TOLNAFTATE ANTIFUNGAL- tolnaftate cream STRATEGIC SOURCING SERVICES 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.

Tolnaftate Antifungal

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

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)
- 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)
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

BHT, PEG-400, PEG-3350, titanium dioxide, white petrolatum

Questions?

call **833-358-6431**

Distributed by: McKesson Corp., via Strategic Sourcing Services LLC. Memphis, TN 38141

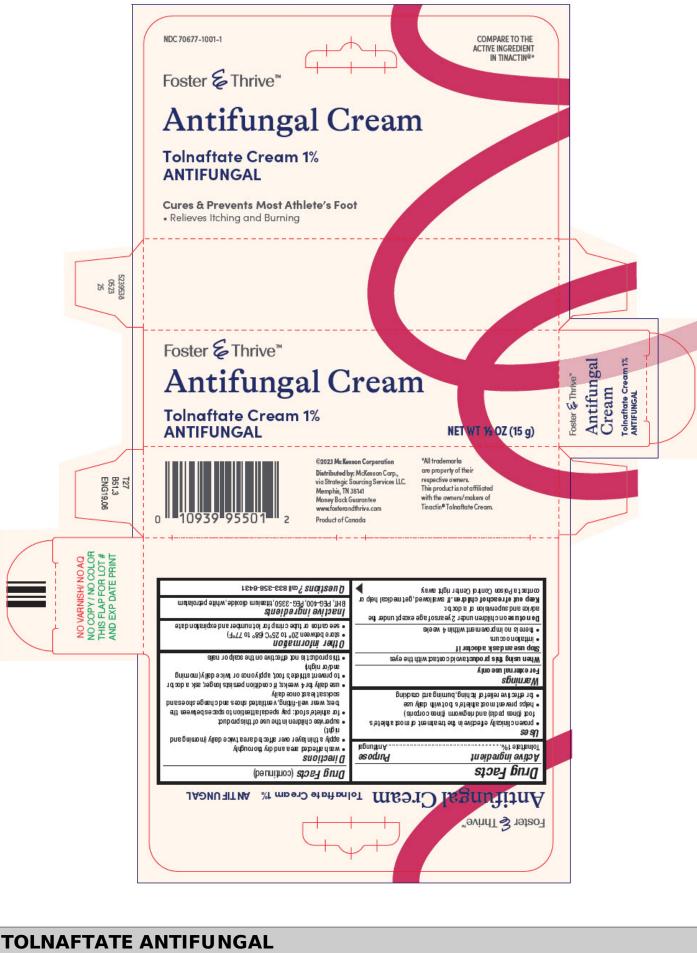
PRINCIPAL DISPLAY PANEL - 15 g Tube Carton

Foster & Thrive™

Antifungal Cream

Tolnaftate Cream 1% ANTIFUNGAL

NET WT ½ OZ (15 g)



tolnaftate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-1001
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	
butylated hydroxytoluene (UNII: 1P9D0Z171K)		
polyethylene glycol 400 (UNII: B697894SGQ)		
polyethylene glycol 3350 (UNII: G2M7P15E5P)		
titanium dioxide (UNII: 15FIX9V2JP)		
petrolatum (UNII: 4T6H12BN9U)		

Product Characteristics			
Color	WHITE (opaque, white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677- 1001-1	1 in 1 CARTON	06/22/2023	
1		15 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	06/22/2023	

Labeler - STRATEGIC SOURCING SERVICES LLC (116956644)

Establishment				
Name	Address	ID/FEI	Business Operations	
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(70677-1001)	

Revised: 6/2023 STRATEGIC SOURCING SERVICES LLC