

ANTIFUNGAL- tolnaftate 1% cream
Chain Drug Marketing Association 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.

Quality Choice Antifungal Cream Tolnaftate 1%

Drug Facts

Active ingredient

Tolnaftate 1%

Purpose

Antifungal

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center immediately.

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 the eyes.

Stop use and ask a doctor if ● irritation occurs ● there is no improvement within 4 weeks improvement

Do not use on children under 2 years of age except under the advice and supervision of a doctor.

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 conditions 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.

Inactive ingredients

Cetyl alcohol, ethylparaben, glycerol, mineral oil, glycerol monostearate, petrolatum, purified water, sodium lauryl sulfate

Other information

- store between 20° to 25°C (68° to 77°F)
- Lot No & Expiration Date: See box or crimp of tube.

Distributed By

Distributed By CDMA Inc.

43157 W 9 Mile Road

Novi, MI. 48375

www.qualitychoice.com

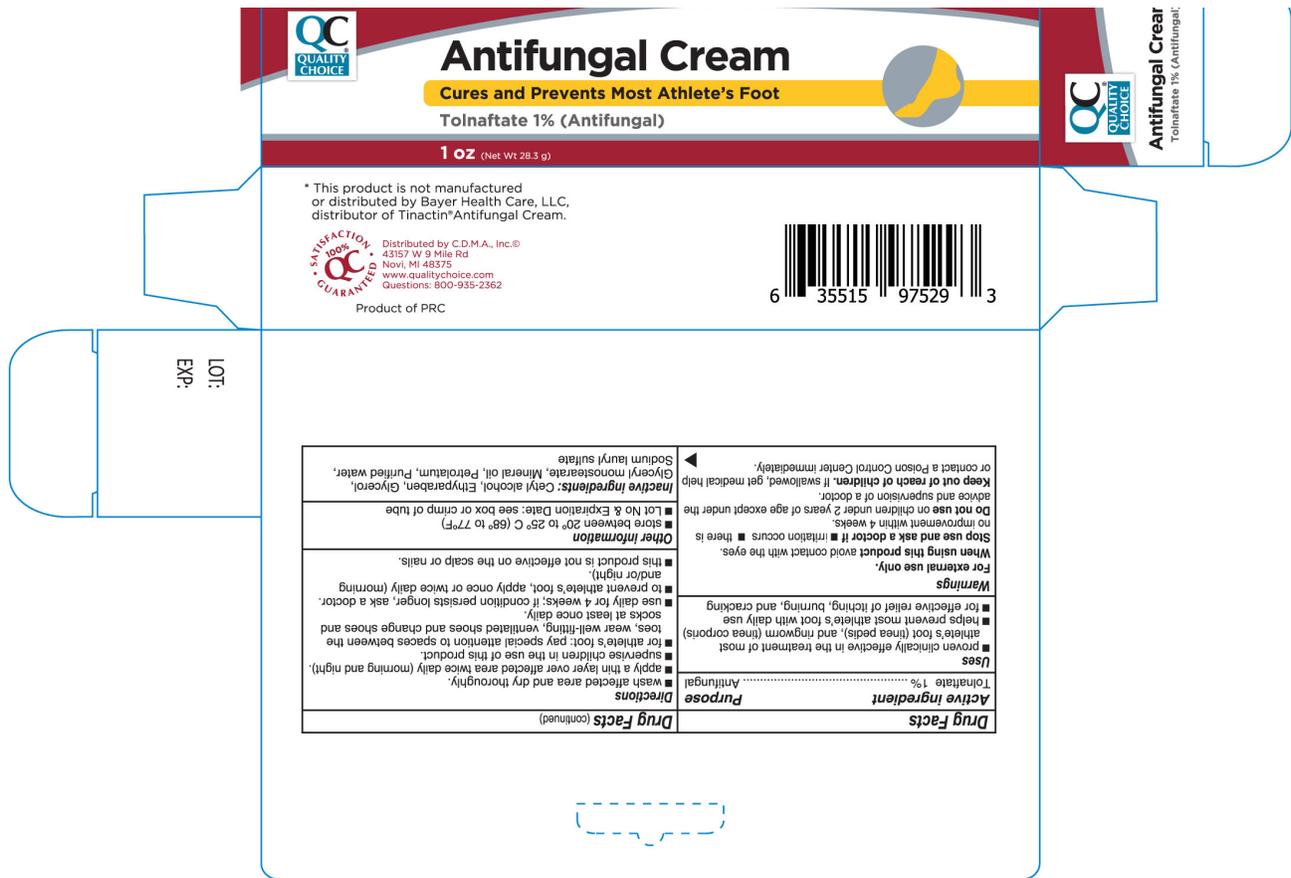
Questions: 800-935-2362

Product of PRC

This product is not manufactured or distributed by Bayer Health Care, LLC. distributor of Tinactin Antifungal Cream

OUTSIDE BOX





INNER TUBE



ANTIFUNGAL
tolnaftate 1% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-685
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
MINERAL OIL (UNII: T5L8T28FGP)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0K00R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-685-01	1 in 1 BOX	08/14/2020	
1		28.3 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	08/14/2020	

Labeler - Chain Drug Marketing Association Inc. (011920774)

Registrant - Trifecta Pharmaceuticals USA, LLC. (079424163)

Revised: 5/2023

Chain Drug Marketing Association Inc.