

## **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.*

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### **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](http://www.essentialproductsusa.com)

## FUNGISOLVE TOLNAFTATE ANTIFUNGAL (TOLNAFTATE) CREAM

<b>CREAM / CREMA</b>	
<b>FUNGISOLVE</b> ANTIFUNGAL / ANTIFÚNGICO	<b>1% Tolnaftate</b> 
<b>CURES MOST ATHLETE'S FOOT</b>	
<b>NET WT. 28g (1.0 oz)</b>	
<b>Drug Facts</b>	
<b>Active ingredient:</b> Tolnaftate 1%.....	<b>Purpose</b> Antifungal
<b>Uses</b> ■ 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	
<b>Warnings</b> 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.	
<b>Directions</b> ■ 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	
<b>Other information</b> Store between 20° to 25°C (68° to 77° F) Tamper evident ■ do not accept if safety seal is torn broken or missing.	
<b>Inactive ingredients</b> Cetareth-6, cety stearyl alcohol, methylparaben, mineral oil, PEG-20 cetyl/stearyl ether, propylene glycol, propylparaben, purified water, sodium m-bisulfite, stearyl alcohol.	
<b>Questions?</b> Call 305 2618762 M-F 9Am to 4PM Eastern Time	
Distributed by essential  Products Miami, FL, 33126 <a href="http://essentialproductsusa.com">essentialproductsusa.com</a>	

## FUNGISOLVE TOLNAFTATE ANTIFUNGAL

tolnaftate cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70242-108
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0K00R)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-15 GLYCERYL STEARATE (UNII: 91245SPD5K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA (UNII: 1211AIM8G7)	
PHOSPHATE ION (UNII: NK08V8K8HR)	
CHLOROCRESOL (UNII: 36W53O7109)	

**Packaging**

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

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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**

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

**Establishment**

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

