FUNGISOLVE TOLNAFTATE ANTIFUNGAL- tolnaftate cream Dannso Corp./d.b.a. Essential Products

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.

FUNGISOLVE Tolnaftate Antifungal Cream

Active Ingredients

Tolnaftate 1%

Purpose

Antifungal

Uses

cures most athlete's foot (tinea pedis), ringworm (tinea corporis) and jock itch (tinea cruris) can prevent recurrence of most athlete's foot relieves sympotoms of athlete's foot including itching, burning, cracking and scaling.

Warnings

For external use only

Do not use

- children under 2 years of age unless directed by a doctor
- on nails or scalp
- in or near the mouth or the eyes
- for vaginal yeast infections

Stop use and ask a doctor if

too much irritation occurs or irratation gets worse

When using this product

avoid contact with the eyes or mouth. If eye contacts occurs, rinse eyes thoroughtly with water.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- adults and children 12 years and over
- wash the affected area and dry thoroughly

- apply a thin layer over affected area twice daily morning and night
- supervis 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 a day.

Other Information

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

do not accept if safety seal is torn broken or missing.

Inactive Ingredients

Ceteareth-6, cety stearyl alcohol, methylparaben, mineral oil, PEG-20 cetyl/stearyl ether, propylene glycol, propylparaben, purified water, sodium m-bisulfite, stearyl alcohol.

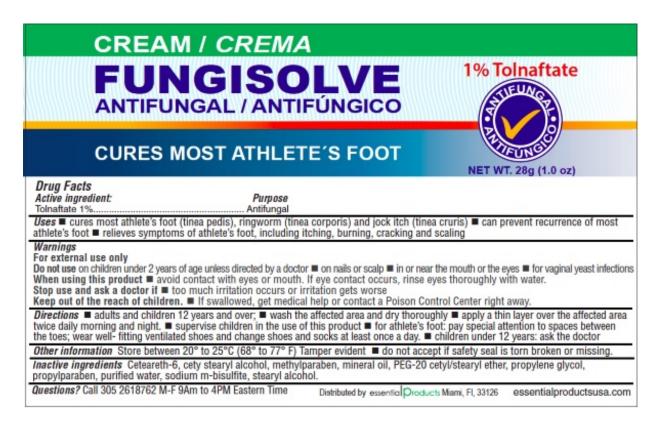
Questions?

Call 305 2618762 M-F 9AM to 4PM Eastern Time

Distributed by:

Essential Productd Miami, FL, 33126 www.essentialproductsusa.com

FUNGISOLVE TOLNAFTATE ANTIFUNGAL (TOLNAFTATE) CREAM



FUNGISOLVE TOLNAFTATE ANTIFUNGAL

tolnaftate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70242-108
Route of Administration	TOPICAL		

ı	Active Ingredient/Active Moiety		
l	Ingredient Name	Basis of Strength	Strength
ı	TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
MINERAL OIL (UNII: T5L8T28FGP)			
GLYCERIN (UNII: PDC6A3C0OX)			
PEG-15 GLYCERYL STEARATE (UNII: 9 1245SPD5K)			
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)			
MYRISTO YL/PALMITO YL O XO STEARAMIDE/ARACHAMIDE MEA (UNII: 1211AIM8 G7)			
PHO SPHATE ION (UNII: NK08 V8 K8 HR)			
CHLOROCRESOL (UNII: 36W53O7109)			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70242-108-01	28 g in 1 TUBE; Type 0: Not a Combination Product	04/30/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/16/2011	

Labeler - Dannso Corp./d.b.a. Essential Products (059741071)

Registrant - Dannso Corp./d.b.a. Essential Products (059741071)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dannso Corp./d.b.a. Essential Products		059741071	LABEL(70242-108)	

Establishment				
Name	Address	ID/FEI	Business Operations	
GADAL Laboratories, Inc		841305639	MANUFACTURE(70242-108)	