AFTATE ATHLETE FOOT CREAM- tolnaftate cream
Sabel Med 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.

Aftate-Tolnaftate Athlete's Foot Cream- 1 oz and 0.5 oz

Active ingredient

Tolnaftate 1%.....

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
- for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks
- if condition persists longer, ask a doctor
- this product is not effective on the scalp or nails

Inactive ingredients

ceteth-20, cetyl alcohol, chlorocresol, mineral oil, propylene glycol, purified water, sodium phosphate monobasic, stearyl alcohol, white petrolatum

Warnings

For external use only

Do not use on children under 2 years of age unless directed by a doctor.

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 (for athlete's foot and ringworm) or 2 weeks (for jock itch)

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

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Purpose

.....Antifungal

Uses

- cures most athlete's foot, jock itch, and ringworm
- relieves itching, burning, cracking, scaling and discomfort which accompany these conditions

AFTATE ATHLETE FOOT CREAM

tolnaftate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70356-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL 1-(2-METHYLBUTYRATE) (UNII: 9Q5W5G6461)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CHLOROCRESOL (UNII: 36W53O7109)	
CETETH-20 (UNII: I835H2IHHX)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70356-001-01	28 g in 1 TUBE; Type 0: Not a Combination Product	12/02/2016	
2	NDC:70356-001-05	14 g in 1 TUBE; Type 0: Not a Combination Product	12/02/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	12/01/2016	

Labeler - Sabel Med LLC (091476000)

Revised: 11/2016 Sabel Med LLC