

FUNGAL NAIL RENEWAL- undecenoic acid liquid
Shengnan (Guangzhou) Cosmetics Co., LTD

Fungal Nail Renewal

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Undecenoic Acid 0.5%

Sterilizing

RESTORES AND RENEWS
HYDRATES DAMAGED NAILS

Do not use on children under 2 years of age unless directed by a doctor.

For external use only.

Avoid contact with the eyes.

Keep out of reach of children section.

Do not use on children under 2 years of age unless directed by a doctor.

Avoid contact with eyes or mucous membranes.

Do not apply to wounds or damaged skin.

Do not use with other ointments, creams, sprays or liniments.

If swelling, blistering or other discomfort occurs, please stop using and consult doctor immediately.

If symptoms have not been relieved after using for more than 7 days, please stop using and consult doctor immediately.

Keep out of reach of children section.

Apply two drops each time, 2-3 times a day, do not rinse with cold water within 2 hours after use.

Store in a cool dry place away from direct sunlight.

Glycerin

Propylene Glycol

Potassium Iodide

Menthol

Camellia Sinensis Seed Oil



FUNGAL NAIL RENEWAL

undecenoic acid liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84019-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
11-HYDROXY-2-UNDECENOIC ACID (UNII: UOM92D5748) (11-HYDROXY-2-UNDECENOIC ACID - UNII:UOM92D5748)	11-HYDROXY-2-UNDECENOIC ACID	0.005 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM IODIDE (UNII: 1C4QK22F9J)	
METAHOMOMENTHOL, (+/-)- (UNII: 73RQD9KEHS)	
CAMELLIA SINENSIS SEED OIL (UNII: O5R6DK2M9K)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84019-201-01	1 in 1 BOX	01/25/2024	
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:84019-201-02	1 in 1 BOX	01/25/2024	
2		20 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:84019-201-03	1 in 1 BOX	01/25/2024	
3		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	01/25/2024	

Labeler - Shengnan (Guangzhou) Cosmetics Co., LTD (541200425)

Establishment

Name	Address	ID/FEI	Business Operations
Shengnan (Guangzhou) Cosmetics Co., LTD		541200425	manufacture(84019-201)

Revised: 1/2024

Shengnan (Guangzhou) Cosmetics Co., LTD