

**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.*

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**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

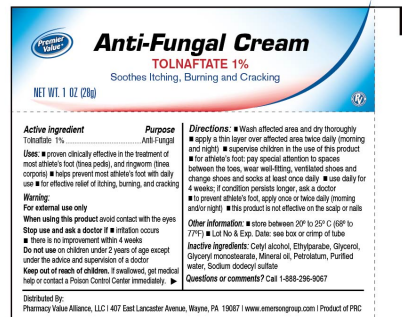
[www.emersongroup.com](http://www.emersongroup.com)

**Packaging**

OUTER BOX



INNERTUBE



TOLNAFTATE CREAM 1%			
tolnaftate cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68016-152
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name		Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)		TOLNAFTATE	10 mg in 1 g
<b>Inactive Ingredients</b>			
Ingredient Name			Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)			
LIGHT MINERAL OIL (UNII: N6K5787QVP)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ETHYLPARABEN</b> (UNII: 14255EXE39)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>GLYCERIN</b> (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.