FAMILY CARE ANTIFUNGAL- tolnaftate cream United Exchange 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.

Family Care Tolnaftate Cream 1 oz 502 (2018) Dingtai

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 prevent 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 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 immediately.

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; 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°C (68° to 77°F)
- Lot No. & Exp. Date: see box or see crimp of tube

Inactive ingredients

cetostearly alcohol, ethylparaben, glycerin, light mineral oil, propylene glycol, purified water, sodium sulfite, stearth-20, stearic acid

Distributed by:

United Exchange Corp.

5836 Corporate Ave.

Cypress, CA 90630 USA



FAMILY CARE ANTIFUNGAL

tolnaftate cream

Pro	duct	Infor	mation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:65923-021

Route of Administration

TOPICAL

ı	Active Ingredient/Active Wolety		
	Ingredient Name	Basis of Strength	Strength
	TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	10 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
PETROLATUM (UNII: 4T6H12BN9U)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
SODIUM SULFITE (UNII: VTK01UQK3G)		
STEARETH-20 (UNII: L0Q8IK9E08)		
GLYCERIN (UNII: PDC6A3C0OX)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
ETHYLPARABEN (UNII: 14255EXE39)		

1	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:65923-021-28	1 in 1 CARTON	0 1/0 2/20 17		
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	0 1/0 2/20 17		

Labeler - United Exchange Corp. (840130579)

Revised: 12/2018 United Exchange Corp.