

NAIL RENU ANTIFUNGAL- miconazole nitrate 2% cream
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 CREAM

Miconazole Nitrate 2%

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

For external use only

When using this product, avoid contact with the eyes

Stop use and ask a doctor if

- irritation occurs
- 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:

- 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 effective on the scalp or nails

Benzoic Acid, Ceramide-3, Cetareth-20, Cetearyl Alcohol, Cinnamomum Zeylanicum (Cinnamon) Bark Oil, Dehydroacetic Acid, Deionized Water, Ethyl Macadamiate, Eucalyptol, Eugenia Caryophyllus (Clove) Bud Oil, Hippophae Rhamnoides (Sea Berry) Fruit and Seed Oils, Melaleuca Alternifolia (Tea Tree) Oil, Olea Europaea (Olive) Fruit Oil, Origanum vulgare (Oregano) Leaf Oil, Propylene Glycol, Thymol, Tocopherol, Triethanolamine, Trimethylpentanediol Adipic Acid Copolymer, Xanthan Gum

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

Other Information

Store at 68° - 77° (20 - 25 C)

NAIL RENU

Miconazole Nitrate 2%

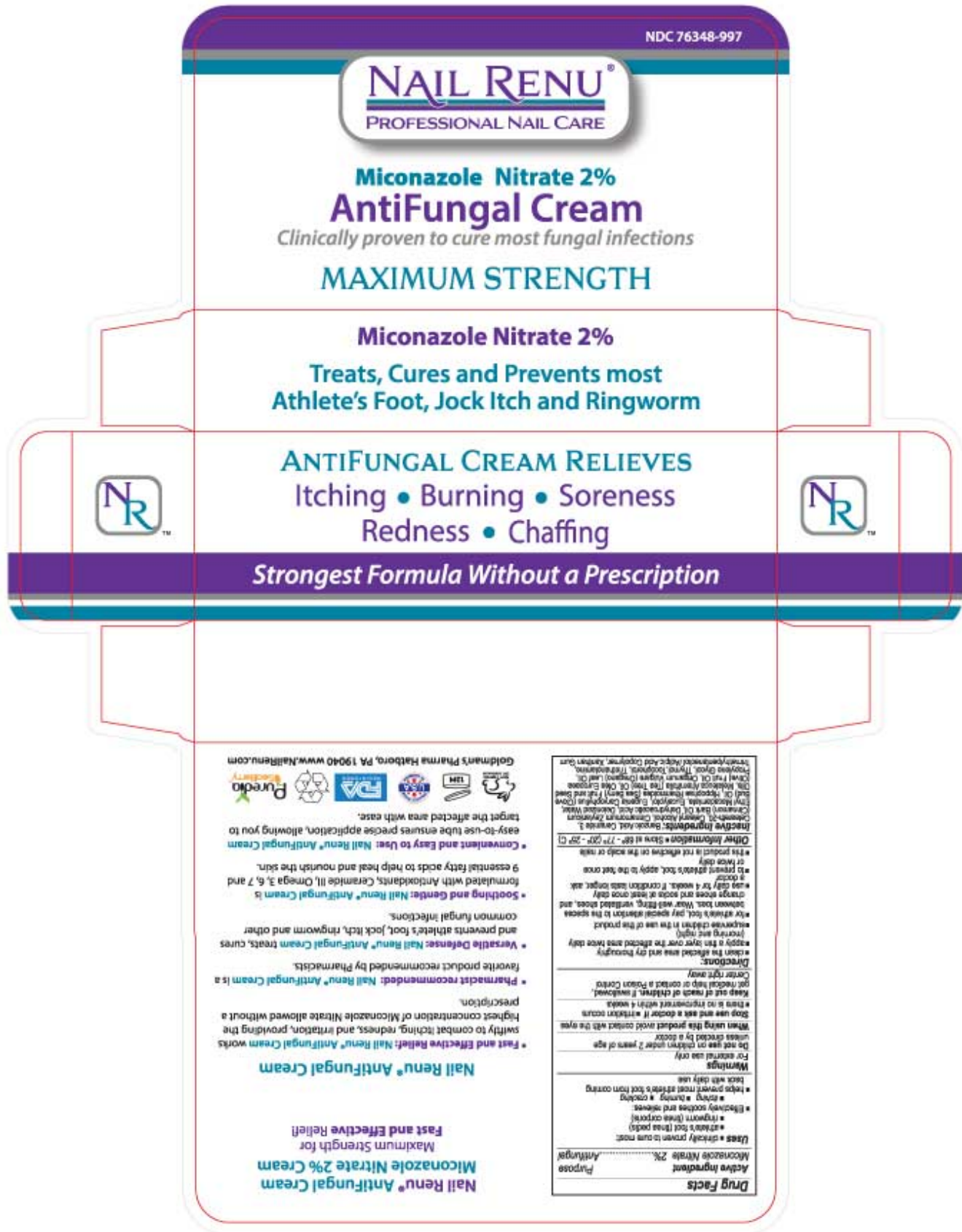
Antifungal Cream

Directions

- Clean the affected area and dry thoroughly
- apply a thin coat over 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, change shoes and socks 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

Size: (L) 5.6.5" (W) 1.828" (D) 1.187"

STRAIGHT TUCK BOX



NDC 76348-997

NAIL RENU[®]
PROFESSIONAL NAIL CARE

**Miconazole Nitrate 2%
AntiFungal Cream**

Clinically proven to cure most fungal infections

MAXIMUM STRENGTH

Miconazole Nitrate 2%
**Treats, Cures and Prevents most
Athlete's Foot, Jock Itch and Ringworm**

ANTIFUNGAL CREAM RELIEVES
**Itching • Burning • Soreness
Redness • Chaffing**

Strongest Formula Without a Prescription



Goldman's Pharma Harbor, PA 19040 www.NailRenu.com
PuroBio Bioactivity
FMA
MA
MA
MA

- **Fast and Effective Relief:** Nail Renu[®] AntiFungal Cream works swiftly to combat itching, redness, and irritation, providing the highest concentration of Miconazole Nitrate allowed without a prescription.
- **Pharmacist recommended:** Nail Renu[®] AntiFungal Cream is a favorite product recommended by Pharmacists.
- **Versatile Defense:** Nail Renu[®] AntiFungal Cream treats, cures and prevents athlete's foot, jock itch, ringworm and other common fungal infections.
- **Soothing and Gentle:** Nail Renu[®] AntiFungal Cream is formulated with Antioxidants, Ceramide II, Omega 3, 6, 7 and 9 essential fatty acids to help heal and nourish the skin.
- **Convenient and Easy to Use:** Nail Renu[®] AntiFungal Cream easy-to-use tube ensures precise application, allowing you to target the affected area with ease.

Nail Renu[®] AntiFungal Cream

Nail Renu[®] AntiFungal Cream
Miconazole Nitrate 2% Cream
Maximum Strength for
Fast and Effective Relief

Drug Facts

Active Ingredient
Miconazole Nitrate 2%.....AntiFungal

Uses • clinically proven to cure most:
• Athlete's foot (tinea pedis)
• Ringworm (tinea corporis)
• Itchy rashes and sores

Warnings
• Do not use on children under 2 years of age unless directed by a doctor.
• When using the product avoid contact with the eyes.
• Stop use and ask a doctor if irritation occurs.
• There is no requirement with 4 weeks.
• Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions:
• Clean the affected area and dry thoroughly (front and right).
• Apply to the base over the affected area once daily.
• For athlete's foot, pay special attention to the spaces between toes. Wear webbing, ventilated shoes, and dry socks.
• For athlete's foot, pay special attention to the spaces between toes. Wear webbing, ventilated shoes, and dry socks.
• Apply to the base over the affected area once daily (front and right).
• For athlete's foot, pay special attention to the spaces between toes. Wear webbing, ventilated shoes, and dry socks.
• Apply to the base over the affected area once daily (front and right).

Other Information • Store at 68° - 77° (20° - 25° C) or cooler.
• This product is not effective on the scalp or nails.
• Do not use on children under 2 years of age unless directed by a doctor.
• When using the product avoid contact with the eyes.
• Stop use and ask a doctor if irritation occurs.
• There is no requirement with 4 weeks.
• Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.



ANEL WILL BE "MIRRORED" ON PLATES.
TTUBE ARTWORK AND UNIT BOX ARTWORK FOR NAIL RENU

NAIL RENU ANTIFUNGAL			
miconazole nitrate 2% cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-997
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)		MICONAZOLE NITRATE	0.6 g in 28 g
Inactive Ingredients			

Ingredient Name	Strength
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
WATER (UNII: 059QF0KO0R)	
EUCALYPTOL (UNII: RV6J6604TK)	
CLOVE OIL (UNII: 578389D6D0)	
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)	
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)	
OREGANO LEAF OIL (UNII: 7D0CGR40U1)	
HIPPOPHAE RHAMNOIDES FRUIT OIL (UNII: TA4JCF9S1J)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
THYMOL (UNII: 3J50XA376E)	
TOCOPHEROL (UNII: R0ZB2556P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CINNAMON BARK OIL (UNII: XE54U569EC)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
ETHYL MACADAMIATE (UNII: ANA2NCS6V1)	
CERAMIDE 3 (UNII: 4370DF050B)	
TROLAMINE (UNII: 9O3K93S3TK)	
TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER (25000 MPA.S) (UNII: 587WKM3S9Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-997-02	1 in 1 BOX	07/24/2023	
1	NDC:76348-997-01	28 g in 1 TUBE; 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	07/17/2023	

Labeler - RENU LABORATORIES, INC. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
Renu Laboratories, Inc.		945739449	manufacture(76348-997)