ANTI- FUNGAL MICONAZOLE NITRATE- miconazole nitrate powder
Premier Brands of America 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.

Premier Solutions MiconazoleAF Powder - Talc Free

Active ingredient

Miconazole nitrate 2%

Purpose

Antifungal

Uses

for the cure of most athlete's foot, jock itch and ringworm

Warnings

For external use only.

Do not use

on children 2 years of age unless directed by a doctor.

When using this product

avoid contact with the eyes.

Stop and ask a doctor if

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

Keep out of reach of children.

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

Directions

- clean the affected area & dry thoroughly
- apply a thin layer of product 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 59º - 86ºF
- lightly shake bottle to loosen settled powder

Inactive ingredient

allantoin, chloroxylenol, fragrance, imidazolidinyl urea, microcrystalline cellulose, tricalicum phosphate, zea mays (corn) starch

Questions?

call 1-866-964-0939

Principal Display Panel

CORE VALUES

Absorbs Moisture

Miconazorb AF

ANTI-FUNGAL POWDER

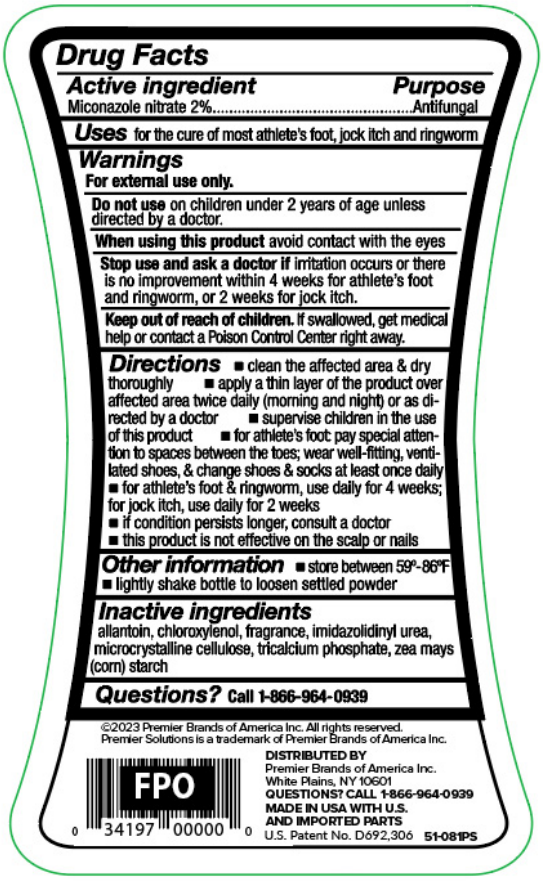
Miconazole Nitrate 2%

Cures Most:
- Athlete's foot
- Jock itch
- Ringworm

Relieves itching, burning, scaling and chafing

Talc-Free

NET WT 2.5 OZ (71 g)



ANTI- FUNGAL MICONAZOLE NITRATE

miconazole nitrate powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:56104-253
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	1.42 g in 71 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALLANTOIN (UNII: 344S277G0Z)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
IMIDUREA (UNII: M629807ATL)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
ZEA MAYS SUBSP. MAYS WHOLE (UNII: 1G5HNE09V8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56104-253-01	71 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/05/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	04/11/2022	

Labeler - Premier Brands of America Inc. (117557458)

Revised: 1/2023

Premier Brands of America Inc.