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

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- irritation occurs
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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

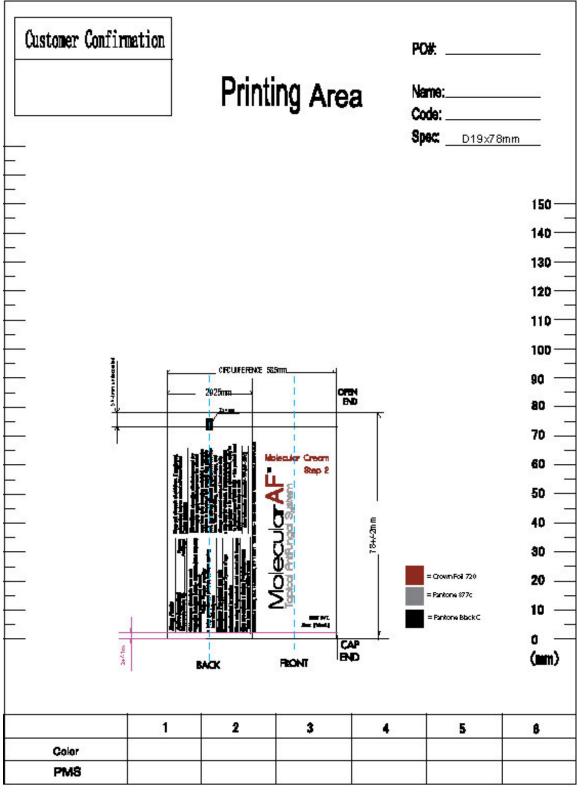
Cetearyl Alcohol, Ceteareth-20, Cinnamonum Verum Oil, Citric Acid, Deionized Water, Emulsifying Wax NF, Ethyl Macadamiate,

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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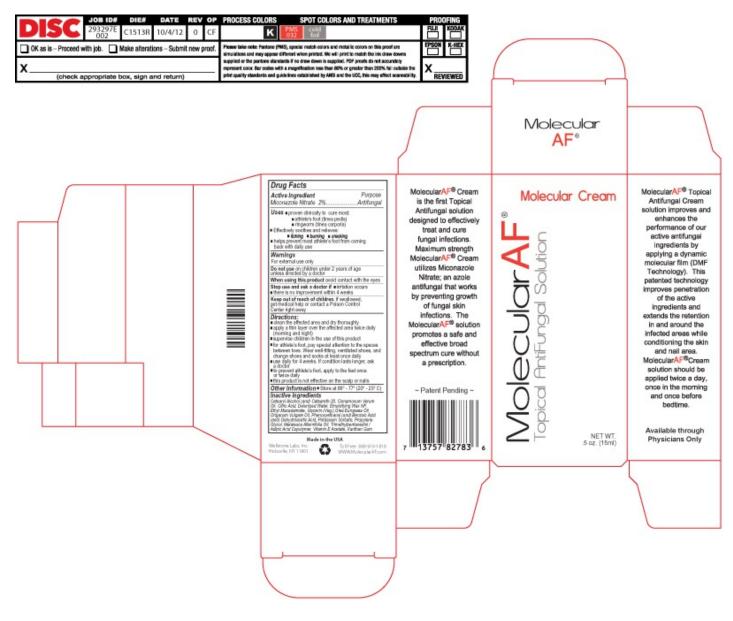


Designer ; Huwei 2011-11-29

Reviewed :

Approval :

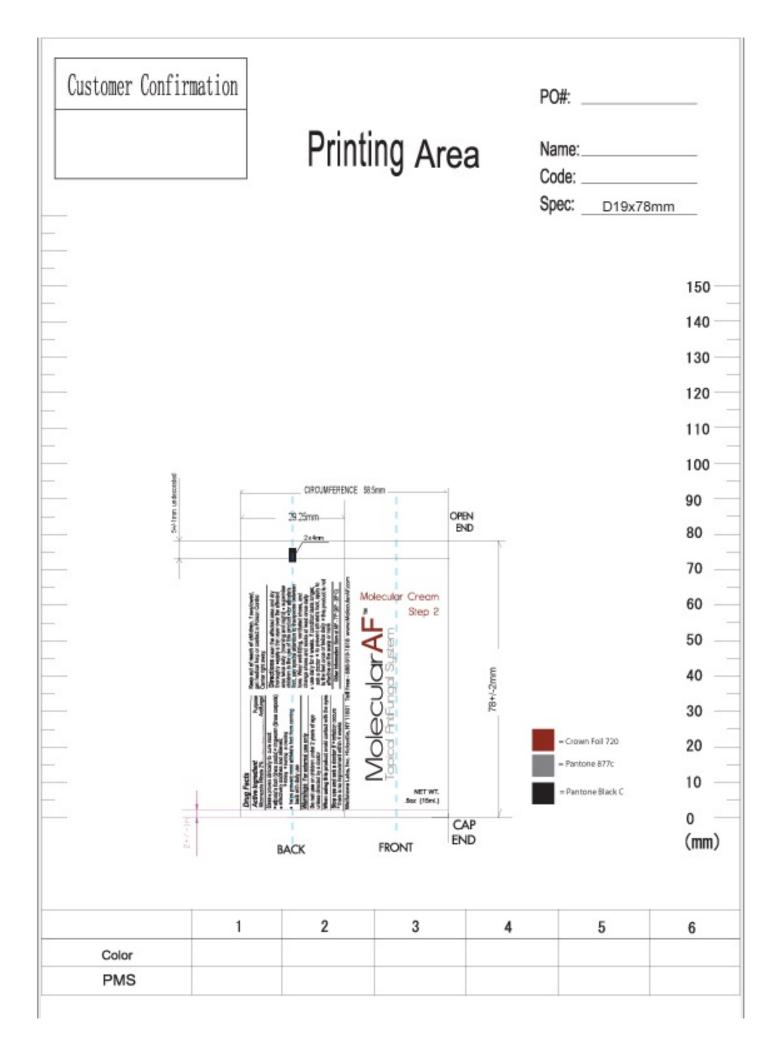
BOX, Principal Display Panel



| 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.