# TOLNAFTATE- antifungal powder spray aerosol, powder The Podiatree Company

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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### Active ingredient

Tolnaftate 1%

### □ □ Purpose

Antifungal

### Uses

- Cures most athlete's foot (tinea pedis), ringworm (tinea corporis) and jock itch (tinea cruris)
- If used daily, can prevent recurrence of athlete's foot
- Relieves symptoms of athlete's foot, including itching, burning, and cracking

### □ Warnings

For external use only.

### Flammable:

Do not use near heat or flame, or while smoking. Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above  $120^{\circ}F$ .

### **When using this product**

- Do not get into eyes or mouth
- 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
- no improvement within 4 weeks for athlete's foot and ringworm; 2 weeks for jock itch

### **Example 2** 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.

### Directions

- Wash affected area and dry thoroughly
- Shake can well and spray a thin layer over the 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 toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily
- Use daily for 4 weeks for athletes foot, ringworm; use daily for 2 weeks for jock itch
- If conditions persist, consult a doctor
- To prevent athlete's foot, apply daily (morning and night)

- This product is not effective on the scalps or nails
- In case of clogging, clear nozzle under running water

### **Other information**

Store between 20° and 30°C (68°F and 86°F)

### **Inactive ingredient**

BHT, isobutane (propellent), PPG-12-buteth-16, SD alcohol 40-B (14%w/w), talc

### **Questions or Suggestions?**

1.855.763.8733 or www.thepodiatreecompany.com. Our commitment to you is 100% satisfaction. If you are not completely satisfied, please contact us directly for a full refund.

### **Principal Display Panel**



NDC 54633-913-04



Quick-drying formula prevents the recurrence of athlete's foot with daily use

Net wt 130 g (4.6 oz)

# ANTIFUNGAL POWDER SPRAY

### Drug Facts Active Ingredient Purpose Tolnaftate 1%. Cures most athlete's foot (tinea pedis), ringworm (tinea corporis) and jock itch (tinea cruris) If used daily, can prevent recurrence of athlete's foot · Relieves symptoms of athlete's foot, including itching, burning and cracking Warnings For external use only Flammable: Do not use near heat or flame, or while smoking. Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F. When using this product • do not get into eyes or mouth • use only as directed Intentional misuse by deliberately concentrating and inhaling contents can be harmful Stop use and ask a doctor if • irritation occurs • no improvement within 4 weeks for athlete's foot and ringworm; 2 weeks for jock itch KEEP 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. Wash affected area and dry thoroughly • Shake can well and spray a thin layer over the 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 toes, wear well-fitting, • ror atmetes floor, pay spectra attention to spaces between uses, wear went intended whose and change shoes and socks at least once daily • Use daily for 4 weeks for athlete's foot and ringworm; use daily for 2 weeks for jock itch. If condition persists, consult a doctor • To prevent athlete's foot, apply daily (morning and night) • This product is not effective on scalp or nails . In case of clogging, clear nozzle under running water Other Information Store between 20° and 30°C (68° and 86°F) Inactive Ingredients BHT, isobutane (propellant), PPG-12-buteth-16, SD Alcohol 40-B (14% w/w), talc Questions or Suggestions? 1.855.763.8733 or www.thepodiatreecompany.com. Our commitment to you is 100% satisfaction. If you are not completely satisfied, please contact us directly for a full refund.

Manufactured for: The Podiatree Company, Holbrook, NY 11741 Made in U.S.A. 7380913040715

### **TOLNAFTATE**

antifungal powder spray aerosol, powder

<b>Product Information</b>	Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54633-913
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	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)		
ISOBUTANE (UNII: BXR49TP611)		
<b>PPG-12-BUTETH-16</b> (UNII: 58CG7042J1)		
ALCOHOL (UNII: 3K9958V90M)		
TALC (UNII: 7SEV7J4R1U)		

l	Packaging				
l	#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
l	1	NDC:54633-913-04	130 g in 1 CANISTER; Type 0: Not a Combination Product	07/01/2013	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	07/01/2013	

## Labeler - The Podiatree Company (078656000)

Revised: 12/2017 The Podiatree Company