TOLNAFTATE - tolnaftate cream Morales Distributors, 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.

Tolnaftate 1 percent

Active ingredient (in each gram)

Tolnaftate 1 percent

Purpose

Antifungal

Uses

- clinically proven to cure most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- helps prevent most athlete's foot from recurring when used daily
- effectively soothes and relieves symptoms of athlete's foot, including itching, burning and cracking

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)
- supervise children in the use of this product
- for athlete's foot, pay special attentional to spaces between the toes, wear well-fitting, ventilated shoes and change shoes and socks at least once daily
- use daily for 4 weeks; if condition persists longer ask a doctor
- to prevent athlete's foot, apply once or twice daily (morning and night)
- this product is not effective on the scalp or nails

Other information

store between 2 degrees and 30 degrees Celsius (36 degrees and 86 degrees Fahrenheit)

Inactive ingredients

carbomer 940, cetyl alcohol, chlorocresol, dibasic sodium phosphate hydrate, glycerin, glyceryl monostearate, light liquid paraffin, purified water, and stearic acid

Package label

NDC NO. 53210-1001-0 Tolnafate 1 percent Cream USP 1 percent Antifungal

Relieves Itching and Burning

Cures and Prevents Athlete's Foot

Prevents and Relieves Itching and Redness

Anti-Itch Cream for Skin Irritations

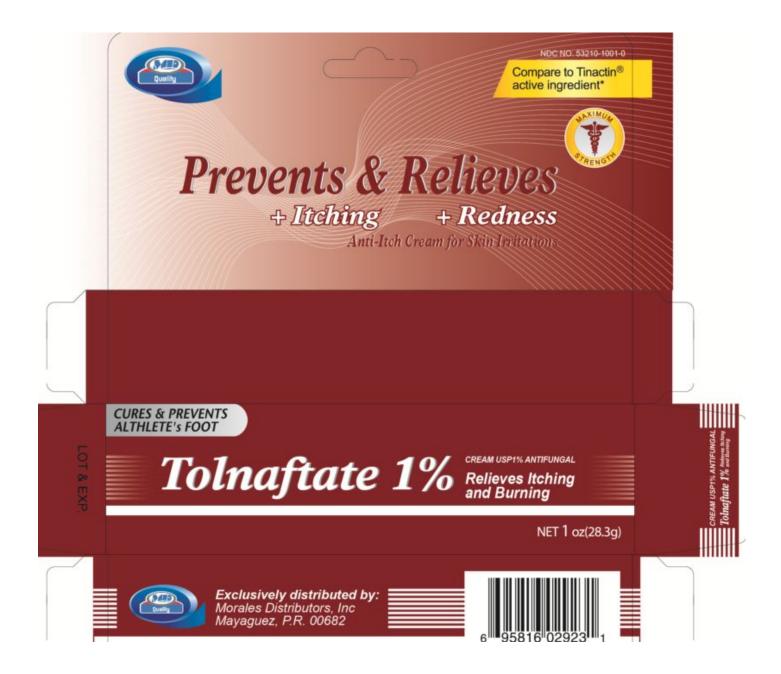
Compare to Tinactin (R) active ingredient This product is not manufactured or distributed by Schering-Plough Healthcare Products, Inc. owner of the registered Trademark Tinactin

Maximum Strength

Net 1 oz(28.3g)

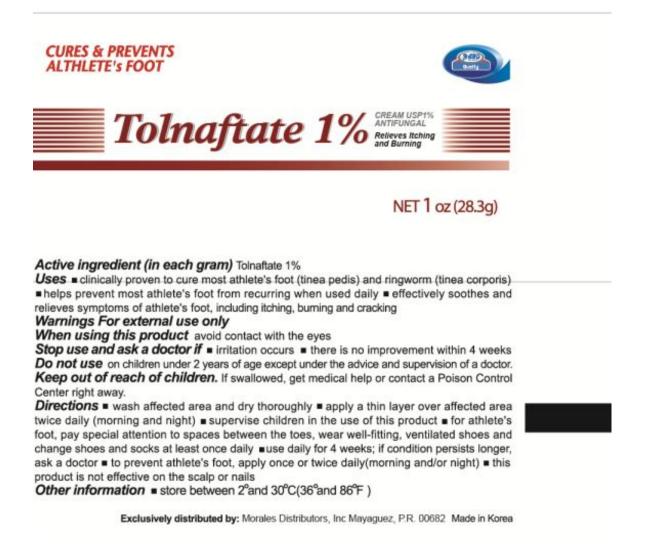
Exclusively distributed by: Morales Distributors, Inc Mayaguez, P.R. 00682

Made in Korea



Tolnaftate 1% Relieves Itching and Burning

Drug Facts	Drug Facts (continued)			
Active ingredient (in each gram) Purpose Tolnaftate 1% Antifungal				
Uses Clinically proven to cure most athlete's foot (tinea pedis) and ringworm (tinea corporis) helps prevent most athlete's foot from recurring when used daily effectively soothes and relieves symptoms of athlete's foot, including itching, burning and cracking				
Warnings ype JPG File	 this product is not effective on the scalp or nails 			
For external use only When using this product avoid contact with the eyes	Other information store between 2° and 30°C(36° and 86°F)			
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Directions wash affected area and dry thoroughly	*This product is not manufactured or distributed by Schering-Plougfi Healthcare Products, Inc., owner of the registered Trademark Tinactin			



ΓOLNAFTATE						
olnaftate cream						
Product Information						
Product T ype	HUMAN OTC DRUG	Item Code (Source) NDO		NDC:532	DC:53210-1001	
Route of Administration	TOPICAL					
Active Ingredient/Active Moi	ety					
Ingredient Name Basis of Stre				trength	Strength	
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV) TOLNAFTAT				2	1 g in 100 g	
Inactive Ingredients						
Ingredient Name					Strength	
CARBOMER HOMOPOLYMER TYPE	C (UNII: 4Q93RC W27E)					
CARBOMER HOMOPOLYMER TYPE CETYL ALCOHOL (UNII: 936JST6JC						

GI	L YCERIN (UNII: PDC6A	3C0OX)							
		ARATE (UNII: 230OU9XXE4)							
	GHT MINERAL OIL (U								
W	ATER (UNII: 059QF0KC	D0 R)							
SI	EARIC ACID (UNII: 4EI	LV7Z65AP)							
Pa	ackaging								
#	Item Code	Package Description	Marketin	g Start Date	Mark	eting End Date			
1	NDC:53210-1001-0	1 in 1 BOX							
1		28 g in 1 TUBE							
N	Marketing Information								
N	Iarketing Category	Application Number or Monogra	ph Citation	Marketing Start	Date M	larketing End Date			
0	ГС monograph final	part333C		09/25/2012					

Labeler - Morales Distributors, Inc. (127151731)

Revised: 9/2012

Morales Distributors, Inc.