purified water, sodium phosphate monobasic, sorbitan monostearate

### **Questions?**

**1-800-432-8534 between 9 am and 4 pm EST, Monday – Friday.**

### **Principal Display Panel**

#### **Actavis**

NDC 0472-0350-56

Compare to the active ingredient in Lotrimin® AF\*

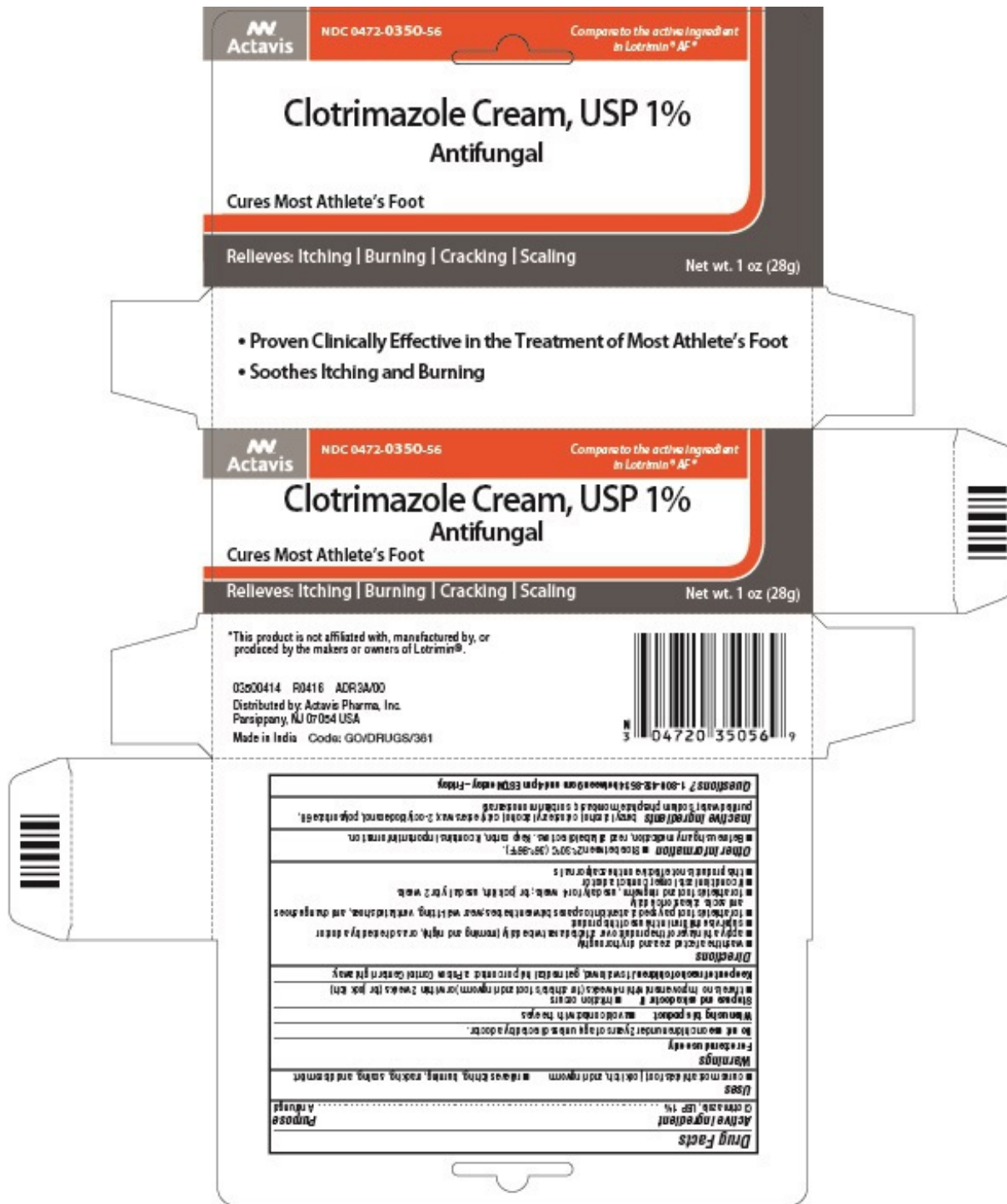
#### **Clotrimazole Cream, USP 1%**

#### **Antifungal**

#### **Cures Most Athlete's Foot**

Relieves: Itching | Burning | Cracking | Scaling

Net wt. 1 oz (28 g)



## CLOTRIMAZOLE ANTIFUNGAL

clotrimazole cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0472-0350
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)		CLOTRIMAZOLE	10 mg in 1 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
BENZYL ALCOHOL (UNII: LKG8494WBH)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
CETYL ESTERS WAX (UNII: D072FFP9GU)				
OCTYLDODECANOL (UNII: 461N1O614Y)				
POLYSORBATE 60 (UNII: CAL22UVI4M)				
WATER (UNII: 059QF0K00R)				
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)				
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0472-0350-56	1 in 1 CARTON	01/03/2017	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL		part333C	01/03/2017	

**Labeler** - Actavis Pharma, Inc. (119723554)

Revised: 11/2019

Actavis Pharma, Inc.