

PURESKIN FUNGAL NAIL RENEWAL- fungal nail renewal liquid
Stellans Inc.

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.

Active Ingredient

Undecylenic Acid 10%

Purpose

Nail Fungus Treatment

Use

Fungal nails
Athlete's Foot
Tinea Manuum
Jock Itch
Ringworm caused by fungus and bacterial infection.

Warnings

For external use only; do not ingest.
Avoid eye contact; maintain dry and clean skin.
Exercise caution when using on severely ulcerated skin.
This product is not a substitute for medication.

Do not use

On open skin wounds

When Using

Stop Use And See A Doctor If
You become pregnant or are planning to get pregnant while using the product.
You are allergic to this product (such as itching, rash swelling of the lips, eyelids, and shortness of breath).

Ask Doctor

If you are allergic to this product. If symptoms persist for over 7 days or worsen, consult your physician. If you are pregnant or breast-feeding - You become pregnant or are planning to ...

Keep Out Of Reach Of Children

Keep out of reach of children. In case of ingestion, call Poison Control Center hotline immediately or seek medical help.

Directions

1. Apply the product twice a day, in the morning and at night.
2. For initial use, soak the affected nail in warm water to soften it. Gently file the nail to make it thinner and remove dirt, being cautious not to harm the nail bed. Apply the product after this step.
3. After the first application, repeat every 2-3 days. File the surface of the affected nail and continue regular usage.

In case of ingestion, seek medical assistance or contact a poison control center immediately.

Other information

- Keep away from direct sunlight or heat
- Store in room temperature

Inactive ingredients

Water, Acetic Acid, Sophora Flavescens, Propylene Glycol, Phenoxyethanol, Fructus Cnidii, Ethanol, Crocus Sativus L

Questions

www.pureskinsupport.com info@pureskinsupport.com
951-265-8930

PRINCIPAL DISPLAY PANEL



印刷工艺:

1.375g银卡+四色+白墨+逆向UV磨砂

2. 烫紫金

3. 盒盖留指甲位

size: 10*4.5cm

工艺: 光银不干胶



PURESKIN FUNGAL NAIL RENEWAL

fungal nail renewal liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83565-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
SOPHORA FLAVESCENS WHOLE (UNII: X8KX602M5L)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CROCUS SATIVUS WHOLE (UNII: Z5C927G4XF)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CNIDIUM MONNIERI FRUIT (UNII: V1IA3S3CUS)	
ACETIC ACID (UNII: Q40Q9N063P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83565-003-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/30/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M005	08/30/2023	

Labeler - Stellans Inc. (111157321)**Establishment**

Name	Address	ID/FEI	Business Operations
Stellans Inc.		111157321	label(83565-003) , manufacture(83565-003)

Revised: 8/2023

Stellans Inc.