FIRST AID ANTIFUNGAL MEDICATED- tolnaftate cream
Anicare Pharmaceuticals Pvt. Ltd

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 monstearate, stearyl alchol.

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 ANTIFUNGAL MEDICATED

tolnaftate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47046-164
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: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Product Characteristics			
Color	white (White to Off-white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47046-164-02	1 in 1 CARTON	01/02/2018	
1	NDC:47046-164-01	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 - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(47046-164)

Revised: 12/2020 Anicare Pharmaceuticals Pvt. Ltd