

WESTERN FAMILY ANTIFUNGAL- tolnaftate cream

Western Family Foods 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.

Western Family®

Antifungal

Drug Facts

Active ingredient

Tolnaftate 1%

Purpose

Antifungal

Uses

- cures most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis)
- helps prevent most athlete's foot with daily use
- for effective relief of
 - itching
 - scaling
 - cracking
 - burning
 - redness
 - soreness
 - irritation
 - discomfort

Warnings

For external use only

Ask a doctor before use

- on children under 2 years of age

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot and ringworm) or within 2 weeks (for jock itch)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

This product is not effective on the scalp or nails.

For athlete's foot and ringworm: use daily for 4 weeks. For jock itch: use daily for 2 weeks.

- clean the affected area and dry thoroughly
- apply a thin layer of the product 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; change shoes and socks at least once daily

Other information

- store at controlled room temperature
- 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:

Western Family Foods, Inc.

P.O. Box 4057

Portland, OR 97208 U.S.A.

PRINCIPAL DISPLAY PANEL - 15 g Tube Carton

AntiFungal Cream

TOLNAFTATE 1% CREAM

FOOT CREAM

NET WT 0.5 OZ (15 g)



COMPARE TO THE ACTIVE INGREDIENT IN TINACTIN®*

Cures & Prevents Most Athlete's Foot Relieves Itching & Burning

LPK-2854-3
0711-3
M308

AntiFungal Cream
TOLNAFTATE 1% CREAM

AntiFungal Cream
TOLNAFTATE 1% CREAM

FOOT CREAM

NET WT 0.5 OZ (15 g)

T27



0531-0-B-3A80

5 01550-00451

Drug Facts (continued)
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Distributed by:
P.O. Box 4057
Portland, OR 97208 USA
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Marla RegisPrada
SATISFACTION
GUARANTEED
QUALITY
Made in Canada

Drug Facts
Active Ingredient
Tolnaftate 1% Antifungal
Purpose
This product is not manufactured or distributed by Schering-Plough HealthCare Products, Inc., owner of the registered trademark Tinactin®.
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WESTERN FAMILY ANTIFUNGAL

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Toinaftate (UNII: 06KB629TKV) (Toinaftate - UNII:06KB629TKV)	Toinaftate	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-020-01	1 in 1 CARTON		
1		15 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	02/17/2006	

Labeler - Western Family Foods Inc (192166072)

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

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(55312-020)