

NAIL RENU- tolnaftate 1% solution
RENU LABORATORIES, INC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

NAIL RENU ANTIFUNGAL SOLUTION

Purpose

Antifungal

Uses

- proven clinically to cure most Fungal nail and Skin infections including athlete's foot (tinea pedis) and ringworm (tinea corporis)
- Effectively relieves itching, burning, cracking and scaling associated with the above conditions.
- helps prevent most athlete's foot from coming back with daily use

Warnings

- **For external use only.**
- **Do not use** on children under 2 years of age unless directed by a doctor
- **When using this product** avoid contact with the eyes, nose, and mouth.

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks
- if swallowed, get medical help or contact a Poison Control Center right away.

KEEP OUT OF REACH OF CHILDREN

If Pregnant or breastfeeding ask a health professional before use.

Directions:

- **clean the affected area** and dry thoroughly
- apply a thin layer over the affected area twice daily (morning and night)
- **supervise children** in the use of this product
- for athlete's foot, pay special attention to the spaces between toes. Wear well-fitting, ventilated shoes, and change shoes and socks at least once daily
- **use daily for 4 weeks.** If condition lasts longer, ask a doctor
- to prevent athlete's foot, apply to the feet once or twice daily
- this product is not intended for/or effective on the scalp.

Other information

- Store at 68° - 77° (20° - 25° C)

Questions or Comments

267-482-0866

www.nailrenu.com

Inactive Ingredients

C12-15 Alkyl Benzoate, Camphor, Ceramide III, Cinnamomum Zeylanicum (Cinnamon) Bark Oil, Cymbopogon Nardus (Citronella) Oil, Ethoxydiglycol, Eugenia Caryophyllum (Clove) Bud Extract, Hippophae Rhamnoides (Sea Berry) Fruit and Seed Oils, Lavandula Angustifolia (Lavender) Oil, Limonene, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Mentha piperita (Peppermint) Leaf Oil, Olea Europaea (Olive Pomace) Oil, Oreganum Vulgare (Oregano) Leaf Oil, Pinene, Prunus Amygdallus Dulcis (Sweet Almond) Oil, Simmondsia Chinensis (Jojoba) Oil, Syzgium Aromaticum (Clove) Bud Oil, Thymol, Tocopherol (Vitamin E), Trimethylpentanediol-Adipic Acid Copolymer

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Tolnaftate

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NAIL RENU

BOX ART

NAIL RENU

tolnaftate 1% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-995
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

Inactive Ingredients

Ingredient Name	Strength
CERAMIDE 3 (UNII: 4370DF050B)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
CLOVE OIL (UNII: 578389D6D0)	
THYMOL (UNII: 3J50XA376E)	
CITRONELLA OIL (UNII: QYO8Q067D0)	
CLOVE (UNII: K48IKT5321)	
TEA TREE OIL (UNII: VIF565UC2G)	
CINNAMON BARK OIL (UNII: XE54U569EC)	
TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER (25000 MPA.S) (UNII: 587WKM3S9Q)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)	
HIPPOPHAE RHAMNOIDES FRUIT OIL (UNII: TA4JCF9S1J)	
OREGANO LEAF OIL (UNII: 7D0CGR40U1)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PINENE (UNII: 996299PUKB)	
JOJOBA OIL (UNII: 724GKU717M)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A18X02B)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
OLIVE OIL (UNII: 6UYK2WLWLE)	
ALMOND OIL (UNII: 66YXD4DKO9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-995-01	1 in 1 BOX	03/22/2023	
1	NDC:76348-995-05	15 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M005	03/22/2023	

Labeler - RENU LABORATORIES, INC. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
Renu Laboratories, Inc.		945739449	manufacture(76348-995)

Revised: 3/2023

RENU LABORATORIES, INC.