

**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.*

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**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

**[www.trifecta-pharma.com](http://www.trifecta-pharma.com)**

### **Packaging**

**OUTER BOX**

**INNER TUBE**

<b>TOLNAFTATE CREAM 1% ANTIFUNGAL</b>			
tolnaftate cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69396-016
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)		TOLNAFTATE	1 g in 100 g
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
ETHYLPARABEN (UNII: 14255EXE39)			
GLYCERIN (UNII: PDC6A3C0OX)			
LIGHT MINERAL OIL (UNII: N6K5787QVP)			
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)			

**PETROLATUM** (UNII: 4T6H12BN9U)

**WATER** (UNII: 059QF0KO0R)

**SODIUM LAURYL SULFATE** (UNII: 368GB5141J)

### 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