

TOLNAFTATE ANTIFUNGAL- tolnaftate cream
Central Texas Community Health Centers

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 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

HOW SUPPLIED

Product: 76413-321

NDC: 76413-321-15 15 g in a TUBE

TOLNAFTATE ANTIFUNGAL (TOLNAFTATE) CREAM

CommUnityCare Federally Qualified Health Centers

TOLNAFATE
1% CREAM
15GM

Date:

Name:

Dr.

USE AS DIRECTED.

USAR COMO INDICADO.

123456

1/1/01

TOLNAFATE 1% CRM15GM NDC 76413-321-15

Batch: 123456

Lot: 123456

Exp: 1/1/01

Taro

TOLNAFTATE ANTIFUNGAL

tolnaftate cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:76413-321(NDC:51672-2020)

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
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
polyethylene glycol 400 (UNII: B697894SGQ)	
polyethylene glycol 3350 (UNII: G2M7P15E5P)	
titanium dioxide (UNII: 15FIX9V2JP)	
petrolatum (UNII: 4T6H12BN9U)	

Product Characteristics

Color	WHITE (opaque, white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76413-321-15	15 g in 1 TUBE; Type 0: Not a Combination Product	01/01/1995	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333C	01/01/1995	

Labeler - Central Texas Community Health Centers (079674019)

Establishment

Name	Address	ID/FEI	Business Operations
Travis County Healthcare District		797039398	RELABEL(76413-321) , REPACK(76413-321)

Revised: 5/2018

Central Texas Community Health Centers