

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

Antifungal Cream (Tolnaftate 1%) Made in the USA

CURES Most:

ATHLETE'S

FOOT/JOCK ITCH

RINGWORM

Net Wt. 1.25 OZ (35.4 g)

The image shows the Principal Display Panel for Dr. Sheffield's Antifungal Cream. The panel is white with a red border. At the top left is the Dr. Sheffield's logo, which features a red circular emblem with a white cross and the text "Dr. Sheffield's" above it. To the right of the logo is the word "Antifungal" in a large, bold, black serif font, with "tolnaftate 1%" in a smaller black serif font below it. To the right of "Antifungal" is a red flame-like graphic. Below "Antifungal" is a red rectangular box with the word "CREAM" in white capital letters. To the right of the "Antifungal" text is a red rectangular box with the text "NDC 11527-051-40" in white. Below the "NDC" box is a red rectangular box with the text "Cures Most:" in white, followed by a list of conditions: "Athlete's Foot", "Jock Itch", and "Ringworm". Below the "Cures Most:" box is a red rectangular box with the text "NET WT. 1.25 oz. (35.4g)". At the bottom left of the panel is a red rectangular box with the text "Active ingredient: Tolnaftate 1%". To the right of this box is a red rectangular box with the text "Purpose: Antifungal Cream". Below the "Active ingredient:" box is a red rectangular box with the text "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." Below the "Uses:" box is a red rectangular box with the text "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." Below the "Warnings:" box is a red rectangular box with the text "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." Below the "Directions:" box is a red rectangular box with the text "Questions? 1-800-222-1087 Made in the USA". At the bottom right of the panel is a red rectangular box with the text "SHEFFIELD PHARMACEUTICALS www.sheffield-pharmaceuticals.com New London, CT 06320 USA".

Dr. Sheffield's

Antifungal

tolnaftate 1% CREAM

NDC 11527-051-40

Cures Most:

- Athlete's Foot
- Jock Itch
- Ringworm

NET WT. 1.25 oz. (35.4g)

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Questions? 1-800-222-1087 **Made in the USA**

SHEFFIELD PHARMACEUTICALS www.sheffield-pharmaceuticals.com New London, CT 06320 USA

Dr. Sheffield's



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tolnaftate 1%

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Questions? 1-800-222-1087 **Made in the USA**

SHEFFIELD PHARMACEUTICALS www.sheffield-pharmaceuticals.com New London, CT 06320 USA



2501375

Principal Display Panel - 1.25 oz Carton

Compare to the active ingredient of Tinactin®*

Dr. Sheffield's



Antifungal

tolnaftate 1%

CREAM

Made in the USA

Cures Most:

- Athlete's Foot
- Jock Itch
- Ringworm

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NET WT. 1.25 oz. (35.4g)



Dr. Washington Wentworth Sheffield invented toothpaste in 1860 and started producing his "Anesthetic Balm" ointment and "Crime Dentifrice" in his laboratory behind his house. This was the beginning of today's Sheffield Pharmaceuticals. Another first occurred in 1879, when he and his son, Dr. Lucius Tracy Sheffield, were the first to package toothpaste, cream and ointments into tubes. Many of today's leading brands were first produced in our laboratory. To this day, Sheffield Pharmaceuticals continues to excel in product development, our long history of product innovation and technical expertise assures you of the consistently high quality and effectiveness that you need and deserve.



SHEFFIELD PHARMACEUTICALS www.sheffield-pharmaceuticals.com New London, CT 06320 USA Questions? 1-800-222-222-1087 Made in the USA

This product is not manufactured or distributed by Eschenbach-Fough Healthcare Products, Inc., owner of the registered trademark "Treat-It".

Drug Facts
Active ingredient Tolnaftate 1% Purpose Antifungal Cream
Uses Cures most athlete's foot (toes, feet), jock itch (inner thighs, groin), ringworm (scalp, face, body). 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. Do not use on or near the eyes. 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.
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Other information Store at controlled room temperature 15°-30°C (59°-86°F). Close cap tightly after use. Inactive ingredients Propylene Glycol, Sodium Phosphate Monobasic, Water
Questions 1-800-222-222-1087

Antifungal CREAM

Dr. Sheffield's
Made in the USA



Dr. Sheffield's
Antifungal
CREAM



Dr. Sheffield's NDC 11527-051-40

CURES Most:

ATHLETE'S

FOOTJOCK ITCH

RINGWORM

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Compare to the active ingredient of Tinactin®*

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Drug Facts	
Active ingredient	Tolnaftate 1%
Purpose	Antifungal Cream
Uses	Cures most athlete's foot (toes, feet), jock itch (inner thigh), ringworm (scalp, face, body). Relieves the itching, irritation, redness, scaling and discomfort which can accompany these conditions.
Warnings	<ul style="list-style-type: none"> 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.
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Other information	<ul style="list-style-type: none"> Store at controlled room temperature 15°-30°C (59°-86°F). Close cap tightly after use.
Inactive ingredients	Cetyl-20, Cetostearyl Alcohol, Chloroform, Mineral Oil, White Petrolatum, Propylene Glycol, Sodium Phosphate Monobasic, Water
Questions 1-800-222-222-1087	

Antifungal CREAM



Made in the USA



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: 059QF0KO0R)	
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
Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(11527-051) , analysis(11527-051)