FUNGISOLVE TOLNAFTATE ANTIFUNGAL- tolnaftate spray 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 Spray

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

Flammable

Do not use while smoking or near heat or flame.

Do not use

• children under 2 years of age unless directed by a doctor

When using this product

- avoid contact with the eyes or mouth, intentional misuse by deliberately concentrating and inhaling the content can be harmful or fatal.
- use only as directed

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athelete's foot and ringworm) or 2 weeks (for jock itch)

Keep out of reach of children.

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

Directions

- wash the affected area and dry thoroughtly
- spray a thin layer over the 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.
- for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks
- if the condiction persists longer, ask a doctor
- this product is not effective on scalp or nails

Other Information

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

Tamper evident do not accept if safety seal is broken or missing.

Inactive Ingredients

Aloe vera, alpha-tocopherol, franfrance, Isopropyl alcohol, Polyethylene Glycol, purified water, sodium m-bisulfite.

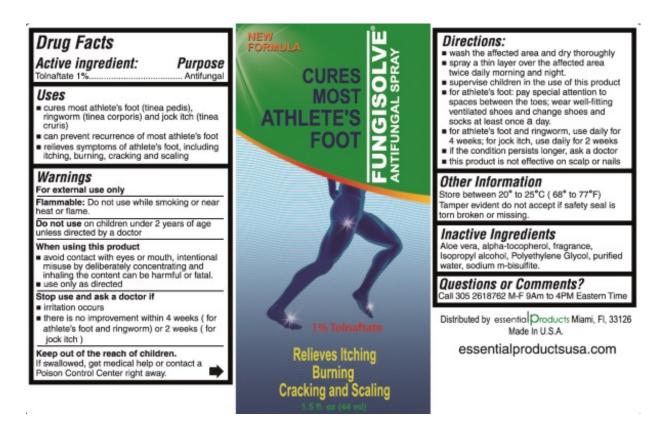
Questions or Comments?

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

Distributed by:

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

FUNGISOLVE TOLNAFTATE ANTIFUNGAL (TOLNAFTATE) SPRAY



FUNGISOLVE TOLNAFTATE ANTIFUNGAL

tolnaftate spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70242-104

Route of Administration TOPICAL

Active Ingredient/Active Moiety

1				
l	Ingredient Name	Basis of Strength	Strength	
ı	TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	10 mg in 1 mL	

Inactive Ingredients

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Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
.ALPHATO COPHEROL (UNII: H4N855PNZ1)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)			
WATER (UNII: 059QF0KO0R)			
SODIUM BISULFITE (UNII: TZX5469Z61)			

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:70242-104- 01	44 mL in 1 BOTTLE, SPRAY; 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(70242-104)

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	Name	Address	ID/FEI	Business Operations

Revised: 4/2016 Dannso Corp./d.b.a. Essential Products