# LUCKY SUPER SOFT ANTIFUNGAL FOR ATHLETES FOOT- tolnaftate powder Blue Sea Aerosol & Daily Care Co.,Ltd

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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# **Antifungal Powder Spray**

#### **Active Ingredient**

Tolnaftate 1%

#### **Purpose**

Antifungal

#### Uses

■ proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis) ■ helps prevent most athlete's foot with daily use ■ for effective relief of itching, burning, and cracking

### Warnings

# For external use only

**Flammable:** Do not use while smoking or near heat or flame

#### Do not use

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

# When using this product

■ avoid contact with eyes ■ use only as directed. Intentional misuse by deliberetely concentrating and inhaling contents can be harmful or fatal ■ contents under pressure. Do not puncture or incinerate.

Do not stire at a temperature above 120°F (49°C1)

#### Stop use and ask a doctor if

■ irritation occurs ■ there is no improvement within 4 weeks

#### Keep out of reach of children

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

#### **Directions**

■ wash affected area and dry thoroughly ■ shake can well and spray a thin layer over 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 ■ use daily for 4 weeks, if conditions persist longer, ask a doctor ■ to prevent

athlete's foot, apply once or twice daily (morning and/or night) ■ this product is not effective on the scalp or nails ■ in case of clogging, clean nozzle with pin

#### Other information

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

#### **Inactive ingredients**

alcohol denat., butane, fragrance, propane, triethanolamine, zea mays (corn) starch

#### **Package Label**



#### LUCKY SUPER SOFT ANTIFUNGAL FOR ATHLETES FOOT

tolnaftate powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72119-001
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
ALCOHOL (UNII: 3K9958V90M)	
BUTANE (UNII: 6LV4FOR43R)	
PROPANE (UNII: T75W9911L6)	
TROLAMINE (UNII: 903K93S3TK)	
STARCH, CORN (UNII: O8232NY3SJ)	

	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:72119-001-85	85 g in 1 CAN; Type 0: Not a Combination Product	02/19/2018		
	2 NDC:72119-001-57	57 g in 1 CAN; Type 0: Not a Combination Product	04/12/2019		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	02/19/2018		

# **Labeler** - Blue Sea Aerosol & Daily Care Co.,Ltd (544373091)

Revised: 2/2020 Blue Sea Aerosol & Daily Care Co.,Ltd