

TOLNAFTATE - tolnaftate cream

LIFElabs, a Division of Atico International, USA, 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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Tolnaftate

Active ingredient

Tolnaftate 1%

Purpose

Antifungal

Uses

- proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis)
- proven effective in the prevention of athlete's foot with daily use
- for effective relief of chafing associated with jock itch
- soothes itchy, scaly skin between the toes and itchy, 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 2 weeks (for jock itch) or 4 weeks (for athlete's foot and ringworm)

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

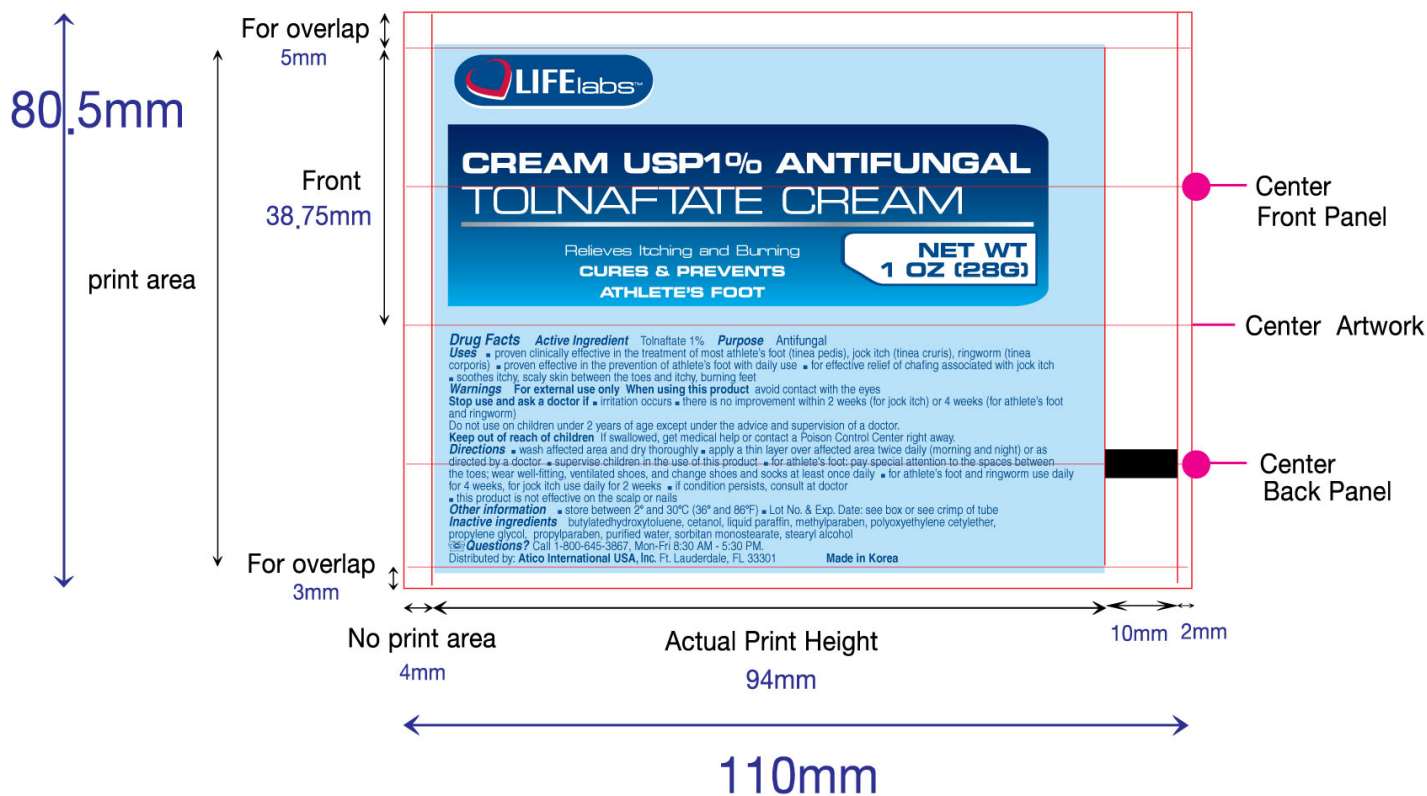
Other information

store between 2° and 30°C (36° and 86°F)

Lot No. and Exp. Date: see box or see crimp of tube

Inactive ingredients

25Ø



TOLNAFTATE

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51852-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Mineral Oil (UNII: T5L8T28FGP)	
Methylparaben (UNII: A218C7HI9T)	

Ceteth-20 (UNII: I835H2IHHX)				
Propylene Glycol (UNII: 6DC9Q167V3)				
Propylparaben (UNII: Z8IX2SC1OH)				
Water (UNII: 059QF0K00R)				
Sorbitan Monostearate (UNII: NVZ4I0H58X)				
Stearyl Alcohol (UNII: 2KR89I4HIY)				
Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51852-102-01	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	11/01/2010		

Labeler - LIFElabs, a Division of Atico International, USA, INC. (073876450)

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