# ATHLETES FOOT- tolnaftate spray 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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#### **Athletes Foot**

# □Active Ingredient □Purpose

Tolnaftate 1% ...... Antifungal

#### **□Uses**

- cures most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- if used daily, can prevent recurrence of athlete's foot
- relieves symptoms of athlete's foot, including itching, burning and cracking

**IKeep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately. Do not use on children under 2 years of age unless directed by a doctor.

DG Health

Athlete's Foot Liquid Spray Tolnaftate 1% Antifungal

Compare to active ingredeint in Tinactin®\*

Cures and prevents most athlete's foot

Relieves burning and itching

Net Wt 5.3oz (150g)

## □ Warnings

#### **IFor external use only.**

**Fluammable.** Do not use while smoking or near heat or flame. Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120oF (49oC).

#### **When using this product**

- avoid contact with eyes and face
- use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal

#### Stop use and ask a doctor if

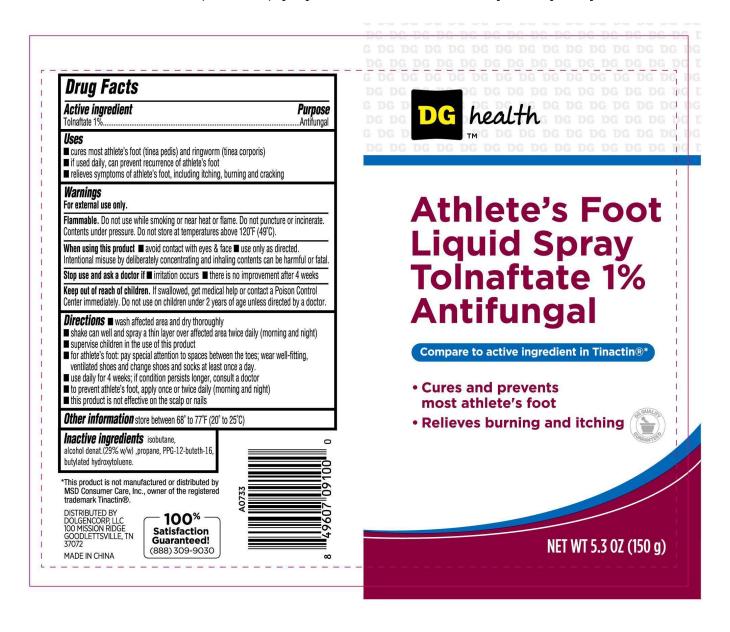
- irritation occurs
- there is no improvement after 4 weeks

#### Directions

- wash affected area and dry thoroughly
- shake can well and spray 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 a day
- use daily for 4 weeks; if condition persists longer, consult a doctor
- to prevent athlete's foot, apply once or twice daily (morning and night)
- this product is not effective on the scalp or nails

## **Inactive Ingredients**

isobutane, alcohol denat. (29% w/w), propane, PPG-12-buteth-16, butylated hydroxytoluene



#### ATHLETES FOOT tolnaftate spray **Product Information** HUMAN OTC DRUG NDC:55910-007 Product Type Item Code (Source) **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			
ISOBUTANE (UNII: BXR49TP611)				
ALCOHOL (UNII: 3K9958V90M)				
PROPANE (UNII: T75W9911L6)				
PPG-12-BUTETH-16 (UNII: 58CG7042J1)				
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)				

ı	Packaging					
	#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
ı	1 N	NDC:55910-007-01	150 g in 1 BOTTLE; Type 0: Not a Combination Product	11/04/2014		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part333C	11/0 4/20 14				

# Labeler - DOLGENCORP, LLC. (068331990)

Establishment						
Name	Address	ID/FEI	Business Operations			
Zhejiang Ludao Cosmetics Co., Ltd.		679885595	manufacture (559 10 - 007)			

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