

**ANTIFUNGAL MICONAZOLE- miconazole nitrate aerosol, spray
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 Antifungal Miconazole Powder Spray

Active ingredient

Miconazole nitrate 2%

Purpose

Antifungal

Uses

- cures most athlete's foot (tinea pedis), ringworm (tinea corporis) and jock itch (tinea cruris)
- relieves symptoms of athlete's foot, including itching, burning and cracking

Warnings

For external use only.

Flammable:

Do not use while smoking or near heat or flame. Do not puncture or incinerate. Contents under pressure. Do not store at temperature above 120°F. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.

When using this product

- avoid contact with the eyes or mouth
- use only as directed

Stop use and ask a doctor if

- irritation occurs
- no improvement within 4 weeks for athlete's foot and ringworm; 2 weeks for jock itch

Do not use

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

Keep out of reach of children

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

Directions

- wash affected area and dry thoroughly
- shake can well and spray a thin layer 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 toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily
- use daily for 4 weeks for athlete's foot and ringworm; use daily for 2 weeks for jock itch; if condition persists, consult a doctor
- this product is not effective on scalp or nails
- if nozzle clogs, clean with a pin

Other information

store between 20 ° and 30 ° C (68 ° and 86 °F)

Inactive ingredients

disteardimonium hectorite, isobutane, kaolin, SD alcohol 40-B, zea mays (corn) starch

Questions

Call 1-866-964-0939

PRINCIPAL DISPLAY PANEL

Athlete's Foot Antifungal Powder Spray

Miconazole Nitrate 2%/

ANTIFUNGAL

Cures Most Athlete's Foot

Relieves Itching, Cracking & Burning

Talc Free

NET WT. 4.6 OZ (130g)

NDC 56104-000-00



POWDER

ATHLETE'S FOOT

ANTIFUNGAL SPRAY

MICONAZOLE NITRATE 2%



CURES MOST ATHLETE'S FOOT

- + Relieves itching, cracking & burning
- + Talc-free

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Drug Facts

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DISTRIBUTED BY:
Premier Brands of America Inc.
White Plains, NY 10601
QUESTIONS? CALL 1-866-964-0939
MADE IN USA WITH U.S. AND IMPORTED PARTS

50-145PS



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ANTIFUNGAL MICONAZOLE

miconazole nitrate aerosol, spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56104-256
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2.6 g in 130 g

Inactive Ingredients

Ingredient Name	Strength
ISOBUTANE (UNII: BXR49TP611)	
ALCOHOL (UNII: 3K9958V90M)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	

ZEA MAYS SUBSP. MAYS WHOLE (UNII: 1G5HNE09V8)

KAOLIN (UNII: 24H4NWX5CO)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56104-256-01	130 g in 1 CANISTER; Type 0: Not a Combination Product	11/02/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	09/29/2021	

Labeler - Premier Brands of America Inc. (117557458)

Revised: 1/2023

Premier Brands of America Inc.