TOLNAFTATE CREAM 1%- tolnaftate cream
Pharmacy Value Alliance, 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%

Drug Facts

Active Ingredient

Tolnaftate 1%

Purpose

Anti-Fungal

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

Keep out of the reach of children

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

Warnings

For External Use Only

When using this product avoid contact with the eyes

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 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

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks

Other Information

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

Inactive ingredients:

Cetyl alcohol, Ethylparabe, Glycerol, Glyceryl Monostearate, Mineral Oil, Petrolatum, Purified Water, Sodium Dodecyl sulfate

Soothes Itching, Burning and Cracking

Distributed By:

Pharmacy Value Alliance, LLC.

407 East Lancaster Avenue, Wayne, PA. 19087 USA

www.emersongroup.com

Packaging

OUTER BOX

INNER TUBE

TOLNAFTATE CREAM 1%

tolnaftate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-152
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**
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

WATER (UNII: 059QF0KO0R)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PETROLATUM (UNII: 4T6H12BN9U)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-152-01	1 in 1 BOX	08/31/2016	
1		28 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	08/23/2016	

Labeler - Pharmacy Value Alliance, LLC. (101668460)

Registrant - Trifecta Pharmaceuticals USA, LLC. (079424163)

Revised: 5/2023 Pharmacy Value Alliance, LLC.