# PREMIER VALUE TOLNAFTATE ANTIFUNGAL - tolnaftate cream CHAIN DRUG CONSORTIUM, LLC

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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## **Drug Facts**

#### Uses

- proven clinically effective in the treatment of athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis)
- proven effective in the prevention of athlete's foot
- effectively soothes and relieves itching associated with jock itch, scaly skin between the toes and burning feet

### Warnings

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

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

- 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 daily
- For athlete's foot and ringworm use daily for 4 weeks, for jock itch use daily for 2 weeks. If condition persists longer consult a doctor
- This product is not effective on the scalp or nails

#### Other Information

Lot No. and Exp. Date: see box or see crimp of the tube. Store between 20° to 25°C (68° to 77°F)

Inactive Ingredients

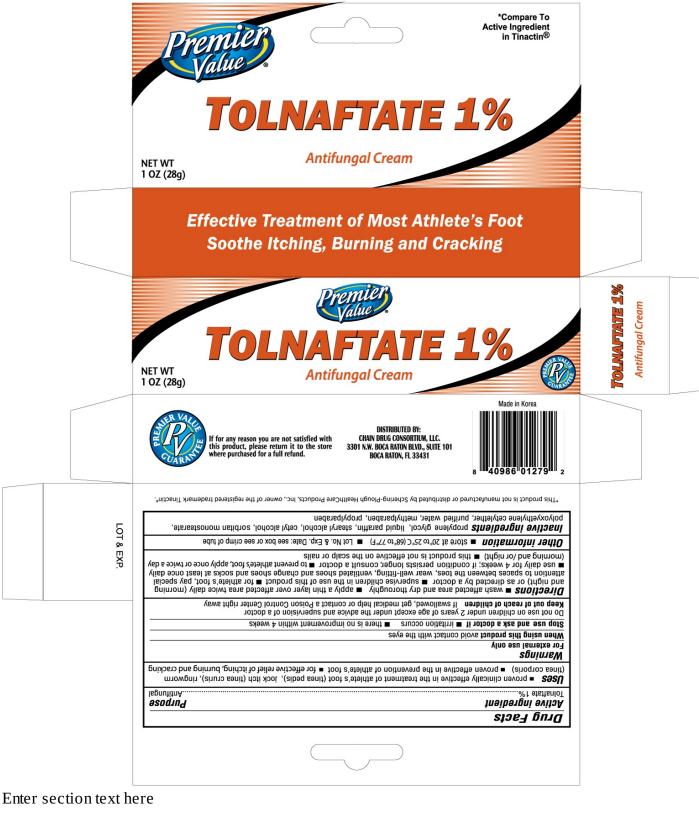
Propylene glycol, liquid paraffin, stearyl alchol, cetyl alcohol, sorbitan monstearate, polyoxyethylene cetylether, purified water, methylparaben, propylparaben.

#### DISTRIBUTED BY:

CHAIN DRUG CONSORTIUM, LLC.

3301 N.W. BOCA RATON BLVD., SUITE 101

BOCA RATON, FL 33431



### PREMIER VALUE TOLNAFTATE ANTIFUNGAL tolnaftate cream **Product Information** HUMAN OTC DRUG NDC:68016-014 Item Code (Source) Product Type

# Active Ingredient/Active Moiety

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	Ingredient Name	Basis of Strength	Strength
	TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	10 mg in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
MINERAL OIL (UNII: T5L8T28FGP)			
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
SORBITAN MONOSTEARATE (UNII: NVZ4I0 H58 X)			
WATER (UNII: 059QF0KO0R)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-014-79	1 in 1 CARTON		
1		28 g in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	0 1/20/20 12		

# Labeler - CHAIN DRUG CONSORTIUM, LLC (101668460)

Revised: 1/2012 CHAIN DRUG CONSORTIUM, LLC