FIRST AID ANTIFUNGAL MEDICATED CREAM 1OZ- tolnaftate cream
First Aid Reserach 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.

Active ingredient Purpose

Tolnaftate 1%---------- Antifungal

Uses

Proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)

Helps preent 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 doctor if

- irritation becomes severe
- 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 immediately.

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

Directions

- wash affected area and dry throughly
- apply a thin layer over affected area twie 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

Other information

store between 20° to 25° (68° to 77°F)

Lot No. & Exp. Date;see box or see crimp of tube

ceteth-20, cetostearyl alcohol, chlorocresol, liquid paraffin, monobasic sodium phosphate dihydrate, propylene glycol, purified water, white petrolatum

Distributed by:

First Aid Research Corp.

Wantagh, NY U.S. A. 11793

Made in Korea

FIRST AID ANTIFUNGAL MEDICATED CREAM 1OZ

tolnaftate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75983-537
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**
CETETH-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHLOROCRESOL (UNII: 36W53O7109)	
PARAFFIN (UNII: I9O0E3H2ZE)	
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:75983-537-28	1 in 1 CARTON		
1		28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	10/09/2014	

Labeler - First Aid Reserach Corp (089405927)

Revised: 10/2014 First Aid Reserach Corp