# 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 power 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.

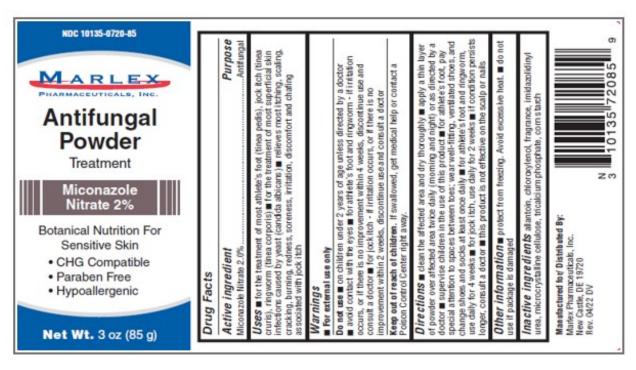
Manufactured For/ Distributed By:

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: 08232NY3SJ)				

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	#	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: 11/2023 Marlex Pharmaceuticals, Inc.