

## **ATHLETES FOOT ANTIFUNGAL- tolnaftate cream**

### **Dollar General**

*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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### **Athlete's Foot Cream**

#### **Antifungal Cream**

#### **Drug Facts**

#### **Active ingredient**

Tolnaftate 1%

#### **Purpose**

Antifungal

#### **Uses**

- prevents the recurrence of most athlete's foot with daily use
- relieves itching, burning, cracking, scaling, and discomfort that accompany these conditions

#### **Warnings**

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

**For external use only.**

**Avoid contact with eyes.**

#### **Stop use and ask a doctor if**

- irritation occurs
- there is no improvement within 4 weeks

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** If swallowed, get medical help or, contact a Poison Control Center right away: 800-222-1222.

#### **Directions**

- wash affected area and dry thoroughly
- apply a thin layer over affected area twice daily (morning and night)
- supervise children in 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
- this product is not effective on scalp or nails

#### **Other information**

- store at 15 to 30°C (59 to 86°F)

- **Tamper Evident:** DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING.

**Inactive ingredients**

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

**Questions or comments?**

**1-888-309-9030**

DISTRIBUTED BY OLD EAST MAIN CO.,  
100 MISSION RIDGE  
GOODLETTSVILLE, TN 37072

**PRINCIPAL DISPLAY PANEL - 28 g Tube Carton**

DG™| health

Compare to the active  
ingredient of TINACTIN®\*

Athlete's Foot Cream  
Antifungal Cream

NET WT 1 OZ (28 g)

DG health

NDC 55910-341-24

Compare to the active ingredient of TINACTIN®\*

# Athlete's Foot Cream

Antifungal Cream

- Cures most athlete's foot
- Relieves itching and burning
- Greaseless and odorless

# Athlete's Foot Cream

Antifungal Cream

NET WT 1 OZ (28 g)

PL3 06508  
1/03

Athlete's  
Foot  
Antifungal Cream

DG health

Compare to the active ingredient of TINACTIN®\*

# Athlete's Foot Cream

Antifungal Cream

NET WT 1 OZ (28 g)

100%  
Satisfaction  
Guaranteed!  
(888) 309-9030

DISTRIBUTED BY OLD EAST MAIN CO.,  
100 MISSION RIDGE  
GOODLETTSVILLE, TN 37072  
MADE IN U.S.A.



\*This product is not manufactured by or distributed by Bayer, the distributor of Tinactin®.

<b>Drug Facts</b>	<b>Directions</b> Apply a thin layer over or affected area twice daily (morning and night). Wash affected area and dry thoroughly before use.
<b>Warnings</b> Do not use on children under 2 years of age unless directed by a doctor. For external use only.	<b>Other information</b> Store at 15° to 30° C (59° to 86° F). Tamper Evident: DO NOT USE IF SEAL OR TUBE IS PUNCTURED OR MISSING. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
<b>Uses</b> Relieves the recurrence of most athlete's foot with daily use. Relieves itching, burning, cracking, scaling, and discomfort that accompany these conditions.	<b>Inactive ingredients</b> cetolin-20, cetin, acryl, glycerol, glycol, propylene glycol, purified sodium phosphate, petrolatum, propylene glycol, purified water, stearyl alcohol.
<b>Active Ingredient</b> Tolnaftate 1% Antifungal	<b>Questions or comments?</b> 1-888-309-9030

Athlete's Foot  
Antifungal Cream

tolnaftate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55910-341
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	0.01 mg in 10 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
CETETH-20 (UNII: I835H2IHHX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHLOROCRESOL (UNII: 36W53O7109)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-341-24	1 in 1 CARTON	10/01/2017	
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	10/01/2017	

**Labeler** - Dollar General (068331990)

### Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(55910-341)