## DG HEALTH ATHLETES FOOT- tolnaftate cream Dolgencorp, 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.

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#### DG Health Athlete's Foot Cream 1oz, Tolnaftate 1% (30502, 2018)

#### **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

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

#### Inactive ingredients

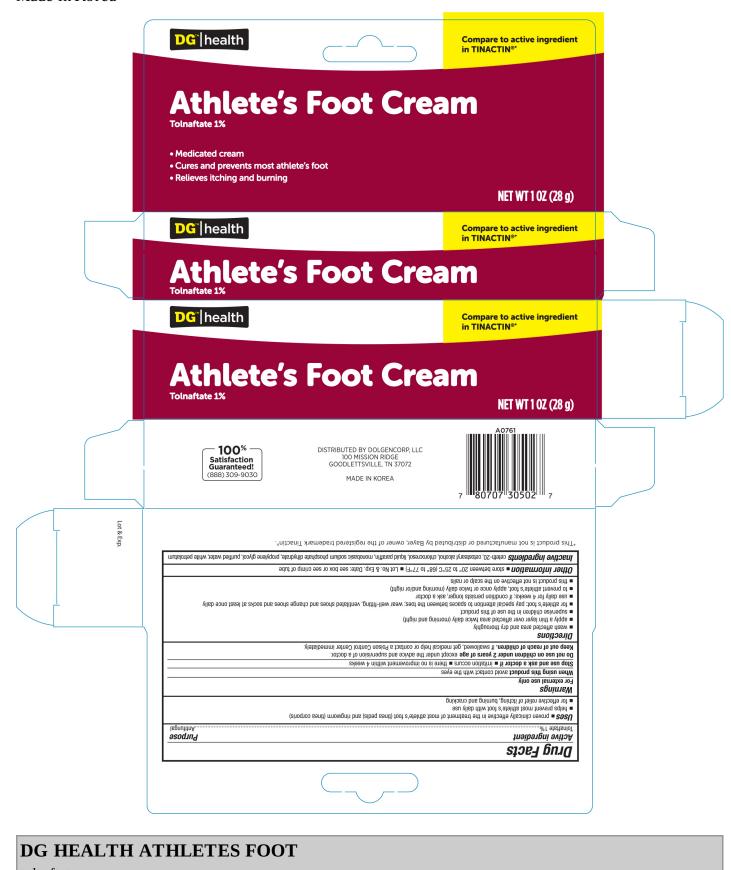
ceteth-20, cetostearly alcohol, chlorocresol, liquid paraffin, monobasic sodium phosphate dihydrate, propylene glycol, purified water, white petrolatum

#### Distributed by:

Dolgencorp, LLC

100 Mission Ridge

Goodlettsville, TN 37072



# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:55910-027

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	
<b>CETETH-20</b> (UNII: 1835H2IHHX)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
CHLOROCRESOL (UNII: 36W53O7109)		
PARAFFIN (UNII: 19 O0 E3H2ZE)		
SO DIUM PHO SPHATE, MO NO BASIC, DIHYDRATE (UNII: 5QWK665956)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
PETROLATUM (UNII: 4T6H12BN9U)		

Packaging					
Ш	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:55910-027-28	1 in 1 CARTON	10/04/2016		
l	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	11/05/2015			

### Labeler - Dolgencorp, LLC (068331990)

Revised: 12/2018 Dolgencorp, LLC