

**PURESKIN FUNGAL NAIL RENEWAL PATCHES- pureskin fungal nail renewal patches patch
Stellans Inc.**

83565-011

Active Ingredient

Undecylenic Acid 8%

Purpose

Antifungal

Use

For repairing nails affected by fungal infections

Warnings

1. Keep out of children's reach. Avoid contact with eyes, mouth, mucous membranes, wounds, or inflamed skin.
2. External use only.
3. Do not use if allergic to any ingredient.
4. Do not use in children.
5. Do not use if pouch is torn or broken.
6. Discontinue use if skin becomes red, swollen, or itchy, and consult a healthcare professional.

Keep Out Of Reach Of Children

Keep Out Of Reach Of Children

Directions

Begin by removing any nail polish. Cleanse nails and surrounding skin, ensuring thorough drying to enhance adhesion.

- a. Peel off protective films and sequentially.
- b. Apply the patch to the affected nail area, removing release paper.
- c. Firmly cover the sides of the toe or finger.
- d. Fold the remaining adhesive to envelop the toe/fingertip.
- e. Maintain the patch for 6-8 hours (overnight use recommended for 3-6 months). Use daily for optimal results. It is recommended to roughen the nail surface before application for better adhesion.

Other information

Store at room temperature. Keep away from moisture and sunlight.
Do not use if seal is broken or missing.

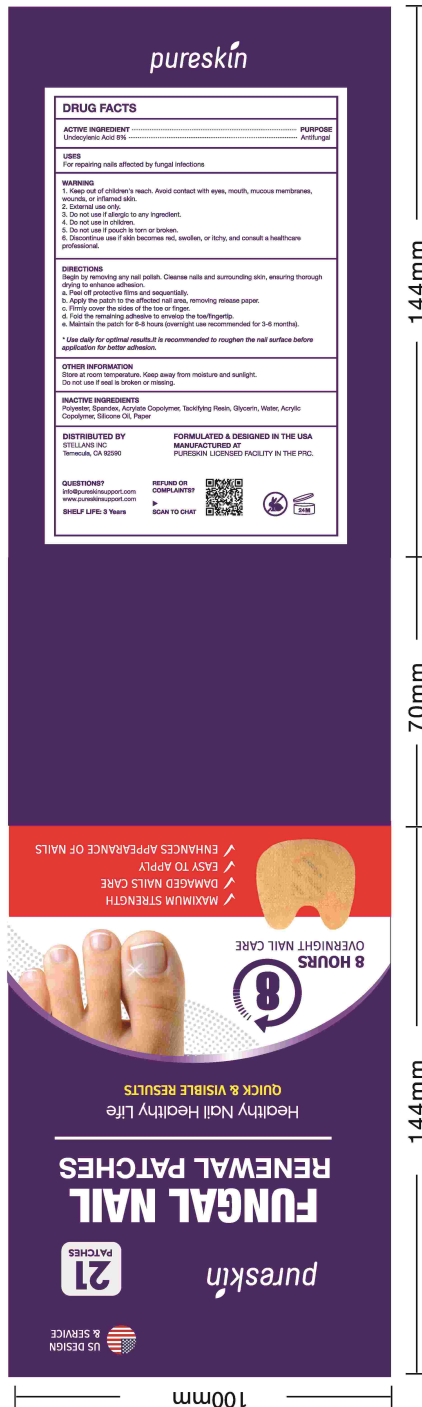
Inactive ingredients

Polyester, Spandex, Acrylate Copolymer, Tackifying Resin, Glycerin, Water, Acrylic Copolymer, Silicone Oil, Paper

Questions

info@pureskinsupport.com
www.pureskinsupport.com

PRINCIPAL DISPLAY PANEL



PURESKIN FUNGAL NAIL RENEWAL PATCHES

pureskin fungal nail renewal patches patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83565-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	8 g in 100

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C00X)	
WATER (UNII: 059QF0KO0R)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83565-011-01	21 in 1 BOX; Type 0: Not a Combination Product	07/15/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	07/15/2024	

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

Name	Address	ID/FEI	Business Operations
Stellans Inc.		111157321	manufacture(83565-011) , label(83565-011)

Revised: 7/2024

Stellans Inc.