

FUNGISOLVE TOLNAFTATE ANTIFUNGAL- tolnaftate liquid
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

Active Ingredients

Tolnaftate 1%

Purpose

Antifungal

Uses

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

Warnings

For external use only use only as directed

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
- use only as directed

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athlete'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 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.
- for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks

- if the condition 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

Butylated hydroxyanisole, DMDM Hyantoin, Ethoxydiglycol, Eucaliptu oil, Glycerin, Methyl Sallicylate, Pepermint oil, Polyethylene Glycol, Propylen glycol.

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)

TREATS EXPOSED NAIL-BED FUNGUS

SOLUTION FUNGISOLVE® ANTIFUNGAL / ANTIFÚNGICO

NEW FORMULA

TREATS EXPOSED NAIL-BED FUNGUS

BEFORE



AFTER



1% Tolnaftate

Maximum effect on fungal infection on skin around adjacent and under the nails.

1.0 fl. oz. (30ml)

SOLUTION FUNGISOLVE® ANTIFUNGAL

LIQUID SOLUTION

Works on exposed nail bed surface where nails are missing, cracked open or otherwise breached, as well as around, adjacent to under nail-tips.

Drug Facts

Active ingredient: Purpose
Tolnaftate 1%..... Antifungal

Uses

- cures most athlete's foot (tinea pedis), ringworm (tinea corporis) and jock itch (tinea cruris)
- relieves symptoms of athlete's foot, including itching, burning, cracking and scaling

Warnings

For external use only

- use only as directed

Advertencias

- Solo para uso externo

Do not use on children under 2 years of age unless directed by a doctor

No usar en niños menores de 2 años de edad a menos que lo indique un médico

When using this product

- avoid contact with eyes or mouth
- use only as directed

Cuando utilice este producto evite el contacto con los ojos y la boca

- Sólo según las indicaciones

Stop use and ask a doctor if

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

Descontinúe el uso de este producto y consulte a su medico si

- se produce irritación
- no hay mejoría en 4 semanas (para el pie de atleta y la tiña de la piel) o 2 semanas (para la tiña inguinal)

essentialproductsusa.com

TREATA EL HONGO EN EL LECHO DE LA UÑA EXPUESTA

SOLUTION FUNGISOLVE® ANTIFUNGICO

NUEVA FORMULA

ANTES



DESPUES



1% Tolnaftate

Efecto máximo en la infección de los hongos en la piel de alrededor y debajo de las uñas.

1.0 fl. oz. (30ml)

SOLUCIÓN FUNGISOLVE® ANTIFÚNGICO

LIQUIDA

CONTINUED

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

Mantenga fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o contacte un centro de control de intoxicación inmediatamente.

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- if the condition persists longer, ask a doctor
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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.

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Butylated hydroxyanisole, DMDM Hydantoin, Ethoxydiglycol, Eucaliptus oil, Glycerin, Methyl Salicylate, Peppermint oil, Polyethylenglycol, Propylen glycol

Questions or Comments?
Call 305 2618762 M-F 9Am to 4PM Eastern Time

Distributed by essentialProducts Miami, FL 33126
Made in U.S.A.

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NDC: 70242-106-01

FUNGISOLVE TOLNAFTATE ANTIFUNGAL

tolnaftate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70242-106
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 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70242-106-01	30 mL in 1 TUBE, WITH APPLICATOR; 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(70242-106)

Establishment

Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	MANUFACTURE(70242-106)

Revised: 4/2016

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