MOLECULAR AF MOLECULAR CREAM- molecular af molecular cream 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.

Molecular AF Molecular Cream

Active Ingredient

Miconazole Nitrate 2%

Purpose

Antifungal

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

- irritation occurs
- there is no improvement with 4 weeks

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

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

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

Other Information

• Store at 68° - 77º (20º - 25º C)

Inactive Ingredients

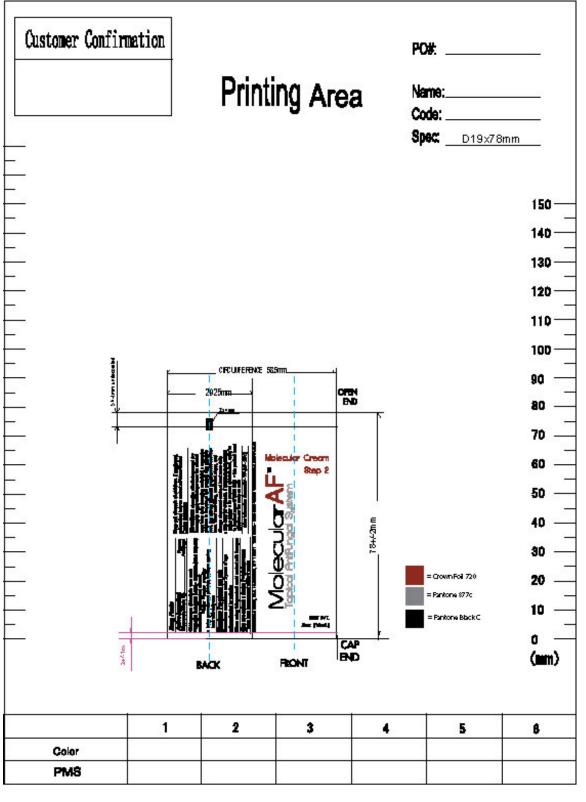
Cetearyl Alcohol, Ceteareth-20, Cinnamonum Verum Oil, Citric Acid, Deionized Water, Emulsifying Wax NF, Ethyl Macadamiate,

Glycerin (Veg.), Melaleuca Alternifolia Oil, Olea Europaea Oil, Origanum Vulgare Oil, Phenoxyethanol, Benzoic Acid,

Dehydroacetic Acid, Propylene Glycol, Trimethylpentanediol / Adipic Acid Copolymer, Vitamin E Acetate, Xanthan Gum

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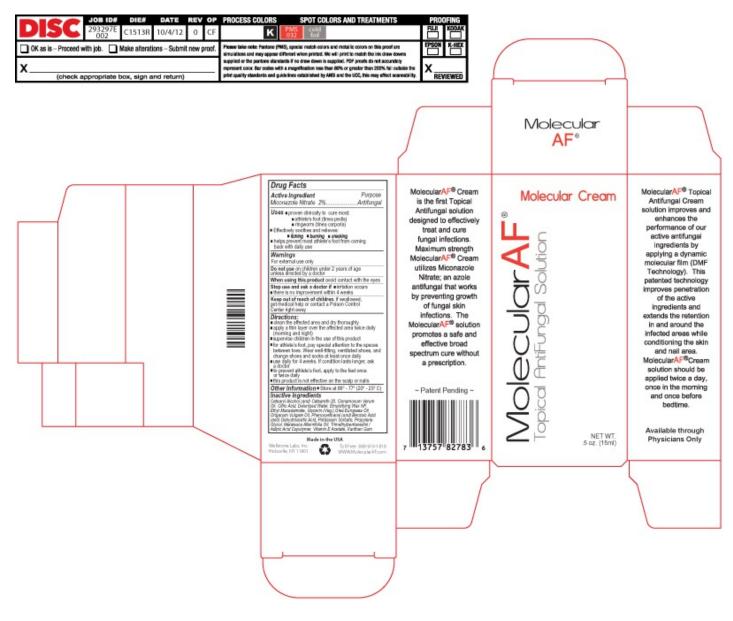


Designer ; Huwei 2011-11-29

Reviewed :

Approval :

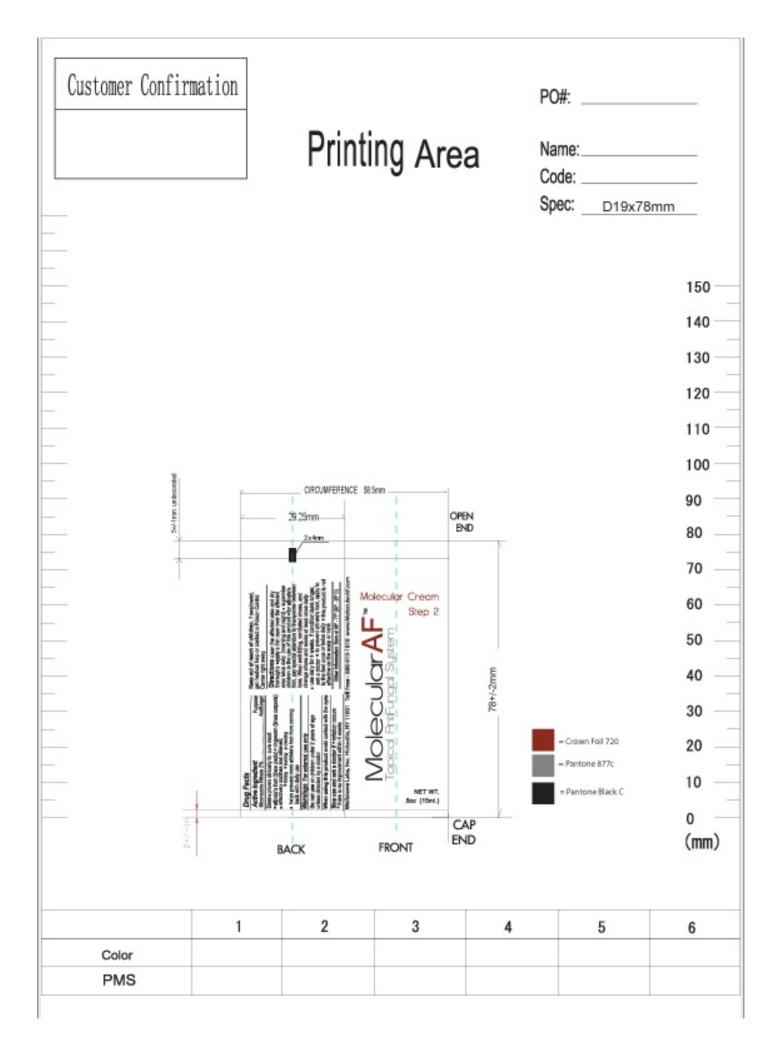
BOX, Principal Display Panel



MOLECULAR AF MOLECULAR CREAM						
molecular af molecular cream	n cream					
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source) ND		NDC:76	C:76348-402	
Route of Administration	TOPICAL					
Active Ingredient/Active	Moiety					
Ingredient Name Basis of Streng				ength	Strength	
Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M) Miconaz			Miconazole Nitra	conazole Nitrate 0.3 g in 14		
Inactive Ingredients						
	Ingredient Name			1	Strength	
Benzoic Acid (UNII: 85KN0B0MIM))					
Water (UNII: 059QF0K00R)						

Xa	Xanthan Gum (UNII: TTV12P4NEE)						
Gly	Glycerin (UNII: PDC6A3C0OX)						
CE	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)						
РО	POLAWAX POLYSORBATE (UNII: Q504PL8E0V)						
TR	TRIMETHYL-1,3-PENTANEDIOL (UNII: WT1X081P0L)						
Те	Tea Tree Oil (UNII: VIF565UC2G)						
Ci	nnamon Oil (UNII	I: E5GY4I6	YCZ)				
Et	hyl Macadamiat	e (UNII: Al	NA2NCS6V1)				
TR	OLAMINE (UNII: 9	903K93S3	TK)				
Ph	enoxyethanol (L	JNII: HIE49	92ZZ3T)				
Or	egano Leaf Oil ((UNII: 7D0	CGR40U1)				
РС	POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)						
Pr	opylene Glycol (UNII: 6DC	9Q167V3)				
οι	Olive Oil (UNII: 6UYK2W1W1E)						
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)							
Product Characteristics							
Color			white (Cream)		Score		
Shape					Size		
Flavor					Imprint Code	print Code	
Co	Contains						
Packaging							
					Marketing Start	Marketing	. End
#	Item Code		Package Description		Date	Date	
1	NDC:76348-402-	1 in 1 BO	X		03/31/2015		
				05/51/2015			

1 NDC:76348-402-01 14 g in 1 TUBE; Type 0: Not a Combination Product



Approval :

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part333C	03/31/2015			
			D		

Labeler - Renu Laboratories, Inc. (945739449)

Establishment						
Name	Address	ID/FEI	Business Operations			
Renu Laboratories, Inc.		945739449	manufacture(76348-402)			

Revised: 1/2022

Renu Laboratories, Inc.