

TOLNAFTATE- tolnaftate cream

Major Pharmaceuticals

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 USP 1%

Purpose

Antifungal

Uses

- for effective treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)
- for effective relief of itchy, scaly skin between the toes
- clears up most athlete's foot infection and with daily use helps keep it from coming back

Warnings

For external use only

Do not use

- on children under 2 years of age unless directed by a doctor

When using this product avoid contact with eyes

Stop use and ask a doctor if

- 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

- use daily for 4 weeks. If condition persists longer, consult a doctor
- pay special attention to the spaces between the toes
- wear well fitting ventilated shoes
- change shoes and socks at least once daily

For ringworm, use daily for 4 weeks. If condition persists longer, consult a doctor.

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)
- Lot No. and Exp date: see crimp on tube or see box

Inactive ingredients

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

Questions?

Adverse Drug Event call (800)616-2471

Dist. By MAJOR PHARMACEUTICALS, 31778 Enterprise Drive, Livonia, MI 48150 USA

Re-Order No. 100497 M-88 Rev. 9/09 Manufactured in USA

Principal Display Panel - 0.5 oz Tube

MAJOR® *Compare to Active Ingredient of Tinactin®

NDC 0904-0722-36

Antifungal

Cream (Tolnaftate 1%) N309040722362

CURES ATHLETE'S FOOT, *This product is not manufactured or

JOCK ITCH AND RINGWORM distributed by Schering-Plough Healthcare

Relives Burning and Itching Products, Inc. owner of the registered

- Odorless • Greaseless • Non-Staining trademark, Tinactin®

Net Wt. 0.5 OZ (14.18 g)

MAJOR® 

*Compare to Active Ingredient of Tinactin®

NDC 0904-0722-36

Antifungal Cream

(Tolnaftate 1%)



**CURES ATHLETE'S FOOT,
JOCK ITCH AND RINGWORM**

Relieves Burning and Itching

• Odorless • Greaseless • Non-Staining

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Active ingredient Tolnaftate USP 1% **Purpose** Antifungal

Uses ■ for effective treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis) ■ for effective relief of itchy, scaly skin between the toes ■ clears up most athlete's foot infection and with daily use helps keep it from coming back **Warnings** **For external use only. Do not use** ■ on children under 2 years of age unless directed by a doctor **When using this product** avoid contact with eyes. **Stop use and ask a doctor if** ■ 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 ■ use daily for 4 weeks. If condition persists longer, consult a doctor ■ pay special attention to the spaces between the toes ■ wear well fitting ventilated shoes ■ change shoes and socks at least once daily. For ringworm, use daily for 4 weeks. If condition persists longer, consult a doctor. 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. **See carton for complete adverse effects reporting information.**

Dist. by: **Major Pharmaceuticals**, 31778 Enterprise Drive, Livonia, MI 48150 USA

Reorder No. 100497 M-88 Rev. 09/09 Manufactured in USA

232590

Principal Display Panel - 0.5 oz Carton

MAJOR® NDC 0904-0722-36

Antifungal *Compare to Active Ingredient of Tinactin®

Cream

(Tolnaftate 1%) Net Wt. 0.5 OZ (14.18 g)

Drug Facts

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Drug Facts (continued)

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Questions?

Adverse Drug Event call (800)616-2471

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Re-Order No. 100497 M-88 Rev. 9/09 Manufactured in USA

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Net Wt. 0.5 OZ (14.18 g)

(Tolnaftate 1%)

Compare to
Active Ingredient
of Tinactin®

Antifungal Cream

NDC 0904-0722-36

MAJOR®

Compare to
Active Ingredient
of Tinactin®

CURES ATHLETE'S FOOT, JOCK ITCH AND RINGWORM

(Tolnaftate 1%)

Antifungal Cream

MAJOR®

508845



3 09040 72236 2



508845

TOLNAFTATE

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-0722	
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: 36W5307109)				
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:0904-0722-36	1 in 1 CARTON	02/11/2010	
1		14.18 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 final	part333C	02/11/2010		

Labeler - Major Pharmaceuticals (191427277)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(0904-0722)