

**GOLD MOUNTAIN BEAUTY FUNGAL NAIL ELIMINATOR- tolnaftate antifungal oil**  
**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.*

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**Gold Mountain Beauty Fungal Nail Eliminator**

**Active Ingredient**

Tolnaftate 1%

**Purpose**

Antifungal

**For external use only**

- Do not use on children under 2 years of age unless directed by a doctor
- Avoid contact with eyes, ears or mouth
- If irritation occurs, discontinue use and consult a doctor
- If swallowed, get medical help or consult a poison control center immediately

**KEEP OUT OF REACH OF CHILDREN**

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Other information

Store at room temperature (59 - 86 degrees F)

**Inactive ingredients**

C12-15 Alkyl Benzoate, Ethyldiglycol, Hippophae Rhamnoides (Sea Berry) Fruit Oil, Hippophae Rhamnoides (Sea Berry) Seed Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Olea Europaea (Olive) Oil, Trimethylpentanediol/Adipic Acid Copolymer

- If irritation occurs, discontinue use and consult a doctor

For questions or comments, please visit: [goldmountainbeauty.com](http://goldmountainbeauty.com)

- If irritation occurs, discontinue use and consult a doctor

Trim nails and file the surface using an emery board

Apply a thin layer of product over affected areas twice daily (morning and night) especially around free edges of nails (under tips) and cuticles and the space around nails

Allow solution to soak into nail or skin

Application to adjacent nails is recommended to prevent the spread of infection

Keep affected areas clean and dry throughout the day

Supervise children in the use of this product

**Warnings**

**For external use only**

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



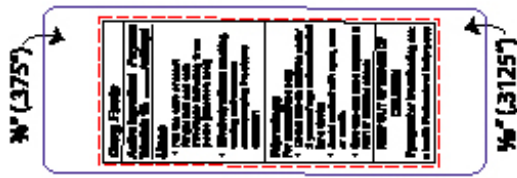


TOP

DELINE  
DOES NOT  
PRINT

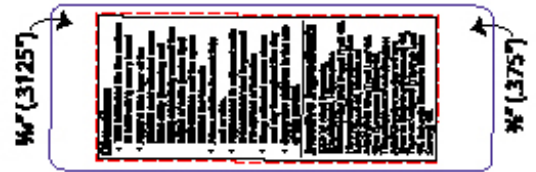


INSIDE TOP



THIS PANEL WILL BE "MIRRORED" ON PLATES.  
"CEBOROIM"

BASE



DEADNER



RELEASE



GOLD MOUNTAIN  
Beauty  
Foot Therapy  
Antifungal  
Fungal Nail Eliminator

## GOLD MOUNTAIN BEAUTY FUNGAL NAIL ELIMINATOR

tolnaftate antifungal oil

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-417
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	0.14 g in 14 g

## Inactive Ingredients

Ingredient Name	Strength
TEA TREE OIL (UNII: VIF565UC2G)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER (25000 MPAS) (UNII: 587WKM3S9Q)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
HIPPOPHAE RHAMNOIDES FRUIT OIL (UNII: TA4JCF9S1J)	
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	
THYME OIL (UNII: 2UK410MY6B)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
WINTER SAVORY OIL (UNII: EP61SM69Z2)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-417-02	1 in 1 BOX	07/02/2018	
1	NDC:76348-417-01	14 g 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	part333C	07/02/2018	

**Labeler** - Renu Laboratories, Inc. (945739449)

## Establishment

Name	Address	ID/FEI	Business Operations
Renu Laboratories Inc.		945739449	manufacture(76348-417)

Revised: 7/2018

Renu Laboratories, Inc.