

AZOLEN- miconazole nitrate liquid
STRATUS PHARMACEUTICALS INC

AZOLEN™

Drug Facts

Active Ingredient

Miconazole Nitrate 2%

Purpose

Topical Antifungal

Uses

- For the treatment of most:
 - athlete's foot
 - jock itch
 - ringworm
- Relieves:
 - itching
 - scaling
 - cracking
 - burning
 - redness
 - discomfort

Warnings

for external use only

Do not use

- on children under 2 years of age unless directed by a doctor
- for diaper rash

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

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

Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center immediately

Directions

- Wash the affected area well with **AZOLEN Anti-Fungal Wash** and let product sit 1-2 minutes before rinsing
- Dry the affected area thoroughly
- Apply the product over the 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
- 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 scalp or nails

Other Information

- Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F) [See USP Controlled Room Temperature]

Inactive Ingredients

Lauramidopropyl Betaine, Laureth-7, Panthenol, Phospholipid EFA, Purified Water, Sodium Chloride, Sodium C14-16 Olefin Sulfonate, Tea Tree Oil.

Questions or Comments?

Call us at **1-800-442-7882**

Distributed by:

Stratus Pharmaceuticals Inc.
Miami, FL 33186

PRINCIPAL DISPLAY PANEL - 170 g Bottle Box

NDC 58980-819-60

AZOLEN™

ANTI-FUNGAL WASH

(MICONAZOLE NITRATE 2%)

NOW TREAT
JOCK ITCH IN
THE SHOWER

SOOTHES AND
CONTROLS MOST:*
JOCK ITCH
ATHLETE'S FOOT
RINGWORM

STRATUS
PHARMACEUTICALS INC

Net Wt 6 oz (170 g)

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AZOLEN

miconazole nitrate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58980-819
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII: 7NNO0D7S5M) | **MICONAZOLE NITRATE** 2 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PANTHENOL (UNII: W9CM0067Z)	
TEA TREE OIL (UNII: VIF565UC2G)	
LAURETH-7 (UNII: Z95S6G8201)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
LAURAMIDOPROPYL BETAINE (UNII: 23D6XVI233)	
LINOLEAMIDOPROPYL PROPYLENE GLYCOL-DIMONIUM CHLORIDE PHOSPHATE (UNII: 5Q87K461JO)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58980-819-60	1 in 1 BOX	09/14/2023	
1		170 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	09/14/2023	

Labeler - STRATUS PHARMACEUTICALS INC (789001641)

Establishment

Name	Address	ID/FEI	Business Operations
TARMAC PRODUCTS INC		059890491	MANUFACTURE(58980-819)

Revised: 10/2024

STRATUS PHARMACEUTICALS INC