

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 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 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



NDC NO: 53210-1001-0

Compare to Tinactin®
active ingredient*



Prevents & Relieves

+ Itching + Redness
Anti-Itch Cream for Skin Irritations

**CURES & PREVENTS
ALTHLETE'S FOOT**

LOT & EXP.

Tolnaftate 1%

CREAM USP1% ANTIFUNGAL
**Relieves Itching
and Burning**

NET 1 oz(28.3g)

CREAM USP1% ANTIFUNGAL
Tolnaftate 1%
*Relieves Itching
and Burning*



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



6 95816 02923 1

Tolnaftate 1%

Relieves Itching and Burning

Drug Facts		Drug Facts (continued)	
Active ingredient (in each gram)	Purpose	<ul style="list-style-type: none"> ■ 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 	
Tolnaftate 1%	Antifungal		
Uses		Other information	
<ul style="list-style-type: none"> ■ 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 		<ul style="list-style-type: none"> ■ store between 2° and 30°C(36° and 86°F) 	
Warnings		Inactive ingredients	
<p>For external use only</p> <p>When using this product avoid contact with the eyes</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ irritation occurs ■ there is no improvement within 4 weeks <p>Do not use on children under 2 years of age except under the advice and supervision of a doctor.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>		carbomer 940, cetyl alcohol, chlorocresol, dibasic sodium phosphate hydrate, glycerin, glyceryl monostearate, light liquid paraffin, purified water, and stearic acid	
Directions		<small>*This product is not manufactured or distributed by Schering-Plough[®] Healthcare Products, Inc., owner of the registered Trademark Tinactin</small>	
<ul style="list-style-type: none"> ■ wash affected area and dry thoroughly 			

Made in Korea

**CURES & PREVENTS
ALHLETE'S FOOT**



Tolnaftate 1%

CREAM USP1%
ANTIFUNGAL
Relieves Itching
and Burning

NET 1 oz (28.3g)

Active ingredient (in each gram) Tolnaftate 1%

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TOLNAFTATE

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53210-1001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HO MO POL YMER TYPE C (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHLOROCRESOL (UNII: 36W53O7109)	

GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53210-1001-0	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	09/25/2012	

Labeler - Morales Distributors, Inc. (127151731)

Revised: 9/2012

Morales Distributors, Inc.