THERA PLUS ANTIFUNGAL TOLNAFTATE- tolnaftate cream FOURSTAR GROUP USA, INC.

Thera plus Antifungal Tolnaftate cream

Drug Facts

Active ingredient

Tolnaftate 1%

Purpose

Anti-Fungal

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 except under the advice and supervision of 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 immediately.

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-

ftting, 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).
- this product is not effective on the scalp or nails.

Other information

- store at room temperature 20° to 25°C (68° to 77°F)
- lot no & expiration date: see box or crimp of tube

Inactive ingredients

cetyl alcohol, ethylparaben, glycerol, glyceryl monostearate, mineral oil, petrolatum, purified water, sodium lauryl sulfate

Questions?

1-888-296-9067 Weekdays 9 AM to 4 PM EST

Package Labeling:

EXP:



Compare to The Active Ingredient Of Tinactin®*

ANTIFUNGALCREAM

Tolnaftate 1%

NET WT 0.5 OZ (14 g)

Active ingredient

Purpose

Tolnaftate 1%Anti-Fungal

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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) ■ this product is not effective on the scalp or nails Other information ■ store between 20° to 25° C (68° to 77°F) ■ Lot No & Expiration Date: see box or crimp of tube *Inactive ingredients:* Cetyl alcohol, Ethylparaben, Glycerol, Glyceryl monostearate, Mineral oil, Petrolatum, Purified water, Sodium lauryl sulfate **Questions?** 1-888-296-9067 Weekdays 9 AM to

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

DISTRIBUTED BY: FOURSTAR GROUP USA, INC. 925 GRANT STREET AKRON, OHIO 44311 MADE IN CHINA

Strength

THERA PLUS ANTIFUNGAL TOLNAFTATE

tolnaftate cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:80684-040

4 PM EST

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 CETYL ALCOHOL (UNII: 936JST6JCN)

ETHYLPARABEN (UNII: 14255EXE39)
GLYCERIN (UNII: PDC6A3C0OX)

GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)

MINERAL OIL (UNII: T5L8T28FGP)

PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:80684-040- 01	1 in 1 BOX	01/30/2022			
1		14 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 Drug	M005	01/30/2022			

Labeler - FOURSTAR GROUP USA, INC. (140099503)

Revised: 10/2023 FOURSTAR GROUP USA, INC.