

**MICONAZOLE NITRATE ANTIFUNGAL POWDER- miconazole nitrate antifungal powder powder**  
**Marlex Pharmaceuticals, Inc.**

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**Active ingredient**

Miconazole Nitrate 2%

**Purpose**

Antifungal

**Uses**

- For the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis)
- For the treatment of most superficial skin infections caused by yeast (candida albicans)
- Relieves most itching, scaling, cracking, burning, redness, soreness, irritation, discomfort and chafing associated with jock itch

**Warnings**

- **For external use only**

**Do not use**

- on children under 2 years of age unless directed by a doctor
- avoid contact with the eyes
- for athlete's foot and ringworm- if irritation occurs, or if there is no improvement within 4 weeks, discontinue use and consult a doctor
- for jock itch - if irritation occurs or if there is no improvement within 2 weeks, discontinue use and consult a doctor

**Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control center right away.

**Directions**

- Clean the affected area and dry thoroughly
- Apply a layer of powder over affected area twice a day (morning and night) or as directed by a doctor
- Supervise children in the use of this product

For athlete's foot, pay special attention to spaces between toes; wear well fitting, ventilated shoes, and change shoes and socks at least once daily

- For athlete's foot and ringworm, use daily for 4 weeks
- For jock itch, use daily for 2 weeks
- If condition persists longer, consult a doctor
- This product is not effective on the scalp or nails.

### Other Information

- Protect from freezing. Avoid excessive heat.
- Do not use if package is damaged

### Inactive ingredients

Allantoin, Chloroxylenol, fragrance, Imidazolidinyl Urea, Microcrystalline Cellulose, Tricalcium Phosphate, Corn starch.

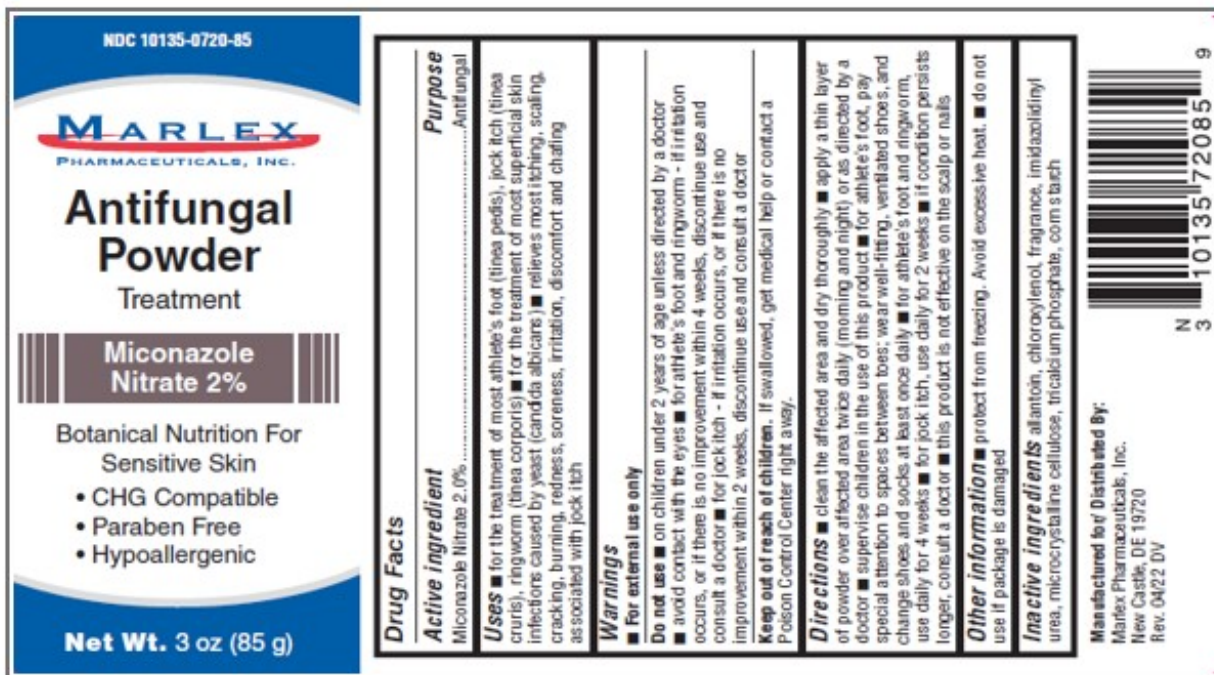
Manufactured For/ Distributed By:

Marlex Pharmaceuticals, Inc.

New Castle, DE 19720

Rev. 04/22 DV

### Principal Display Panel



## MICONAZOLE NITRATE ANTIFUNGAL POWDER

miconazole nitrate antifungal powder powder

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:10135-720 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength  | Strength     |
|--|--------------------|--------------|
| <b>MICONAZOLE NITRATE</b> (UNII: VW4H1CYW1K) (MICONAZOLE - UNII: 7NNO0D7S5M) | MICONAZOLE NITRATE | 2 g in 100 g |

**Inactive Ingredients**

| Ingredient Name                                      | Strength |
|--|----------|
| <b>CHLOROXYLENOL</b> (UNII: 0F32U78V2Q)              |          |
| <b>IMIDUREA</b> (UNII: M629807ATL)                   |          |
| <b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U) |          |
| <b>TRICALCIUM PHOSPHATE</b> (UNII: K4C08XP666)       |          |
| <b>ALLANTOIN</b> (UNII: 344S277G0Z)                  |          |
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)               |          |

**Packaging**

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:10135-720-85 | 85 g in 1 BOTTLE; Type 0: Not a Combination Product | 05/01/2022           |                    |

**Marketing Information**

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M005                                     | 05/01/2022           |                    |

**Labeler** - Marlex Pharmaceuticals, Inc. (782540215)

Revised: 10/2024

Marlex Pharmaceuticals, Inc.