

## **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.*

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### **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 symptoms 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 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
- spray 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**

Aloe vera, alpha-tocopherol, fragrance, 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**

<p><b>Drug Facts</b></p> <table border="1"> <tr> <td><b>Active ingredient:</b></td> <td><b>Purpose</b></td> </tr> <tr> <td>Tolnaftate 1%.....</td> <td>Antifungal</td> </tr> </table> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ cures most athlete's foot (tinea pedis), ringworm (tinea corporis) and jock itch (tinea cruris)</li> <li>■ can prevent recurrence of most athlete's foot</li> <li>■ relieves symptoms of athlete's foot, including itching, burning, cracking and scaling</li> </ul> <p><b>Warnings</b></p> <p>For external use only</p> <p><b>Flammable:</b> Do not use while smoking or near heat or flame.</p> <p><b>Do not use</b> on children under 2 years of age unless directed by a doctor</p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>■ avoid contact with eyes or mouth, intentional misuse by deliberately concentrating and inhaling the content can be harmful or fatal.</li> <li>■ use only as directed</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ irritation occurs</li> <li>■ there is no improvement within 4 weeks ( for athlete's foot and ringworm) or 2 weeks ( for jock itch )</li> </ul> <p><b>Keep out of the reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away. ➔</p>	<b>Active ingredient:</b>	<b>Purpose</b>	Tolnaftate 1%.....	Antifungal	<p><b>NEW FORMULA</b></p> <p><b>CURES MOST ATHLETE'S FOOT</b></p> <p><b>FUNGISOLVE<sup>®</sup> ANTIFUNGAL SPRAY</b></p>  <p><b>1% Tolnaftate</b></p> <p><b>Relieves Itching Burning Cracking and Scaling</b></p> <p><b>1.5 fl. oz (44 ml)</b></p>	<p><b>Directions:</b></p> <ul style="list-style-type: none"> <li>■ wash the affected area and dry thoroughly</li> <li>■ spray a thin layer over the affected area twice daily morning and night.</li> <li>■ supervise children in the use of this product</li> <li>■ 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.</li> <li>■ for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks</li> <li>■ if the condition persists longer, ask a doctor</li> <li>■ this product is not effective on scalp or nails</li> </ul> <p><b>Other Information</b></p> <p>Store between 20° to 25°C ( 68° to 77°F) Tamper evident do not accept if safety seal is torn broken or missing.</p> <p><b>Inactive Ingredients</b></p> <p>Aloe vera, alpha-tocopherol, fragrance, Isopropyl alcohol, Polyethylene Glycol, purified water, sodium m-bisulfite.</p> <p><b>Questions or Comments?</b></p> <p>Call 305 2618762 M-F 9Am to 4PM Eastern Time</p>
<b>Active ingredient:</b>	<b>Purpose</b>					
Tolnaftate 1%.....	Antifungal					

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

essentialproductsusa.com

# 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

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

## Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SODIUM BISULFITE (UNII: TZX5469Z6I)	

## 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** - 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(70242-104)

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Revised: 4/2016

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