

**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.

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

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For questions or comments, please visit: goldmountainbeauty.com

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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

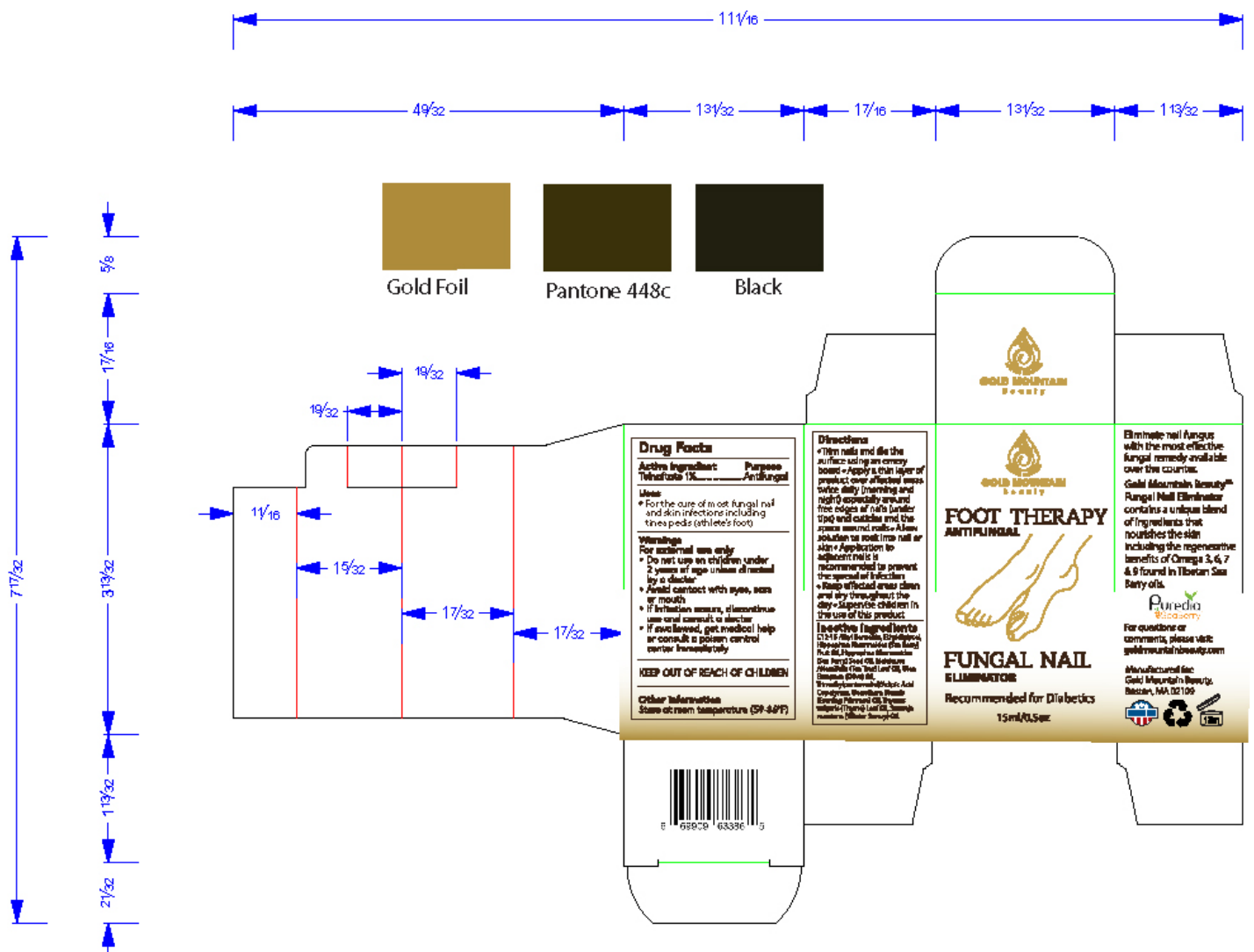
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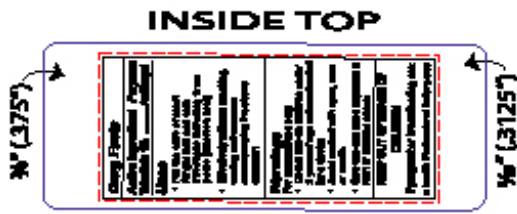
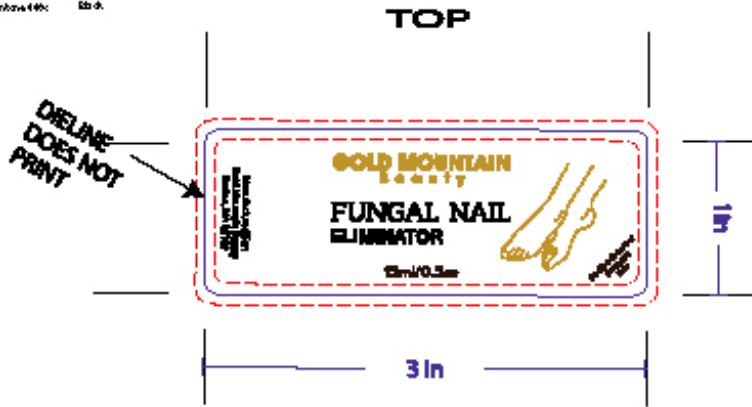
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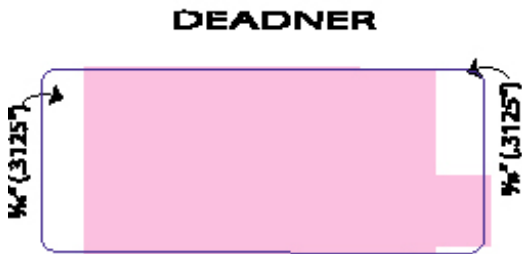
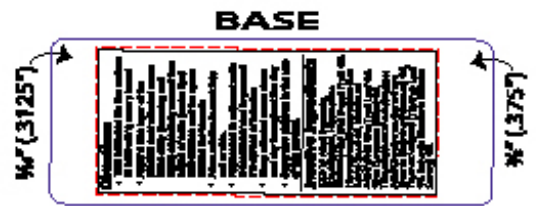
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THIS PANEL WILL BE "MIRRORED" ON PLATES. "CEB00011M"



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
THYME OIL (UNII: 2UK410MY6B)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
WINTER SAVORY OIL (UNII: EP61SM69Z2)	
TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER (25000 MPA.S) (UNII: 587WKM3S9Q)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
HIPPOPHAE RHAMNOIDES FRUIT OIL (UNII: TA4JCF9S1J)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
TEA TREE OIL (UNII: VIF565UC2G)	
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)	

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: 1/2022

Renu Laboratories, Inc.