

ATHLETES FOOT- tolnaftate solution/ drops
Imperial Feet B.V.

Athlete's Foot 75 mL NDC 83837-002-01

Active Ingredient

Tolnaftate 1%

Warnings

- . Do not use on children under 2 years of age unless directed by a doctor.
- . For external use only.
- . Avoid contact with the eyes.
- . If irritation occurs or there is no improvement within 4 weeks, discontinue use and consult a doctor.

Ask a doctor

If irritation occurs or there is no improvement within 4 weeks, discontinue use and consult a doctor.

Stop Use

If irritation occurs or there is no improvement within 4 weeks, discontinue use and consult a doctor.

Inactive Ingredient

Inactive Ingredients Almond Oil, Alpha-Bisabolene, Calendula Officinalis Flower, Chamomile, Chlorphenesin, Glycerin, Methyl-Gluceth-20, Phenoxyethanol, Piroctone Olamine, Polysorbate 20, Polyethylene Glycol 400, Polyoxyl 40 Hydrogenated Castor Oil, Squalene, Water

Other Information

Store between 20 C and 30 C (68 F and 86 F)

Purpose

Antifungal

Directions

- Wash the affected area and dry thoroughly.
- Apply a thin layer of the product over affected area twice daily (morning and night) or

as directed by a doctor.

- Supervise children in the use of this product.
- Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.
- If condition persists longer, consult a doctor.

Keep out of reach of children

Supervise children in the use of this product

Use

Cures most Athlete's Foot

Principal Display Panel / Product Label



The solution for
ATHLETE'S FOOT

Anti fungal feet treatment
 and healthier looking feet

Drug Facts	
Active Ingredient	Purpose
Tolnaftate 1%	Antifungal
Uses	
Cures most Athlete's Foot	
Warnings	
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Directions	
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Other Information	
<ul style="list-style-type: none"> • Store between 20°C and 30°C(68°F and 86°F) 	
Inactive Ingredients	
Almond Oil, Alpha-Bisabolene, Calendula Officinalis Flower, Chamomile, Chlorphenesin, Glycerin, Methyl-Gluceth-20, Phenoxyethanol, Piroctone Olamine, Polysorbate 20, Polyethylene Glycol 400, Polyoxyl 40 Hydrogenated Castor Oil, Squalene, Water	

Ref.:31975/03



75 ml/2.5 OZ



www.imperialfeet.com

Manufactured for Imperial Feet Inc. by Creative Essences, 15320 Cornet St, Santa Fe Springs, CA 90670 USA

ATHLETES FOOT

tolnaftate solution/ drops

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:83837-002

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	0.3 g in 100 mL
CHLORPHENESIN (UNII: I670DAL4SZ)	0.2 g in 100 mL
PIROCTONE OLAMINE (UNII: A4V5C6R9FB)	0.05 g in 100 mL
ALMOND OIL (UNII: 66YXD4DKO9)	1 g in 100 mL
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	13 g in 100 mL
WATER (UNII: 059QF0KO0R)	0.3 g in 100 mL
SQUALENE (UNII: 7QWM220FJH)	0.1 g in 100 mL
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	3 g in 100 mL
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	0.1 g in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.75 g in 100 mL
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.1 g in 100 mL
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	0.3 g in 100 mL
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	70 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.3 g in 100 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83837-002-01	75 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	02/19/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	02/19/2024	

Labeler - Imperial Feet B.V. (386790021)

Registrant - Creative Essences Inc (079120182)

Establishment			
Name	Address	ID/FEI	Business Operations
Creative Essences Inc		079120182	manufacture(83837-002)

