

## **FIRST AID ANTIFUNGAL MEDICATED- tolnaftate cream**

**First Aid Research Corp.**

*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.*

-----

### **First Aid Antifungal Medicated Cream**

#### ***Active ingredient***

Tolnaftate 1%

#### ***Purpose***

Antifungal

#### ***Uses***

- proven clinically effective in the treatment of athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)
- proven effective in the prevention of 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

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

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### ***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 shoes and change 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 scalps or nails

#### ***Other information***

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

**Inactive ingredients**

petrolatum, cetanol, liquid paraffin, methylparaben, polyoxyethylene, propylene glycol, propylparaben, purified water, sorbitan monostearate, stearyl alcohol.

Distributed by:

First Aid Research Corp.

Jupiter, Florida, USA 33478

Made in India

**PRINCIPAL DISPLAY PANEL**

**First Aid Antifungal Medicated Cream**

**NET WT 1 OZ (28 g)**

**FIRST AID RESEARCH**  **Antifungal Medicated Cream**  
**Tolnaftate**

<b>Drug Facts</b>	
<b>Active ingredients</b> Tolnaftate 1%	<b>Purpose</b> Antifungal
<b>Uses</b> proven clinically effective in the treatment of athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis) ■ proven effective in the prevention of athlete's foot with daily use ■ for effective relief of itching, burning and cracking	
<b>Warnings</b> For external use only. When using this product avoid contact with eyes Stop use and ask a doctor if ■ irritation occurs ■ there is no improvement within 4 weeks Do not use on children under 2 years of age except under the advice and supervision of a doctor Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> ■ 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 shoes and change 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 scalps or nails	
<b>Other information</b> ■ store between 20 to 25 °C (68 and 77°F) ■ Lot No & Expiration Date: See box or see crimp	
<b>Inactive ingredients</b> petrolatum, cetanol, liquid paraffin, methylparaben, polyoxyethylene, propylene glycol, propylparaben, purified water, sorbitan monostearate, stearyl alcohol	

6 8 14428100537 27

Made in India

Distributed by:  
**FIRST AID RESEARCH CORP.**  
Jupiter, Florida USA 33478

**CREAM USP 1%**

**Tolnaftate**  
**Antifungal Medicated Cream**

NET WT 1 OZ (28 g)



## FIRST AID ANTIFUNGAL MEDICATED

tolnaftate cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75983-002
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
PETROLATUM (UNII: 4T6H12BN9U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MINERAL OIL (UNII: T5L8T28FGP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	

**Product Characteristics**

<b>Color</b>	white (White to Off-white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75983-002-28	1 in 1 CARTON	01/02/2018	
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	01/02/2018	

**Labeler** - First Aid Research Corp. (089405927)**Registrant** - Anicare Pharmaceuticals Pvt. Ltd (916837425)**Establishment**

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(75983-002)

Revised: 1/2018

First Aid Research Corp.