

CR-371059 TOLNAFTATE 1% CREAM- cr-371059 tolnaftate 1% cream cream
Rugby Laboratories

CR-371059 Tolnaftate 1% Cream

Active Ingredient

Tolnaftate 1%

Purpose

Antifungal

Uses

- Proven effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- Helps prevent most athlete's foot with daily use
- For effective relief of itching, burning, and cracking

Warnings

- **For External Use Only**
- This product is not effective on the scalp or nails

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

Keep out of reach of children

- If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away
- 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° to 77°F)

Inactive Ingredients

Ceteth-20, Cetostearyl Alcohol, Chlorocresol, Mineral Oil, Propylene Glycol, Sodium Phosphate Dihydrate, White Soft Paraffin (Petrolatum)

Questions and Comments?

1-800-645-2158

Label



NDC 0536-1315
Compare to
ingredient of

Tolnaftate 1%

Antifungal Cream

Cures and prevents most athlete's foot
Relieves itching and burning

NET WT 0.5 OZ (14 g)



NDC 0536-1315
Compare to
ingredient of

Tolnaftate 1%

Antifungal Cream

Cures and prevents most athlete's foot
Relieves itching and burning

NET WT 0.5 OZ (14 g)

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

Distributed by: RUGBY® LABORATORIES
Livonia, MI 48152
www.rugbylaboratories.com

Made in India KD/739

Lot #

Exp Date.

Rev. 03/21 R-129 Re-order



Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away. 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.	g Facts 1% Tolnaftate Antifungal Ingredient Purpose Effective in the treatment of athlete's foot (tinea pedis) and prevent most athlete's foot with itching. Internal Use Only Product is not effective on the nails. Keep this product avoid contact
Other Information Store between 20° to 25°C (68° to 77°F). Inactive Ingredients Ceteth-20, Cetostearyl Alcohol, Chlorocresol, Mineral Oil, Propylene Glycol, Sodium Phosphate Monobasic Dihydrate, White Soft Paraffin (Petrolatum). Questions and Comments? 1-800-645-2158 Keep box for complete Drug Facts.	Stop use and ask a doctor if Irritation occurs. There is no improvement within 4 weeks. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away. 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.



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1315
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)			TOLNAFTATE	1 g in 100 g
Inactive Ingredients				
Ingredient Name				Strength
CETETH-20 (UNII: I835H2IHHX)				
MINERAL OIL (UNII: T5L8T28FGP)				
CHLOROCRESOL (UNII: 36W53O7109)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)				
PETROLATUM (UNII: 4T6H12BN9U)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
Product Characteristics				
Color			Score	
Shape		FREEFORM	Size	
Flavor			Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1315-43	1 g in 1 BOX; Type 0: Not a Combination Product	03/01/2021	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M005	03/01/2021	

Labeler - Rugby Laboratories (079246066)