**TINACTIN- tolnaftate aerosol, spray**
**Bayer HealthCare 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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**Tinactin ®**

***Drug Facts***

**Active ingredient**

Tolnaftate 1 %

**Purpose**

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**

**Flammable:** Do not use while smoking or near heat or flame

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

**When using this product**

- Avoid contact with the eyes
- use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.
- contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F.

**Stop use and ask a doctor if**

- irritation occurs
- there is no improvement within 4 weeks

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

**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 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)

**Inactive ingredients**

butylated hydroxytoluene, isobutane, PPG-12-buteth-16, SD alcohol 40-B (29% v/v)

**Questions?**

1-866-360-3266

**PRINCIPAL DISPLAY PANEL - 150g Can Label**

***TOUGH ACTIN***'

***Tinactin*** ®

***ANTIFUNGAL***

*tolnaftate*

***Cures and***

***prevents most***

***athlete's foot***

***LIQUID SPRAY***

***cools the burn***

***Relieves itching & burning***

NET WT 150g (5.3 oz)


# TINACTIN

tolnaftate aerosol, spray

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:11523-0165 |
| **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 |
|---|---|
| **BUTYLATED HYDROXYTOLUENE** (UNII: 1P9D0Z171K) | |
| **ISOBUTANE** (UNII: BXR49TP611) | |
| **PPG-12-BUTETH-16** (UNII: 58CG7042J1) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:11523-0165-3 | 150 g in 1 CAN; Type 0: Not a Combination Product | 09/23/1993 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part333C | 09/23/1993 | |

## Labeler - Bayer HealthCare LLC (112117283)

Revised: 9/2023

Bayer HealthCare LLC