

THERACARE ANTIFUNGAL CREAM- tolnaftate cream

Veridian Healthcare

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.

TheraCare Antifungal Cream

Drug Facts

Active ingredient

Tolnaftate 1%

Purpose

Antifungal

Uses

- proven clinically 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

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

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 right away. (1-800-222-1222)

Directions

adults and children 2 years of age and over:

- 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

- to prevent athlete's foot, apply once or twice daily (morning and/or night)
- this product is not effective on the scalp or nails

Children under 2 years of age: consult a physician

Other information

store between 20° to 25°C (68° to 77°F)

- do not use if tube seal under cap is broken

Inactive ingredients

ceteth-20, cetostearyl alcohol, cetyl alcohol, chlorocresol, light mineral oil, petrolatum, propylene glycol, sodium phosphate, sodium phosphate dibasic monohydrate, water

Questions?

Toll Free 1-866-326-1313

PRINCIPAL DISPLAY PANEL - 35.4 g Tube Carton

CLINICALLY
EFFECTIVE

Soothing Relief Antifungal Cream

TONAFATE

Drug Facts

Active ingredient *Propolis*
Tonafate 1% *Antifungal*

Uses
is proven clinically 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
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
if there is no improvement within 4 weeks

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. (1-800-822-1222)

Drug Facts (continued)

Directions
adults and children 2 years of age and over:
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
to prevent athlete's foot, apply once or twice daily (morning and/or night)
this product is not effective on the scalp or nails
Children under 2 years of age consult a physician.

Other information Store at 20°-25°C (68°-77°F)
do not use if tube end under cap is broken

Inactive ingredients carbox-30, cetylalcohol, ethyl alcohol, chloroform, light mineral oil, polydimethylsiloxane, propylene glycol, sodium phosphate, sodium phosphate dibasic monohydrate, water

*This product is not manufactured or distributed by Bayer, owner of the registered trademark, Triostat®.



Manufactured for:
TheraCare, Inc.
1175 Lakeside Drive
Carmel, IN 46031 USA
www.theracare.com
www.theracare.com
Made in India
998-1928 04/22 VCF10082
80022 Western Healthcare, LLC
MODEL 19-224
TOLL-FREE
Customer Care Help Line
1-866-326-1313
Mon-Fri 8:30 am-6:30 pm CST

LOT
EXP

COMPARE TO TRINACTIN® ANTIFUNGAL
ACTIVE INGREDIENT*

NET WT 1.25 OZ (35.4g)



Soothing Relief
Antifungal Cream
TONAFATE

NDC 21981-094-01

Soothing Relief
Antifungal Cream
TONAFATE

TREATS & PREVENTS
FUNGUS GROWTH



Relief Itching & Burning
Athlete's Foot • Jock Itch • Ringworm

ANTIFUNGAL



Theracare Antifungal Cream

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71101-934
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
CETETH-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHLOROCRESOL (UNII: 36W5307109)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, DIBASIC, MONOHYDRATE (UNII: BWZ7K44R51)	
PETROLATUM (UNII: 4T6H12BN9U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

SODIUM PHOSPHATE (UNII: SE337SVY37)

Product Characteristics

Color	white (White to Off-white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71101-934-01	1 in 1 CARTON	06/01/2022	
1		35.4 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	06/01/2022	

Labeler - Veridian Healthcare (830437997)

Registrant - Veridian Healthcare (830437997)

Establishment

Name	Address	ID/FEI	Business Operations
ANICARE PHARMACEUTICALS PRIVATE LIMITED		916837425	manufacture(71101-934)

Revised: 6/2022

Veridian Healthcare