

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 symptoms 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 irritation gets worse

When using this product

avoid contact with the eyes or mouth. If eye contact occurs, rinse eyes thoroughly 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

Cetareth-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

CREAM / CREMA

FUNGISOLVE™

ANTIFUNGAL / ANTIFÚNGICO

1% Tolnaftate



CURES MOST ATHLETE'S FOOT

NET WT. 14g (0.5 oz)

Drug Facts

Active ingredient: 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 symptoms of athlete's foot, including itching, burning, cracking and scaling

Warnings

For external use only

Do not use on 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

When using this product ■ avoid contact with eyes or mouth. If eye contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if ■ too much irritation occurs or irritation gets worse

Keep out of the reach of children. ■ If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ adults and children 12 years and over; ■ wash the affected area and dry thoroughly ■ apply a thin layer over the 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 a day.

■ children under 12 years: ask the doctor

Other information

Store between 20° to 25°C (68° to 77° F) Tamper evident ■ do not accept if safety seal is torn broken or missing.

Inactive ingredients Cetareth-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

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FUNGISOLVE TOLNAFTATE ANTIFUNGAL

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70242-107
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
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-15 GLYCERYL STEARATE (UNII: 91245SPD5K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA (UNII: 1211AIM8G7)	
PHOSPHATE ION (UNII: NK08V8K8HR)	
CHLOROCRESOL (UNII: 36W53O7109)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70242-107-05	14 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 - Danso Corp./d.b.a. Essential Products (059741071)

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

Establishment

Name	Address	ID/FEI	Business Operations
Danso Corp./d.b.a. Essential Products		059741071	LABEL(70242-107)

Establishment

Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	MANUFACTURE(70242-107)

Revised: 4/2016

Dannso Corp./d.b.a. Essential Products