

**AZOLEN- miconazole nitrate liquid**  
**STRATUS PHARMACEUTICALS 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.*

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**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)

NDC 58980-819-60



ANTI-FUNGAL WASH

(MICONAZOLE NITRATE 2%)

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JOCK ITCH IN  
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SOOTHES AND  
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AZOLEN

miconazole nitrate liquid

Product Information

Table with 4 columns: 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
<b>MICONAZOLE NITRATE</b> (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>PANTHENOL</b> (UNII: W9CM0067Z)	
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	
<b>LAURETH-7</b> (UNII: Z95S6G8201)	
<b>SODIUM C14-16 OLEFIN SULFONATE</b> (UNII: O9W3D3YF5U)	
<b>LAURAMIDOPROPYL BETAINE</b> (UNII: 23D6XVI233)	
<b>LINOLEAMIDOPROPYL PROPYLENE GLYCOL-DIMONIUM CHLORIDE PHOSPHATE</b> (UNII: 5Q87K461JO)	
<b>WATER</b> (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 FINAL	part333C	09/14/2023	

**Labeler** - STRATUS PHARMACEUTICALS INC (789001641)**Establishment**

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

Revised: 9/2023

STRATUS PHARMACEUTICALS INC