

EMONINAIL ANTIFUNGAL- undecylenic acid liquid
Pure Source, LLC

EmoniNail Antifungal Solution

Drug Facts

Active Ingredient

Undecylenic Acid 10.00%

Purpose

Topical Antifungal

Uses

Proven clinically effective in the treatment of most fungal infections related/associated to tinea pedis (athlete's foot) or tinea corporis (ringworm).

Warnings

- For external use only

Do not use

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

Stop use and ask a doctor if,

- If irritation occurs or if 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.

When using this product,

avoid contact with eyes.

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.
- 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 daily.
- For athlete's foot and ringworm: use daily for 4 weeks. If condition persists longer, consult a doctor.

- This product is not effective on the scalp or nails.

Other Information

- Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

Aqua (Deionized Water), SD-Alcohol 40B, Cetearyl Alcohol, Helianthus Annuus (Sunflower) Seed Oil, Cetyl Alcohol, Polysorbate-20, Polycrylamide, C13-C14 Isoparaffin, Laureth-7, Glycerin, Melaleuca Alternifolia (Tea Tree) Oil, Phenoxyethanol, Ethylhexylglycerin.

Other information

Store between 20° to 30°C (68° to 86°F)

Package Labeling:



MAXIMUM STRENGTH

ANTIFUNGAL SOLUTION

Distributed by: GG Healthworks, Inc.
 EmoniNail.com | info@EmoniNail.com | +1 551-333-5286
 .8FL OZ/24 ML

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Email: info@EmoniNail.com

Questions?



EMONINAIL ANTIFUNGAL

undecylenic acid liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65121-071
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of	Strength
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Ingredient Name	Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
GLYCERIN (UNII: PDC6A3C0OX)	
TEA TREE OIL (UNII: VIF565UC2G)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65121-071-08	24 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	05/01/2020	

Labeler - Pure Source, LLC (080354456)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	manufacture(65121-071)

Revised: 11/2023

Pure Source, LLC