#### TOLNAFTATE ANTIFUNGAL- tolnaftate cream Taro Pharmaceuticals U.S.A., 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 Antifungal Cream 1%**

#### Drug Facts

### Active ingredient

Tolnaftate 1%

## Purpose

Antifungal

### Uses

- proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- helps prevent most athlete's foot with daily use
- for effective relief of itching, burning and cracking

## Warnings

### For external use only

When using this product avoid contact with 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 attention 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/or night)
- this product is not effective on the scalp or nails

## Other information

- store between 20° to 25°C (68° to 77°F)
- see carton or tube crimp for lot number and expiration date

## **Inactive ingredients**

BHT, PEG-400, PEG-3350, titanium dioxide, white petrolatum

#### Questions?

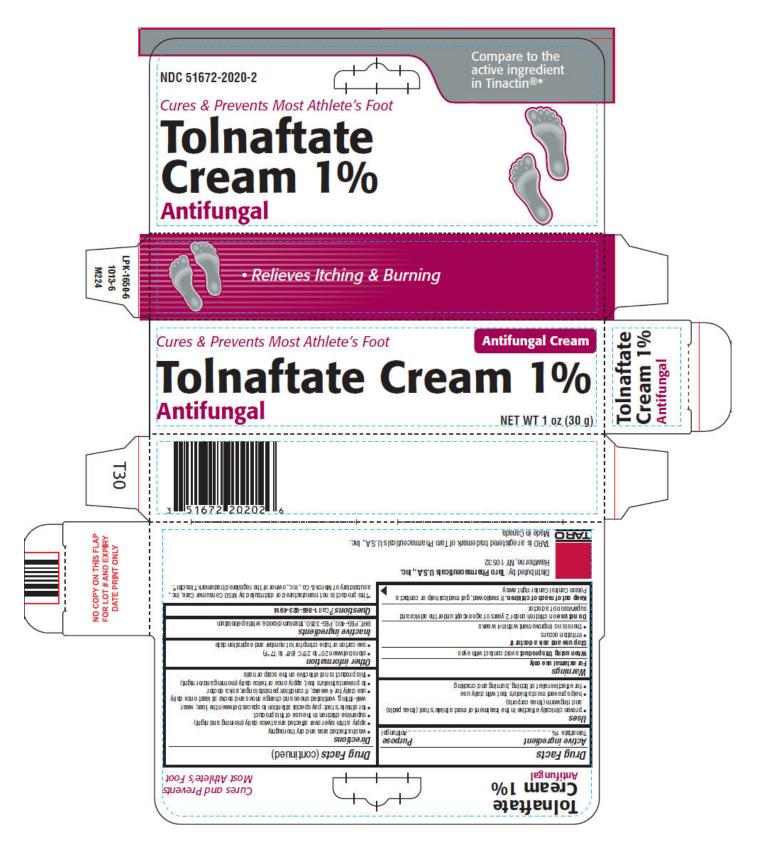
Call **1-866-923-4914** 

Distributed by: **Taro Pharmaceuticals U.S.A., Inc.** Hawthorne, NY 10532

### PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

Cures & Prevents Most Athlete's Foot

Antifungal Cream 1% Tolnaftate Cream 1% Antifungal NET WT 1 oz (30 g)



TOLNAFTATE ANTIFUNGAL								
tolnaftate cream								
Product Information								
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2020					
Route of Administration	TOPICAL							

	t/Active Moiety					
	Ingredient Name		<b>Basis of Strength</b>		Strength	
Tolnaftate (UNII: 06KB629TKV) (Tolnaftate - UNII:06KB629TKV)			To lna ftate 1 g		1 g in 100 g	
Inactive Ingredie						
Ingredient Name					Strength	
butylated hydroxytoluene (UNII: 1P9D0Z171K)						
	400 (UNII: B697894SGQ)					
	<b>3350</b> (UNII: G2M7P15E5P)					
titanium dioxide (UNII: 15FIX9V2JP)						
petrolatum (UNII: 4T6	(HI2BN9U)					
Product Charact	eristics					
Color	WHITE (opaque, white)		Score			
Shape			Size			
Flavor			Imprint Code			
Contains						
Packaging					der Trad Der	
	Package Description	Marl	eting Start Date	Marke	ting End Dat	
# Item Code	<b>Package Description</b> 1 in 1 CARTON	<b>Mari</b> 0 1/0 1/	0	Marke	ting End Dat	
Item Code           NDC:51672-2020-1		0 1/0 1/	0	Marke	ting End Dat	
<ul> <li># Item Code</li> <li>1 NDC:51672-2020-1</li> <li>1</li> </ul>	1 in 1 CARTON	0 1/0 1/	1995	Marke	ting End Dat	
<ul> <li><i>Item Code</i></li> <li>NDC:51672-2020-1</li> <li>NDC:51672-2020-2</li> </ul>	1 in 1 CARTON 15 g in 1 TUBE; Type 0: Not a Combination Produ	0 1/0 1/ ct 0 1/0 1/	1995	Marke	ting End Dat	
Fraging         #       Item Code         1       NDC:51672-2020-1         2       NDC:51672-2020-2         2       NDC:51672-2020-2	1 in 1 CARTON 15 g in 1 TUBE; Type 0: Not a Combination Produ 1 in 1 CARTON	0 1/0 1/ ct 0 1/0 1/	1995	Marke	ting End Dat	
<ul> <li>Item Code</li> <li>NDC:51672-2020-1</li> <li>NDC:51672-2020-2</li> </ul>	1 in 1 CARTON 15 g in 1 TUBE; Type 0: Not a Combination Produ 1 in 1 CARTON	0 1/0 1/ ct 0 1/0 1/	1995	Marke	ting End Dat	
<ul> <li># Item Code</li> <li>1 NDC:51672-2020-1</li> <li>1 NDC:51672-2020-2</li> </ul>	1 in 1 CARTON 15 g in 1 TUBE; Type 0: Not a Combination Produ 1 in 1 CARTON 30 g in 1 TUBE; Type 0: Not a Combination Produ	0 1/0 1/ ct 0 1/0 1/	1995	Marke	ting End Dat	
<ul> <li># Item Code</li> <li>1 NDC:51672-2020-1</li> <li>1 NDC:51672-2020-2</li> <li>2 NDC:51672-2020-2</li> </ul>	1 in 1 CARTON 15 g in 1 TUBE; Type 0: Not a Combination Produ 1 in 1 CARTON 30 g in 1 TUBE; Type 0: Not a Combination Produ	0 1/0 1/ ct 0 1/0 1/ ict 0 1/0 1/	1995		eting End Dat	

# Labeler - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment						
Name	Address	ID/FEI	Business Operations			
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-2020)			

Revised: 1/2020

Taro Pharmaceuticals U.S.A., Inc.