FUNGAL NAIL TREATMENT MAXIMUM STRENGTH LIQUID- tolnaftate, undecylenic acid liquid Guangzhou Ruijiu Electronic Technology Co., Ltd.

FUNGAL NAIL TREATMENT MAXIMUM STRENGTH LIQUID

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TOLNAFTATE 1% UNDECYLENIC ACID 25%

Anti-fungal and Nail Renewal

Antifungal use on fingernails, toenails, and the immediately adjacentskin.

- ·Prevents the recurrence of most athlete's foot with daily use.
- ·For all caused by nail fungus, nail discoloration, nail thickening, nailsplitting, nail crumbling.

For external use only.

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

avoid contact with the eyes

Irritation occurs

There is no improvement within 4 weeks

If accidental ingestion occurs, get medical help or contact a PoisonControl Center right away.

Apply once daily, preferably at bedtime or at least eight hours before washing. Clean and thoroughly dry the affected area, then use the applicator brush provided to cover all affected nails. Ensure that the application is evenly distributed across the entire nail plate.

OTHER INFORMATIONSHAKE WELL BEFORE USEStore at room temperature 15°-30°C(59°-86°F)

□ Protect from freezing; if freezing occurs.warm to room temperatureKeep tightly closed when not in use

ALCOHOL
DIMETHICONE
C12-15 ALKYL LACTATE
ETHYLHEXYLGLYCERIN
TOCOPHEROL
SOPHORA FLAVESCENS ROOT
PHENOXYETHANOL
WATER



FUNGAL NAIL TREATMENT MAXIMUM STRENGTH LIQUID

tolnaftate, undecylenic acid liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83767-003	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100 mL	
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	25 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)			
TOCOPHEROL (UNII: R0ZB2556P8)			
WATER (UNII: 059QF0KO0R)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
C12-15 ALKYL LACTATE (UNII: GC844VRD7E)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
ALCOHOL (UNII: 3K9958V90M)			

Packaging		
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83767-003- 01	6 in 1 PACKAGE	12/19/2024	
1		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	12/19/2024	

Labeler - Guangzhou Ruijiu Electronic Technology Co., Ltd. (631973699)

Establishment				
Name	Address	ID/FEI	Business Operations	
Guangzhou Ruijiu Electronic Technology Co., Ltd.		631973699	manufacture(83767-003)	

Revised: 12/2024 Guangzhou Ruijiu Electronic Technology Co., Ltd.