MOLECULAR AF- tolnaftate 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.

MOLECULAR AF

Active Ingredient

Tolnaftate 1%

Purpose

Antifungal

Stop use and ask a doctor if
- there is no improvement within 4 weeks

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

www.MolecularAF.com

888-919-1818

Stop use and ask a doctor if
- irritation occurs
- there is no improvement within 4 weeks

Molecular AF

Topical Antifungal System

Dynamic Oil

Other information Store at 68º - 77º

(20º - 25º C)

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 the 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

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

CITRIC ACID MONOHYDRATE, DIETHYLENE GLYCOL MONOETHYL ETHER, ETHYL MACADAMIATE

OLIVE OIL, POTASSIUM SORBATE, TEA TREE OIL

Uses proven clinically to cure most:

athlete's foot (tinea pedis)

ringworm (tinea corporis)

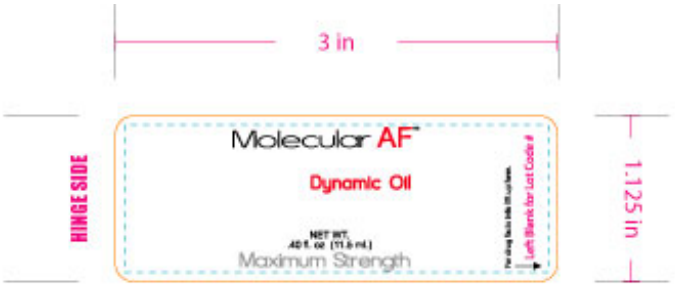
effectively soothes and relieves:

itching

burning

cracking

helps prevent most athlete's foot from coming back with daily use



TOP (FACE)

Please keep all text within the blue dotted line.
Graphics may bleed off the label (1/16" required)

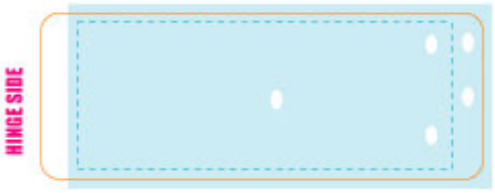
140253-04
BZ 10/HP

FLIPSIDETOP (BACK SIDE OF TOP LABEL/MIRROR IMAGE)

Please keep all text and graphics within the blue dotted line.

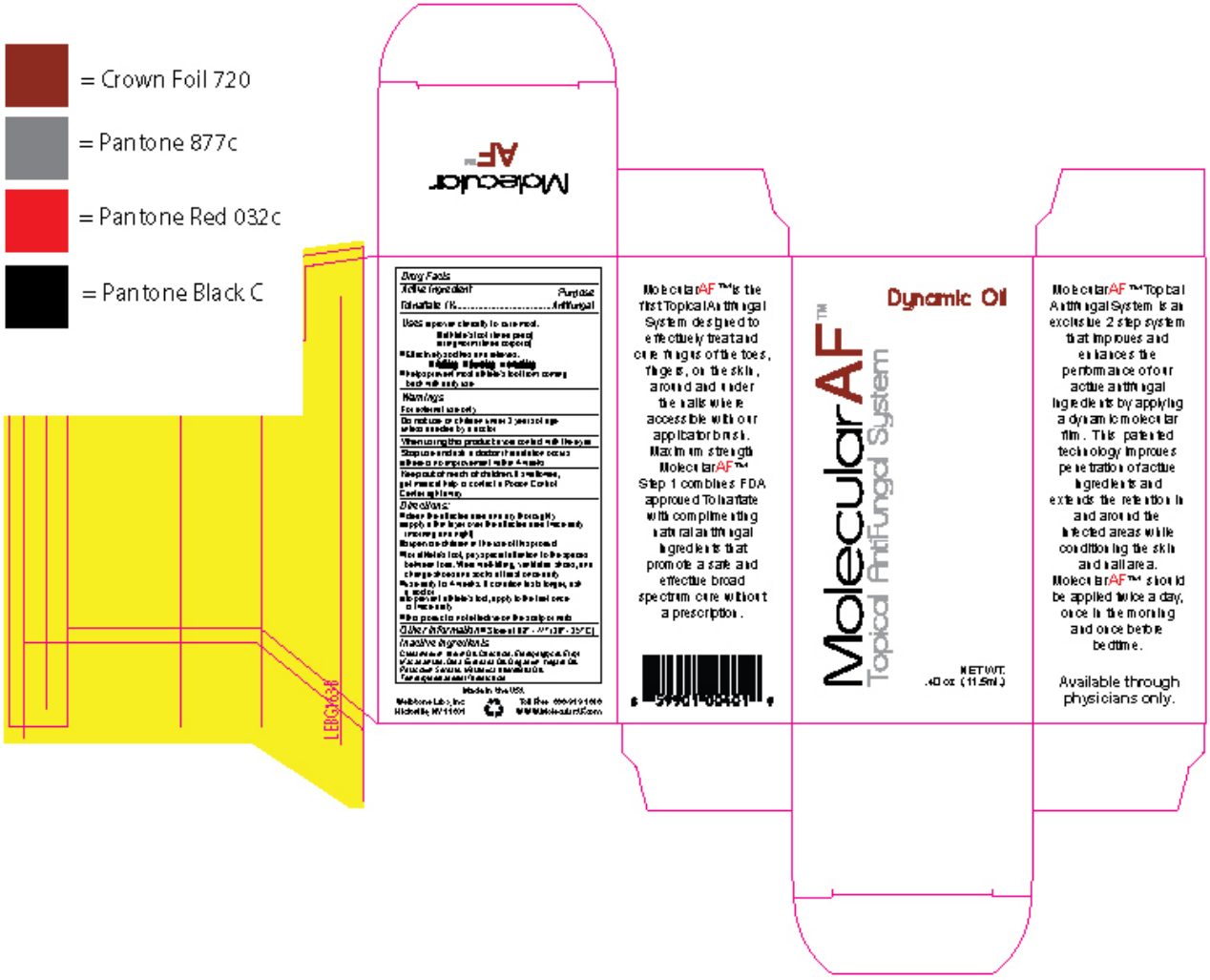
BASE LABEL

Please keep all text and graphics within the blue dotted line.



DEADNER
(.0625" SMALLER THAN RELEASE)

RELEASE



MOLECULAR AF

tolnaftate oil

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76348-401
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	0.01 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CINNAMON OIL (UNII: E5GY4I6YCZ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ETHYL MACADAMIATE (UNII: ANA2NCS6V1)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
TEA TREE OIL (UNII: VIF565UC2G)	
OLIVE OIL (UNII: 6UYK2W1W1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-401-01	11.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2011	
2	NDC:76348-401-02	11.5 mL in 1 BOX; Type 0: Not a Combination Product	07/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M005	07/01/2011	

Labeler - Renu Laboratories, Inc. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
Renu Laboratories, Inc.		945739449	manufacture(76348-401)

Revised: 2/2023 Renu Laboratories, Inc.