

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

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.

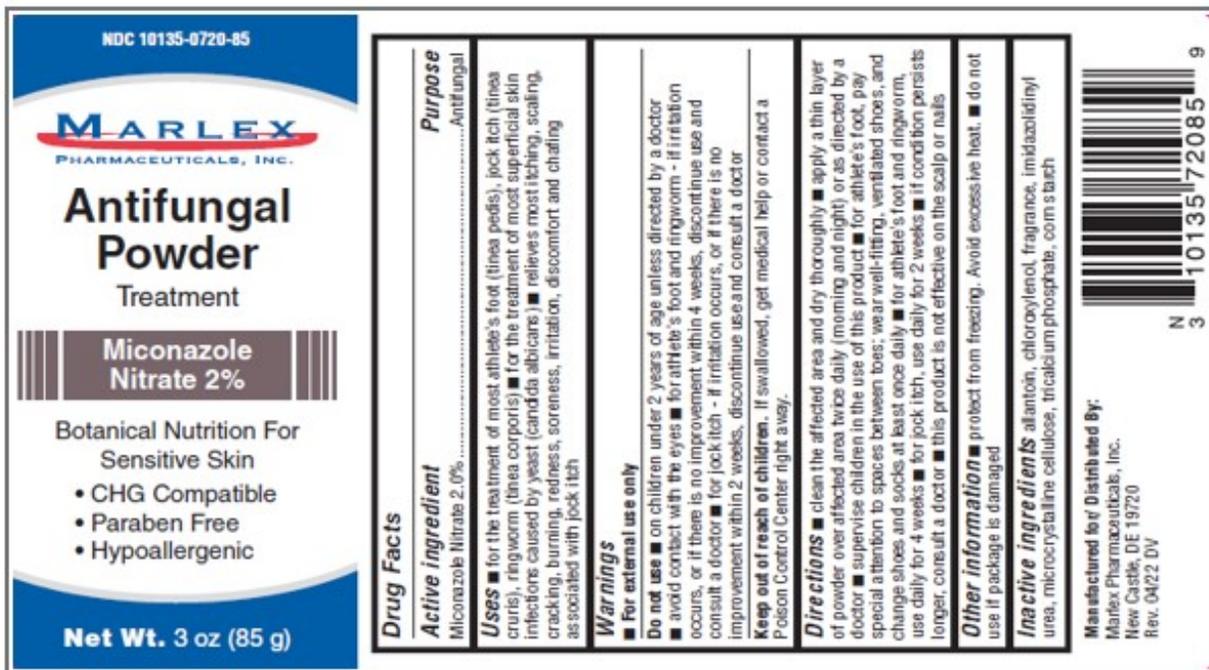
Manufactured For/ Distributed By:

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10135-720
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII: 7NNO0D7S5M)	MICONAZOLE NITRATE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
IMIDUREA (UNII: M629807ATL)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
ALLANTOIN (UNII: 344S277G0Z)	
STARCH, CORN (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: 11/2025

Marlex Pharmaceuticals, Inc.