

PERSONAL CARE ANTIFUNGAL - tolnaftate spray
Personal Care Products, Inc.

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.

Drug Facts Active ingredient

Tolnaftate 1%

Purpose

Antifungal

Keep out of reach of children

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.

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

Warnings

For external use only

Flammable. Do not use while smoking or near heat or flame. Do not puncture or incinerate. Contents under pressure Do not store in temperature above 120°F (49°C).

When using this product

- avoid contact 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 the spaces between the toes, wear well-fitting, ventilated shoes and change shoes and socks at least once 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)

- in case of clogging, clean nozzle with a pin

Other information

store between 68° to 77°F (20° to 25°C)

Inactive ingredients

alcohol, isobutane, perfume, propane, n-butane, talc powder.

ANTI FUNGAL POWDER SPRAY Label**PERSONAL CARE®****ANTIFUNGAL POWDER SPRAY****For Athlete's Foot****TOLNAFTATE 1%**

*Compare to the Active Ingredients in Tinactin®

Cures and Prevents Most Athlete's Foot

Relieves Itching and Burning

*This product is not manufactured or distributed by Schering-Plough HealthCare Products, Inc., owner of the registered trademark Tinactin®

Distributed by: Personal Care Products, Inc. Bingham Farms, MI 48025-3463

Made in China

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PERSONAL CARE ANTIFUNGAL

tolnaftate spray

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:29500-0035 |
| 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 |
|------------------------------|----------|
| ALCOHOL (UNII: 3K9958V90M) | |
| ISOBUTANE (UNII: BXR49TP611) | |
| PROPANE (UNII: T75W9911L6) | |

BUTANE (UNII: 6LV4FOR43R)

TALC (UNII: 7SEV7J4R1U)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:29500-0035-3 | 100 g in 1 CANISTER; 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 | 05/21/2010 | |

Labeler - Personal Care Products, Inc. (966155082)

Revised: 9/2015

Personal Care Products, Inc.