

ANTIFUNGAL- miconazole nitrate powder
Advanced Rx LLC

Active Ingredient

Miconazole Nitrate 2%

Purpose

Antifungal

Uses

- for the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), and 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.

When using this product avoid contact with the eyes.

Stop and ask a doctor if

- for athlete's foot and ringworm - if irritation occurs, or if there is no improvement within 4 weeks
- for jock itch - if irritation occurs, or if there is no improvement within 2 weeks

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 thin layer of powder over affected area twice daily (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 the 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 conditions persist longer, consult a doctor

- this product is not effective on the scalp or nails

Other information

- Store between 20° to 25°C (68° to 77°F)
- Protect from freezing. Avoid excessive heat.
- Do not use if package is damaged.

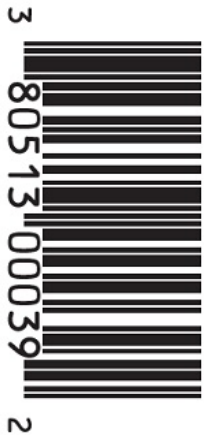
Inactive ingredients

allantoin, chloroxylenol, corn starch, fragrance, imidazolidinyl urea, microcrystalline cellulose, tricalcium phosphate.

Questions?

call toll free 1-800-630-8895

Principal Display Panel



Drug Facts

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PUREGEN LABS

NDC 80513-771-03

TREATMENT
FOR SKIN WITH FUNGAL INFECTION


**ANTIFUNGAL
POWDER**

MICONAZOLE NITRATE 2%

CHG COMPATIBLE

PARABEN FREE

HYPOALLERGENIC



NET WT 3 OZ (85 G)

Distributed by:
ADVANCED RX LLC
1942 NE 163rd St
North Miami Beach, FL
33162 U.S.A

LABOND001W-0

ANTIFUNGAL

miconazole nitrate powder

Product Information

Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:80513-771	
Route of Administration		TOPICAL				
Active Ingredient/Active Moiety						
Ingredient Name				Basis of Strength		Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII: 7NNO0D7S5M)				MICONAZOLE NITRATE		20 mg in 1 g
Inactive Ingredients						
Ingredient Name					Strength	
ALLANTOIN (UNII: 344S277G0Z)						
CHLOROXYLENOL (UNII: 0F32U78V2Q)						
STARCH, CORN (UNII: O8232NY3SJ)						
IMIDUREA (UNII: M629807ATL)						
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)						
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)						
Packaging						
#	Item Code	Package Description		Marketing Start Date		Marketing End Date
1	NDC:80513-771-03	85 g in 1 BOTTLE; Type 0: Not a Combination Product		01/01/2025		
Marketing Information						
Marketing Category		Application Number or Monograph Citation		Marketing Start Date		Marketing End Date
OTC Monograph Drug		M005		01/01/2025		

Labeler - Advanced Rx LLC (042795108)

Registrant - Advanced Rx LLC (042795108)

Establishment			
Name	Address	ID/FEI	Business Operations
Davion, Inc		079536689	manufacture(80513-771)