

CLOTRIMAZOLE - clotrimazole 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.

LIFElabs, a Division of Atico International USA, INC.

Clotrimazole

Active Ingredient

Clotrimazole 1%

Purpose

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.

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 a day
- for athlete's foot and ringworm use daily for 4 weeks, for jock itch use daily for 2 weeks
- if conditions persist longer, ask a doctor
- this product is not effective on the scalp or nails

Other information

store between 2^o and 30^o C (30^o and 86^o F) Lot No. and Exp. Date: see box or see crimp of tube

Inactive ingredients

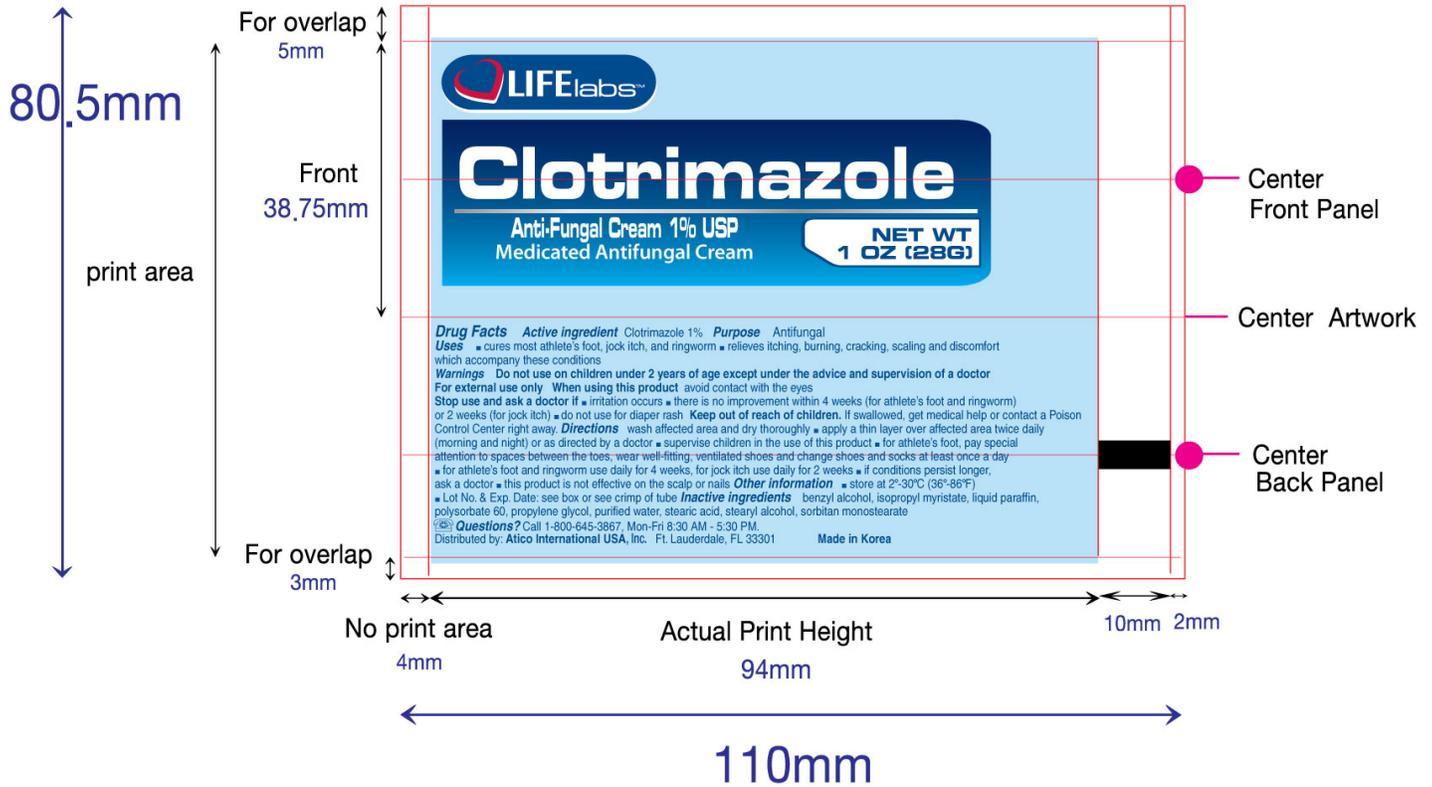
benzyl alcohol, isopropyl myristate, liquid parafin, polysorbate 60, propylene glycol, purified water, stearic acid, stearyl alcohol, sorbitan monostearate

Questions?

143 mm



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CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51852-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Clotrimazole (UNII: G07GZ97H65) (Clotrimazole - UNII:G07GZ97H65)	Clotrimazole	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Benzyl Alcohol (UNII: LKG8494WBH)	

Isopropyl Myristate (UNII: 0RE8K4LNJS)	
Mineral Oil (UNII: T5L8T28FGP)	
Polysorbate 60 (UNII: CAL22UVI4M)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0K00R)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Stearyl Alcohol (UNII: 2KR89I4HIY)	
Sorbitan Monostearate (UNII: NVZ4I0H58X)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51852-103-01	1 in 1 BOX		
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 - LIFE Labs, a Division of Atico International USA, INC. (073876450)

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