

TOLNAFTATE ANTIFUNGAL- tolnaftate cream

Amerisource Bergen

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% Cream

Antifungal Cream

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 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
AmerisourceBergen
1300 Morris Drive
Chesterbrook, PA 19087

PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

**GOOD
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PHARMACY®**

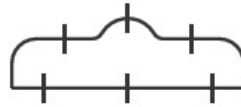
Compare to the Tinactin® active ingredient*

NDC 24385-032-03

Tolnaftate 1% Cream
Antifungal Cream

Cures & Prevents Most Athlete's Foot

NET WT 1 oz (30 g)



Compare to the Tinactin® active ingredient*

NDC 24385-032-03

Tolnaftate 1% Cream

Antifungal Cream

Cures & Prevents Most Athlete's Foot

Relieves Itching & Burning
Odorless, Greaseless Cream



NDC 24385-032-03

Tolnaftate 1% Cream

Antifungal Cream

Cures & Prevents Most Athlete's Foot



Compare to the Tinactin® active ingredient*

NDC 24385-032-03

Tolnaftate 1% Cream

Antifungal Cream

Cures & Prevents Most Athlete's Foot

NET WT 1 oz (30 g)

894-352



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AmerisourceBergen
1300 Morris Drive
Chesterbrook, PA 19087

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AND EXP DATE PRINT

This product is
not manufactured
or distributed by
Schering-Plough
HealthCare
Products, Inc.,
owner of the
registered trademark
Tinactin®.

Active ingredient Tolnaftate 1%.....	Purpose Antifungal
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TOLNAFTATE ANTIFUNGAL

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24385-032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Tolnaftate (UNII: 06KB629TKV) (Tolnaftate - UNII:06KB629TKV)	Tolnaftate	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:24385-032-03	1 in 1 CARTON		
1		30 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 - Amerisource Bergen (007914906)**Registrant** - Taro Pharmaceuticals U.S.A., Inc. (145186370)**Establishment**

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(24385-032)

