

**TINACTIN- tolnaftate aerosol, powder**  
**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
- in case of clogging, clean nozzle with pin

## **Other information**

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

## **Inactive ingredients**

alcohol denat. (11% v/v), butylated hydroxytoluene, isobutane, PPG-12-buteth-16, talc

## **Questions?**

1-866-360-3266

## **PRINCIPAL DISPLAY PANEL - 133g Can Label**

***TOUGH ACTIN'*** ®

***Tinactin***®

*tolnaftate* **ANTIFUNGAL**

***Cures and prevents***

***most athlete's foot***

Relieves itching

& burning

***POWDER SPRAY***

***goes on dry***

**NET WT 133g (4.6 oz)**

**TOUGH ACTIN'**  
**Tinactin**  
tolnaftate ANTIFUNGAL

**CURES AND PREVENTS  
MOST ATHLETE'S FOOT**

*Relieves itching  
& burning*

**POWDER SPRAY**  
goes on dry

NET WT 133g (4.6 oz)

LOT CODE AREA  
NO PRINT IN THIS AREA  
BACK PANEL ONLY

<b>Drug Facts</b>	
<b>Active Ingredient</b> (To Deliver) Tolnaftate 1%	<b>Purpose</b> Antifungal
<b>Uses</b>	
<ul style="list-style-type: none"> <li>■ proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)</li> <li>■ helps prevent most athlete's foot with daily use    ■ for effective relief of itching, burning and cracking</li> </ul>	
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<b>Other information</b> store between 20° to 25°C (68° to 77°F)	
<b>Inactive ingredients</b> butylated hydroxytoluene, isobutane, PPG-12-buteth-10, SD alcohol 40-B (11% v/v), talc	
<b>Questions?</b> 1-866-360-3266	

**Visit us at [www.tinactin.com](http://www.tinactin.com)**

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Dist by: Bayer HealthCare LLC  
Whippany, NJ 07981  
Product of Finland.

2D Code  
Quiet Zone  
7 mm

2D Code  
Quiet Zone  
9 mm to 10 mm

<b>TINACTIN</b>			
tolnaftate aerosol, powder			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11523-0777
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	10 mg in 1 g
<b>Inactive Ingredients</b>			

Ingredient Name	Strength
<b>ISOBUTANE</b> (UNII: BXR49TP611)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>PPG-12-BUTETH-16</b> (UNII: 58CG7042J1)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

**Product Characteristics**

<b>Color</b>	white (White to off-white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523-0777-2	133 g in 1 CAN; Type 0: Not a Combination Product	09/23/1993	



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MOST ATHLETE'S FOOT**

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## 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.