

TOLNAFTATE- tolnaftate cream
Sheffield Pharmaceuticals LLC

Drug Facts

Active ingredient

Tolnaftate USP 1%

Purpose

Antifungal Cream

Uses

- Cures most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis).
- Relieves the itching, irritation, redness, scaling and discomfort which can accompany these conditions.

Warnings

- **Do not use on children under 2 years of age unless directed by a doctor.**
- **For external use only avoid contact with eyes.**
- Irritation occurs or if there is no improvement within 4 weeks (for athlete's foot and ringworm)irritation occurs or if there is no improvement within 2 weeks (for jock itch).

Keep this and all drugs out of the reach of children.In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions

- Clean the affected area and dry thoroughly.
- Apply a thin layer of the product over the affected area twice daily (morning and night) or as directed by a doctor.
- 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.
- Change shoes and socks at least once daily.
- For athlete's foot and ringworm, use daily for 4 weeks.
- For jock itch, use daily for 2 weeks.
- If condition persists longer, consult a doctor.
- This product is not effective on the scalp or nails.

Other information

- Store at controlled room temperature 15°-30°C (59°-86°F).
- Close cap tightly after every use.

Inactive ingredients

Ceteth-20, Cetostearyl Alcohol, Chlorocresol, Mineral Oil, White Petrolatum, Propylene Glycol, Sodium Phosphate Monobasic, Water

Questions?

1-800-222-1087

Principal Display Panel - 1.25 oz Tube

Dr. Sheffield's NDC 11527-051-40

1% Tolnafate

Antifungal Cream

CURES Most:

ATHLETE'S FOOT

JOCK ITCH

RINGWORM

Net Wt. 1.25 OZ (35.4 g)



NDC 11527-051-40

Compare to the active ingredient in Tinactin®*

Antifungal Cream

Cures most: • Athlete's Foot • Jock Itch • Ringworm
1% TOLNAFTATE

NET WT. 1.25 OZ. (35g)



Active ingredient: Tolnaftate 1% **Purpose:** Antifungal Cream

Uses: Cures most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis). Relieves the itching, irritation, redness, scaling and discomfort which can accompany these conditions. **Warnings:** • Do not use on children under 2 years of age unless directed by a doctor. • For external use only. • Avoid contact with eyes. • If irritation occurs or if there is no improvement within 4 weeks (for athlete's foot or ringworm) or within 2 weeks (for jock itch), discontinue use and consult a doctor. • Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. **Directions:** Clean the affected area and dry thoroughly. Apply a thin layer of this product over affected area twice daily (morning and night), or as directed by a doctor. 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 daily. For athlete's foot and ringworm, use daily for 4 weeks. For jock itch, use daily for 2 weeks. If conditions persist longer, consult a doctor.

This product is not effective on the scalp or nails. **Questions? 1-800-222-1087**

*This product is not manufactured or distributed by ©Bayer, owner of the registered trademark Tinactin®.

Distributed by Sheffield Pharmaceuticals, 170 Broad Street, New London, CT 06320 www.sheffieldpharma.com

Made in USA OF U.S. & Imported Ingredients and Components

2501377

Principal Display Panel - 1.25 oz Carton

Dr. Sheffield's NDC 11527-051-40

1% Tolnafate

Antifungal Cream

CURES Most:

ATHLETE'S FOOT

JOCK ITCH

RINGWORM

Net Wt. 1.25 OZ (35.4 g)



Compare to the active ingredient in Tinactin®*

CURES & PREVENTS MOST:

- ATHLETE'S FOOT
- JOCK ITCH
- RINGWORM

RELIEVES ITCHING & BURNING



RELIEVES ITCHING & BURNING FROM:
ATHLETE'S FOOT, JOCK ITCH & RINGWORM



NDC 11527-051-40

LOT
EXP

Antifungal Cream

1% TOLNAFTATE

NET WT. 1.25 OZ. (35g)



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170 Broad Street, New London, CT 06320
www.sheffieldpharma.com
Questions? 1-800-222-1087

Made in USA
OF U.S. & IMPORTED
INGREDIENTS AND COMPONENTS



5440367

*learn more at www.sheffieldpharma.com

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Drug Facts
Active ingredient Tolnaftate 1% Antifungal Cream
Purpose Relieves most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis).
Uses Cures most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis), scaling and discomfort which can accompany these conditions.
Warnings Do not use on children under 2 years of age unless directed by a doctor. For external use only. Avoid contact with eyes. If irritation occurs or if there is no improvement within 4 weeks (for athlete's foot or ringworm) or within 2 weeks (for jock itch), discontinue use and consult a doctor. Keep this and all drugs out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.
Directions Clean the affected area and dry thoroughly. Apply a thin layer of this product over affected area twice daily (morning and night), or as directed by a doctor. 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 daily. For athlete's foot and ringworm, use daily for 4 weeks. For jock itch, use daily for 2 weeks. This product is not effective on the scalp or nails. If conditions persist longer, consult a doctor.
Other information Store at controlled room temperature 20°-25°C (68°-77°F). Close cap tightly after use.
Inactive ingredients Propylene Glycol, Sodium Phosphate Monobasic, Water
Questions 1-800-222-1087

TOLNAFTATE
tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11527-051
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
WATER (UNII: 059QF0K00R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-20 (UNII: I835H2IHHX)	
CHLOROCRESOL (UNII: 36W53O7109)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11527-051-40	1 in 1 CARTON	10/07/2009	
1		35.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:11527-051-51	1 in 1 CARTON	10/07/2009	
2		14 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	10/07/2009	

Labeler - Sheffield Pharmaceuticals LLC (151177797)**Registrant** - Sheffield Pharmaceuticals LLC (151177797)**Establishment**

Name	Address	ID/FEI	Business Operations
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Revised: 2/2025

Sheffield Pharmaceuticals LLC