

FUNGAL NAIL TREATMENT MAXIMUM STRENGTH LIQUID- tolnaftate 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 adjacent skin.

Prevents the recurrence of most athlete's foot with daily use

For all caused by nail fungus, nail discoloration, nail thickening, nail splitting, 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 Poison Control 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

Store at room temperature 15--30°C(59°-86°F)

Protect from freezing; if freezing occurs, warm to room temperature

Keep tightly closed when not in use

ALCOHOL

DIMETHICONE

C12-15 ALKYL LACTATE

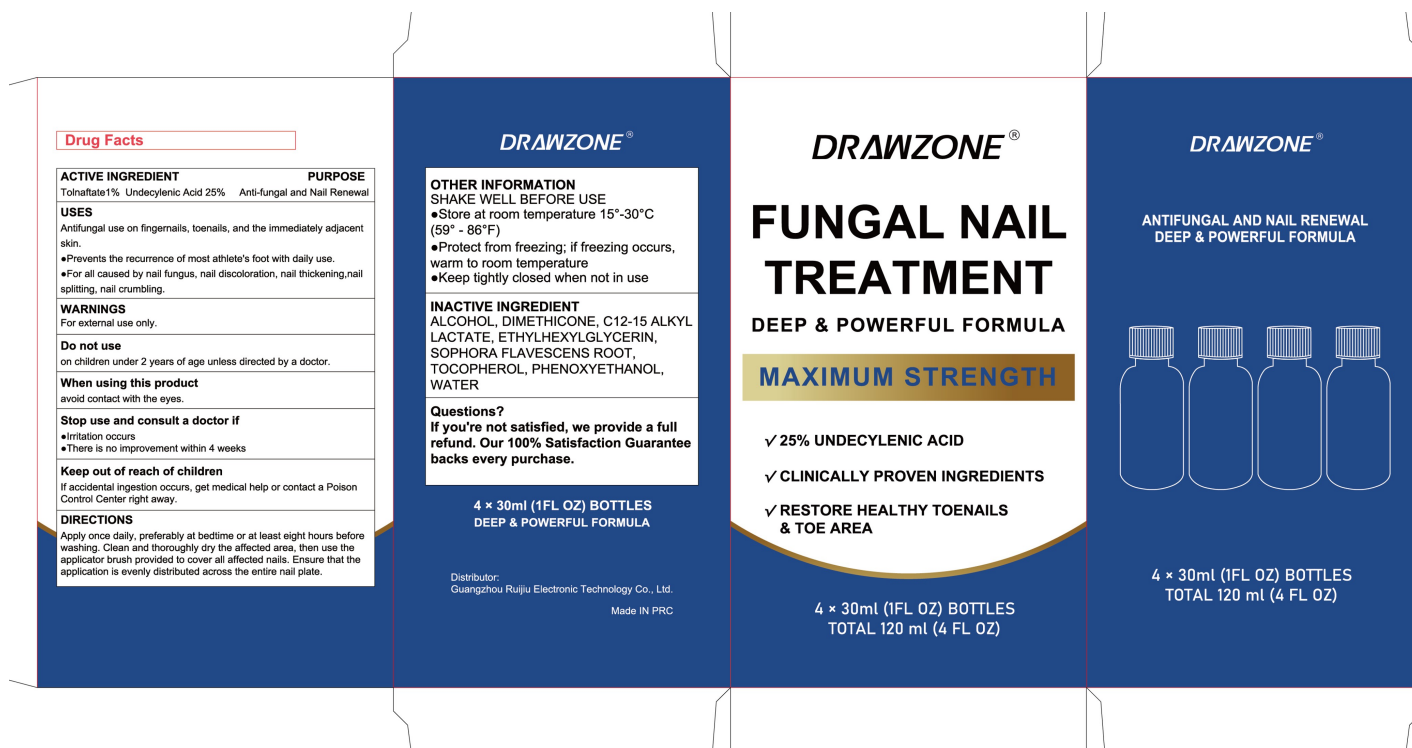
ETHYLHEXYLGLYCERIN

SOPHORA FLAVESCENS ROOT

TOCOPHEROL

PHENOXYETHANOL

WATER



FUNGAL NAIL TREATMENT MAXIMUM STRENGTH LIQUID

tolnaftate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83767-501
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
C12-15 ALKYL LACTATE (UNII: GC844VRD7E)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83767-501-01	2 in 1 PACKAGE	08/28/2024	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:83767-501-02	4 in 1 PACKAGE	08/28/2024	
2		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	08/28/2024	

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

Name	Address	ID/FEI	Business Operations
Guangzhou Ruijiu Electronic Technology Co., Ltd.		631973699	manufacture(83767-501)