TOLNAFTATE CREAM 1% ANTIFUNGAL- tolnaftate cream Trifecta Pharmaceuticals Usa Llc

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 Cream 1% ANTIFUNGAL CREAM

Drug Facts

Active ingredient

Tolnaftate 1%

Purpose

Anti-Fungal

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 healthcare professional 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 healthcare professional.

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 healthcare professional.
- 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

Cetostearyl alcohol, ethylparaben, glycerol, light mineral oil, monostearin, petrolatum, purified water, sodium dodecyl sulfate

Other information

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

100% GUARANTEED

Cures and Prevents Most Athlete's Foot

Distributed by:

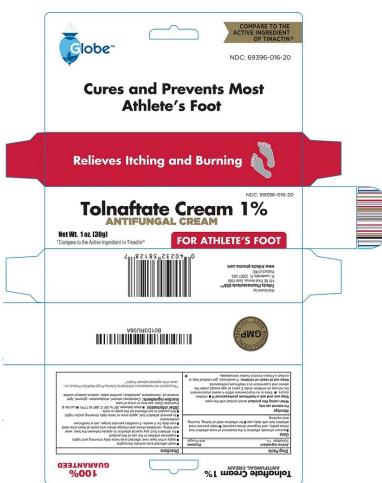
Trifecta Pharmaceuticals USA™

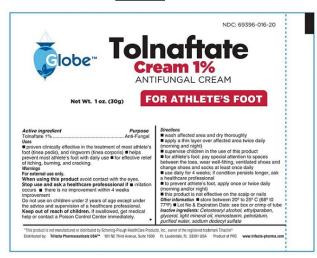
101 NE Third Avenue, Suite 1500 Ft. Lauderdale, FL 33301 USA Product of PRC

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Packaging

<u>OUTER BOX</u> <u>INNER TUBE</u>





TOLNAFTATE CREAM 1% ANTIFUNGAL

tolnaftate cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69396-016

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
GLYCERYL MONOSTEARATE (LINII: 2300LI9XXE4)	

PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:69396-016- 20	1 in 1 BOX	04/09/2016			
1		30 g in 1 TUBE; Type 0: Not a Combination Product				
2	NDC:69396-016- 05	1 in 1 BOX	04/09/2016			
2		15 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	04/09/2016			

Labeler - Trifecta Pharmaceuticals Usa Llc (079424163)

Revised: 1/2023 Trifecta Pharmaceuticals Usa Llc