AZOLEN- miconazole nitrate tincture
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.

AZOLEN™
TINCTURE

Drug Facts

Active Ingredient

Miconazole Nitrate 2%

Purpose

Topical Antifungal

Uses

- Cures most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- For effective relief of itchy, scaly skin between the toes.

WARNINGS

- For external use only.
- Do not use on children under 2 years of age except under supervision of doctor.
- Avoid contact with eyes.

If irritation occurs or if there is no improvement within four weeks, discontinue use and consult a doctor.

Keep out of the reach of children. If swallowed, get medical help or contact poison control center immediately.

Directions

- Clean and dry the affected area.
- Cover the affected area with a thin layer twice a day (a.m. and p.m.) on skin, under nails and surrounding cuticle areas.
- Supervise children in the use of this product.
- For athlete's foot and ringworm use daily for four (4) weeks.
- This product is not effective on scalp or nails.

Other Information

- Store at 25°C (77°F); excursions permitted to 15°C - 30°C (59° - 86°F). [See USP Controlled Room Temperature]. Protect from freezing. If freezing occurs, warm to room temperature.

Inactive Ingredients

Benzyl Alcohol, Glacial Acetic Acid, Isopropyl Alcohol, Laureth-4, Purified Water and Sodium

Hydroxide Solution.

For more information, see enclosed package insert.

Questions?

1-800-442-7882

Distributed by:
STRATUS PHARMACEUTICALS INC
12379 SW 130th Street
Miami, Florida 33186

PRINCIPAL DISPLAY PANEL - 29.57 mL Bottle Carton

NDC 58980-818-10

AZOLEN™
TINCTURE

(MICONAZOLE NITRATE USP, 2%)

TOPICAL ANTIFUNGAL

Distributed by:
STRATUS

NET VOL.: 1.0 FL OZ (29.57 mL)

NDC 58980-818-10

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NET VOL.: 1.0 FL OZ (29.57 mL)

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NDC 58980-818-10

AZOLEN™

TINCTURE

(MICONAZOLE NITRATE USP, 2%)

TOPICAL ANTIFUNGAL

Distributed by:

STRATUS

NET VOL.: 1.0 FL OZ (29.57 mL)

VC-AT1-2012-340

Drug Facts (continued)

Directions

• Clean and dry the affected area. • Cover the affected area with a thin layer twice a day (a.m. and p.m.) on skin, under nails and surrounding cuticle areas. • Supervise children in the use of this product. • For athlete's foot and ringworm use daily for four (4) weeks. • This product is not effective on scalp or nails.

Other Information • Store at 20ºC to 25ºC (68ºF to 77ºF), excursions permitted between 15ºC and 30ºC (between 59ºF and 86ºF). [See USP Controlled Room Temperature]. Protect from freezing. If freezing occurs, warm to room temperature.

Inactive Ingredients: Benzyl Alcohol, Glacial Acetic Acid, Isopropyl Alcohol, Laureth-4, Purified Water and Sodium Hydroxide Solution.

For more information, see enclosed package insert.

Questions?: 1-800-442-7882

STRATUS PHARMACEUTICALS INC

AZOLEN

miconazole nitrate tincture

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58980-818
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Benzyl Alcohol (UNII: LKG8494WBH)	
Acetic Acid (UNII: Q40Q9N063P)	
Isopropyl Alcohol (UNII: ND2M416302)	
Laureth-4 (UNII: 6HQ855798J)	
Sodium Hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58980-818-10	1 in 1 BOX		
1		29.57 mL in 1 BOTTLE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333C	12/01/2011	

Labeler - Stratus Pharmaceuticals, Inc. (789001641)

Establishment

Name	Address	ID/FEI	Business Operations
Sonar Products Inc		104283945	MANUFACTURE(58980-818)

Revised: 2/2013 Stratus Pharmaceuticals, Inc.