

## **ZAPOTOL CLOTRIMAZOLE- clotrimazol cream**

**Zapotol 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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### **Active ingredient**

### **Purpose**

Clotrimazole 1%----- Antifungal

### **Uses**

- Cures most athlete's foot, jock itch, and ringworm
- relieves itching, burning, cracking, scaling and discomfort which accompany these conditions

### **Warnings**

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

For external use only

☐**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 2 weeks (for jock itch)
- do not use for diaper rash

### **Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away.

### **Direction**

- Wash affected area and dry thoroughly
- Apply a thin layer 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 a day
- 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**

Lot No. & Exp. Date; see box or see crimp of the tube

Store between 20°C to 25°C (68°F to 77°F)

### **Inactive ingredients**

benzyl alcohol, isopropyl myristate, liquid paraffin, polysorbate 60, propylene glycol, purified water, sorbitan monostearate, stearic acid, stearyl alcohol

### **DISTRIBUTED BY:**

PRODUCTOS ZAPOTOL CORP.

Van Nuys, CA 91402

888-927-6865

Made in Korea



## ZAPOTOL CLOTRIMAZOLE

clotrimazol cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59428-359
<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 100 g

### Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PARAFFIN (UNII: I9O0E3H2ZE)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	

<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58 X)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4HIY)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59428-359-28	1 in 1 CARTON	10/13/2016	
1		28 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	08/07/2012	

**Labeler** - Zapotol Corp. (186063850)

Revised: 10/2016

Zapotol Corp.