FAMILY WELLNESS ANTIFUNGAL- tolnaftate cream Family Dollar

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.

Family Wellness Anti-Fungal Cream Tolnaftate 1% 0.5 oz (6504, 2019)

Active Ingredient

Tolnaftate 1%...... Antifungal

Uses

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

Purpose

- helps prevent most athlete's foot with daily use
- for effective relief of itching, burning, and cracking

Warnings

For external use only

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

Keep out of reach of children. If swallowed, get medical help or contact a Poision 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, ventilated shoes and change shoes and socks at least once daily
- for athlete's foot and ringworm, use daily for 4 weeks. If conditions persist longer, consult 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 at room temperature 20-25°C (68-77°F)

Inactive ingredients

butylated hydroxytoluene, cetanol, ceteth-20, liquid paraffin, methylparaben, propylene glycol, propylparaben, purified water, sorbitan, monostearate, stearyl alcohol

DISTRIBUTED BY:

10611 MONOROE RD., MATTHEWS, NC 28105

MADE IN SOUTH KOREA



FAMILY WELLNESS ANTIFUNGAL

tolnaftate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-300
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	
CETETH-20 (UNII: I835H2IHHX)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
METHYLPARABEN (UNII: A218 C7H19 T)		
PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E)		
SORBITAN MONOSTEARATE (UNII: NVZ4I0 H58 X)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)		
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)		

]	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-300-14	1 in 1 BOX	11/08/2016	
1		14 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	0 1/2 1/2 0 14		

Labeler - Family Dollar (024472631)

Revised: 3/2019 Family Dollar