

LEADER ANTIFUNGAL TOLNAFTATE- tolnaftate cream
CARDINAL HEALTH

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.

Active ingredient	Purpose
Tolnaftate 1%.....	Antifungal

Uses

- proven clinically effective in the treatment of athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis)
- proven effective in the prevention of athlete's foot with daily use
- for effectively relief of itching, burning and cracking

Warnings

For external use only

When using this product avoid contact with the eyes.

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks

Do not use on children under 2 years of age except under the advice and supervision of a doctor.

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
- 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
- use daily for 4 week; if condition persists longer, ask a doctor
- this product is not effective on the scalp or nails

Other Information

- store between 20° to 25°C (68° to 77°F)
- Lot No. & Exp. Date: see box or see crimp of tube

Inactive Ingredients

butylated hydroxytoluene, cetanol, liquid paraffin, methylparaben, polyoxyethylene cetyl ether, propylene glycol, propylparaben, purified water, sorbitan monostearate, stearyl alcohol

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com

1-800-200-6313

Made in Korea



Compare to **Tinactin**[®]
active ingredient*

Antifungal Cream

1% TOLNAFTATE

Effective in the treatment of most athlete's foot
Soothes and relieves the itching, burning and cracking of most athlete's foot

NDC 37205-197-10



Antifungal Cream

1% TOLNAFTATE

NET WT 1 OZ (28g)



Made in Korea

All Leader[®] Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.
1-800-200-6313
www.myleader.com
CIN 2534121
DUBLIN, OHIO 43017
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*This product is not manufactured or distributed by Bayer, owner of the registered trademark Tinactin[®]

Drug Facts

Active ingredient
Tolnaftate 1% Antifungal

Purpose

Uses = proven clinically effective in the treatment of athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis) ■ proven effective in the prevention of athlete's foot with daily use ■ for effective relief of itching, burning and cracking

Warnings
For external use only
When using this product avoid contact with the eyes
Stop use and ask a doctor if ■ irritation occurs ■ there is no improvement within 4 weeks

Do not use on children under 2 years of age except under the advice and supervision of a doctor

Directions ■ wash affected area and dry thoroughly ■ apply 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)

Other information ■ store between 20° to 25°c (68° and 77°f) ■ lot no. & exp. date: see box or see crimp of tube

Inactive ingredients butylated hydroxytoluene, cetanol, liquid paraffin, methylparaben, polyoxyethylene cetyl ether, propylene glycol, propylparaben, purified water, sorbitan monostearate, stearyl alcohol

Questions or comments? 1-800-814-8028

LOT & EXP.

LEADER ANTIFUNGAL TOLNAFTATE			
tolnaftate cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-197
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)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PARAFFIN (UNII: I9O0E3H2ZE)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-197-10	1 in 1 CARTON	10/10/2016	
1		28 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	03/01/2012	

Labeler - CARDINAL HEALTH (097537435)

Revised: 7/2017

CARDINAL HEALTH