

FLAWLESS NAILS- tolnaftate 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.

Flawless Nails

Tolnaftate

MyFlawlessNails LLC

Fairfield, CT 06824

www.MyFlawlessNails.com

FLAWLESS NAILS

Nail Fungus Eliminator

Medical Strength

Clinically Proven

15ML (0.5FL.OZ)

Other information: Store at 68° - 77°

Inactive Ingredients

C12-15 Alkyl Benzoate, Camphor, Ceramide III, Cinnamoniun 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 Amygdalus Dulcis (Sweet Almond) Oil, Simmondsia Chinensis (Jojoba) Oil, Syzgium Aromaticum (Clove Bud) Oil, Thymol, Tocopherol Acetate, Trimethyl-Adipic Acid Copolymer.

Antifungal

Uses

- proven clinically to cure most:
- athlete's foot (tinea pedis)
- ringworm (tinea corporis)

- Effectively soothes and relieves:
- itching
- burning
- cracking
- 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

Stop use and ask a doctor if

- there is no improvement within 4 weeks

Keep out of reach of children.

Get medical help or contact a Poison Control Center right away.

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

When using this product, avoid contact with the eyes

Keep out of reach of children.

Get medical help or contact a Poison Control Center right away

Directions

clean the affected area and dry thoroughly

apply a thin layer over the affected area twice daily

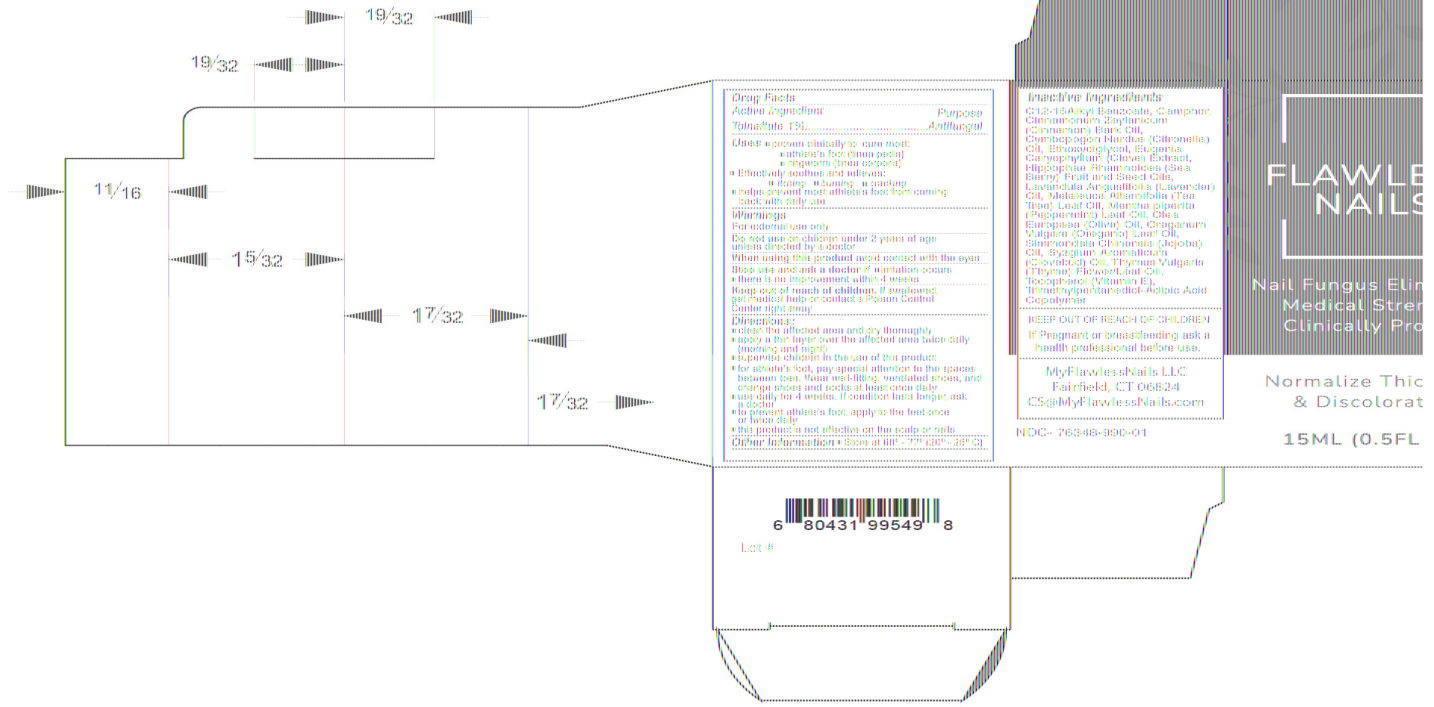
supervise children in the use of this product

for athletes foot pay special attention to the spaces between toes

use daily for 4 weeks

FLAWLESS NAILS LABEL AND FLAWLESS NAILS BOX

FLAWLESS NAILS - NUNITO
Package font - Gotham Light



Drug Facts

Active Ingredient	Purpose
Tolnaftate 1%	Antifungal

Uses • proven clinically to cure most:
• athlete's foot (tinea pedis)
• ringworm (tinea corporis)

• Effectively soothes and relieves:
• itching • burning • cracking

• 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
Stop use and ask a doctor if a irritation occurs
• if there is no improvement within 4 weeks
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions:
• to 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 washable, 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 effective on the scalp or nails

Other Information • Store at 68° - 77° (20° - 25° C)

Inactive Ingredients
C12-15 Alkyl Benzoate, Camphor, Cinnamomum Zeylanicum (Cinnamon) Bark Oil, Cymbopogon Nardus (Citronella) Oil, Ethoxydiglycol, Eugenia Caryophyllum (Cloves) Extract, Hippophae Rhamnoides (Sea Berry) Fruit and Seed Oil, Lavandula Angustifolia (Lavender) Oil, Melissa Atractylolla (Tea Tree) Leaf Oil, Miantha piperita (Peppermint) Leaf Oil, Citrus Europaea (Lime) Oil, Citrus Aurantium Vulgare (Grapefruit) Leaf Oil, Simmondsia Chinensis (Jojoba) Oil, Sygium Aromaticum (Clovebud) Oil, Thymus Vulgaris (Thyme) Flower/Leaf Oil, Tocopherol (Vitamin E), Trimethylpentanediol-2-Propyl Acetate Copolymer

KEEP OUT OF REACH OF CHILDREN
If Pregnant or breastfeeding ask a health professional before use.

MyFlawlessNails LLC
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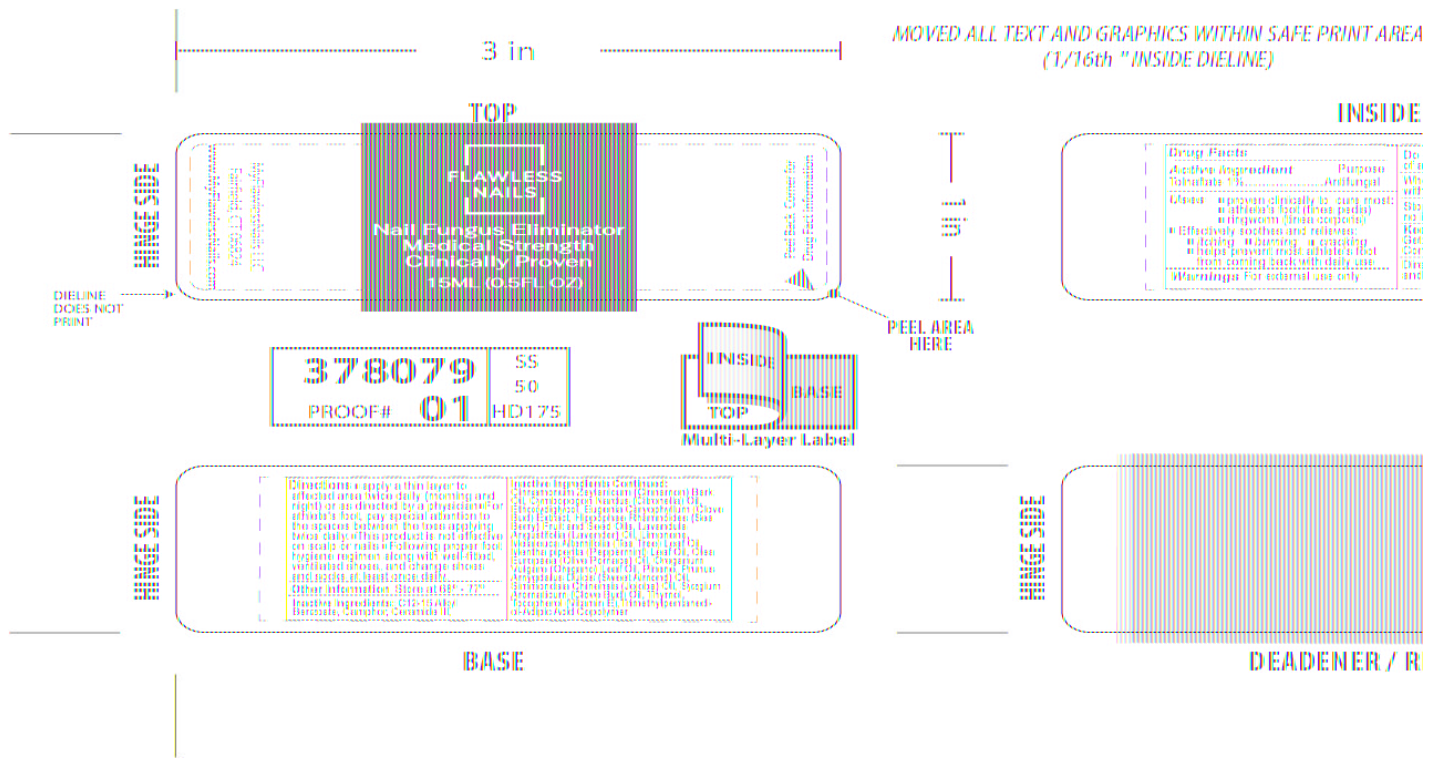
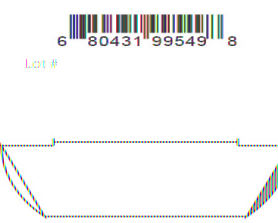
NDC: 76348-990-01

FLAWLESS NAILS

Nail Fungus Eliminator
Medical Strength
Clinically Proven

Normalize Thick & Discolored

15ML (0.5FL



FLAWLESS NAILS

tolnaftate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-990
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
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
CINNAMON BARK OIL (UNII: XE54U569EC)	
HIPPOPHAE RHAMNOIDES FRUIT OIL (UNII: TA4JCF9S1J)	
TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER (25000 MPA.S) (UNII: 587WKM3S9Q)	
PINENE (UNII: 996299PUKB)	
ALMOND OIL (UNII: 66YXD4DKO9)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CLOVE (UNII: K48IKT5321)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
TEA TREE OIL (UNII: VIF565UC2G)	
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
CITRONELLA OIL (UNII: QYO8Q067D0)	
CERAMIDE 3 (UNII: 4370DF050B)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
OREGANO LEAF OIL (UNII: 7D0CGR40U1)	
JOJOBA OIL (UNII: 724GKU717M)	
CLOVE OIL (UNII: 578389D6D0)	
THYMOL (UNII: 3J50XA376E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-990-02	1 in 1 BOX	04/03/2023	
1	NDC:76348-990-01	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	04/03/2023	

Labeler - RENU LABORATORIES, INC. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
RENU LABORATORIES		945739449	manufacture(76348-990)

Revised: 1/2023

RENU LABORATORIES, INC.