

TOPCARE TOLNAFTATE ANTIFUNGAL- tolnaftate cream

Topco Associates 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.

TopCare®

Tolnaftate Antifungal Cream

Drug Facts

Active ingredient

Tolnaftate 1%

Purpose

Antifungal

Uses

- cures most athlete's foot, jock itch, and ringworm
- relieves itching, burning, cracking, scaling, redness, soreness, irritation and discomfort

Warnings

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

For external use only.

Avoid contact with eyes.

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks for athlete's foot and ringworm or 2 weeks for jock itch

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away: 800-222-1222.

Directions

- wash affected area and dry thoroughly
- apply a thin layer 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 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 condition persists longer, consult a doctor
- this product is not effective on the scalp or nails

Other information

- store at 15 to 30°C (59 to 86°F)

- **Tamper Evident:** DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING.

Inactive ingredients

ceteth-20, cetyl alcohol, chlorocresol, mineral oil, monobasic sodium phosphate, petrolatum, propylene glycol, purified water, stearyl alcohol

Questions or comments?

866-323-0107 or www.natureplex.com

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007

PRINCIPAL DISPLAY PANEL - 14 g Tube Carton

NDC 36800-052-60

TopCare
health™

PRESCRIPTION STRENGTH

Athlete's Foot Cream

TOLNAFTATE CREAM 1% • ANTIFUNGAL

• OUR PHARMACISTS •
RECOMMEND

NET WT 0.5 OZ (14 g)

COMPARE TO TINACTIN®
ACTIVE INGREDIENT*

Athlete's Foot Cream

Cures & Prevents Most Athlete's Foot

RELIEVES:

- Itching • Burning
- Cracking • Scaling

Greaseless and Odorless

PL31652B
V01

NDC 36800-052-60

TopCare
health™

PRESCRIPTION STRENGTH

Athlete's Foot Cream

TOLNAFTATE CREAM 1% • ANTIFUNGAL



NET WT 0.5 OZ (14 g)

**Athlete's
Foot Cream**
TOLNAFTATE CREAM 1%
ANTIFUNGAL

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
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QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com
PRODUCT OF USA



Scan here for
more information.
Call 1-888-423-0139
for more information.

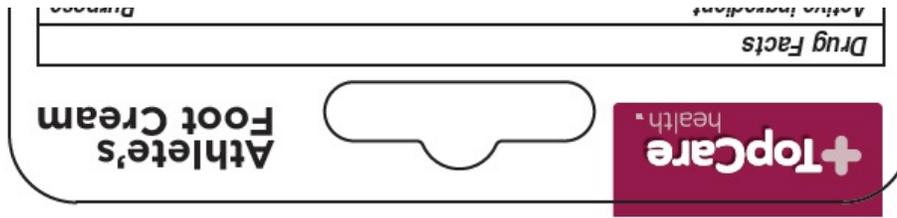


*This product is not manufactured by
or distributed by Bayer, the distributor
of Tinactin®.



This TopCare® product is laboratory
tested to guarantee its highest quality.
Your total satisfaction is guaranteed.

Active ingredient Tolnaftate 1%.....Antifungal
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Warnings Do not use on children under 2 years of age unless directed by a doctor. For external use only. Avoid contact with eyes.
Stop use and ask a doctor if ■ irritation occurs ■ there is no improvement within 4 weeks for athlete's foot and ringworm or 2 weeks for jock itch If pregnant or breastfeeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away: 800-222-1222.
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Questions or comments? 866-323-0107 or www.naturepharm.com



TOPCARE TOLNAFTATE ANTIFUNGAL

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-052
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)	
Polyethylene glycol 400 (UNII: B697894SGQ)	
Polyethylene glycol 3350 (UNII: G2M7P15E5P)	
titanium dioxide (UNII: 15FIX9V2JP)	
petrolatum (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-052-60	1 in 1 CARTON	02/17/2006	
1		14.2 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	02/17/2006	

Labeler - Topco Associates LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(36800-052)

