# LAKESIA- clotrimazole cream OPMX 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**

### **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 cover 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

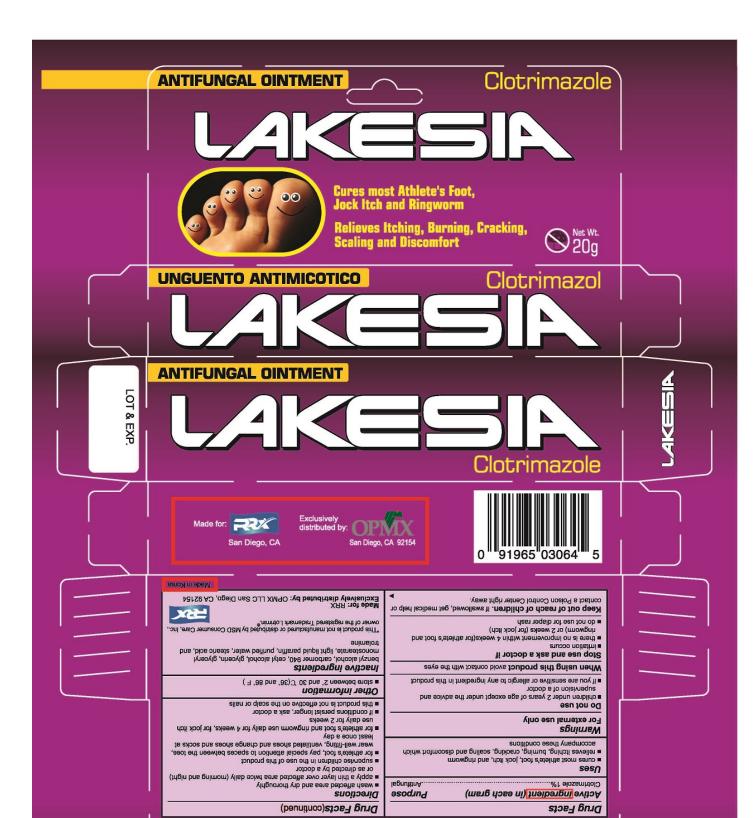
#### Other information

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

## **Inactive ingredients**

Benzyl alcohol, Carbomer940, Cetyl alcohol, Glycerin, Clyceryl monostearate, Light liquid paraffin, Myristoyl/palmitoyl oxostearamide/arachamide MEA, PEG-15 glyceryl stearate, Stearic acid, Trolamine, Purified water

Lakesia



**TNEMTNIO JADNU-ITNA** 

**Glotnimazole** 

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-064	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1 g in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
BENZYL ALCOHOL (UNII: LKG8494WBH)		
CARBOMER 940 (UNII: 4Q93RCW27E)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
PARAFFIN (UNII: 1900E3H2ZE)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TROLAMINE (UNII: 9O3K93S3TK)		
WATER (UNII: 059QF0KO0R)		

l	Packaging				
l	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
ı	1 NDC:69729-064-20	1 in 1 BOX			
l	1	20 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	07/02/2015		

## **Labeler -** OPMX LLC (029918743)

Revised: 7/2015 OPMX LLC