FUNGAL NAIL RENEWAL- oil liquid Shenzhen Xiaomai Manufacturing Co., Ltd.

Active Ingredient

Tolnaftate1%

Undecylenic Acid 25%

Purpose

Fungal nails, Athlete's Foot, Tinea Manuum, Jock Itch, Ringwormcaused by fungus and bacterial infection. For all caused by nail fungus, nail discoloration, nail thickening, nail splitting, nail crumbling.

Use

For nails

Warnings

- -For external use only
- -Keep away from fire and flame

Do not use

This product is not a substitute for medication.

When Using

For external use only, do not ingest. Avoid eye contact; maintain dry and clean skin. Exercise caution when using on severely ulcerated skin. Keep out of reach of children.

Stop Use

Keep Out Of Reach Of Chlidren:if swallowed,get medical help or contact a Poison Control Center right away."

Ask Doctor

When Pregnant or breast-feeding.

Keep Oot Of Reach Of Children

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Directions

Apply the product twice a day, in the morning and at night. For initial use, soak the affected nail in warm water to soften itGently file the nail to make it thinner and remove dirt, beingcautious not to ham the nail bed. Apply the product after this step. After the first application, repeat every 2-3 days. File the surfaceof the affected nail and continue regular usage.*In case of ingestion, seek medical assistance or contact apoison control center immediately.

Other information

Please store in a cool, dry place away from direct sunlight.

Inactive ingredients

Undecylenic Acid, Tolnaftate, Ethyl Lactate, Aqua, Lactic Acid, Resacetophenone, Acetic Acid, Sophora Flavescens Extract, Stellera Chamaejasme Leaf/Stem Extract, Crocus Sativus StyleExtract, Eucalyptol, Aloe Barbadensis Leaf Extract, CarthamusTinctorius (Safflower) Seed Oil, Hydrogenated PolyisobuteneLavandula Angustifolia (Lavender) Oil, Melaleuca Alternifolia(Tea Tree) Leaf Oil, Oryza Sativa (Rice) Bran Oil, PrunusAmygdalus Dulcis (Sweet Almond) Oil, Sesamum Indicum(Sesame) Seed Oil, Simmondsia Chinensis (Jojoba) Seed Oil. Tocopheryl Acetate, Olea Europaea (Olive) Fruit Oil.



FUNGAL NAIL RENEWAL

oil liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83872-329	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 30 mL	
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	8 g in 30 mL	

Inactive Ingredients			
Ingredient Name	Strength		
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)			
HYDROGENATED POLYISOBUTENE 8 (UNII: 7YR4ZFS62E)			
ETHYL LACTATE (UNII: F3P750VW8I)			
LACTIC ACID (UNII: 33X04XA5AT)			
RESACETOPHENONE (UNII: UC3V356VZC)			
WATER (UNII: 059QF0KO0R)			
ACETIC ACID (UNII: Q40Q9N063P)			
STELLERA CHAMAEJASME WHOLE (UNII: 80N0P0DD9J)			
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)			

l	P	ackaging			
	#	# Item Code Package Description		Marketing Start Date	Marketing End Date
		NDC:83872- 329-01	30 mL in 1 BOTTLE, UNIT-DOSE; Type 0: Not a Combination Product	07/17/2024	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	505G(a)(3)	07/17/2024		

Labeler - Shenzhen Xiaomai Manufacturing Co., Ltd. (712999147)

Establishment				
Name	Address	ID/FEI	Business Operations	
Shenzhen Xiaomai Manufacturing Co., Ltd.		712999147	manufacture(83872-329)	

Revised: 7/2024 Shenzhen Xiaomai Manufacturing Co., Ltd.