

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.

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

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

Distributed by:

Dolgencorp, LLC

100 Mission Ridge

Goodlettsville, TN 37072

Made in Korea



DG HEALTH ATHLETES FOOT

tolnaftate cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:559 10-027

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: 2DMT128MIS)	
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:55910-027-28	1 in 1 CARTON	10/04/2016	
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