

MICOCILEN- undecylenic acid cream

Arymar 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.

Micocilen

Drug Facts

Active Ingredient

Undecylenic Acid 15%

Purpose

Antifungal

Uses

- proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)

Warnings

- **For external use only**

If pregnant or breast feeding consult a healthcare professional before use

Do not use on children under 2 years of age except under advice and supervision of a doctor

Use only as directed by a doctor on persons with highly sensitive skin

When using this product avoid contact with the eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

Directions

- wash the affected area and dry thoroughly
- apply a thin layer of 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

Other Information

- Keep tightly closed when not in use
- Store away from excessive heat and cold

Inactive ingredients

Purified Water, Cetyl Alcohol, Acrylate/Sodium Acryloyl Dimethyl Taurate Copolymer, Glycerol Monostearate, Caprylic Triglyceride, Polysorbate 20, Phenol, Salicylic Acid, Tea Tree Oil.

Distributed by: Arymar Inc.

8004 NW 154 St. #343 Miami Lakes FL 33016

PRINCIPAL DISPLAY PANEL - 29.5 ml Tube Carton

- *Dries Quickly, Non-Oily Formula*
- *Easy to Apply*

Micocilen

**Antifungal
Cream**

*Cures & Prevents Most Athlete's Foot
Relieves Itching and Burning*

Net Cont. 1 Fl. Oz (29.5 ml)



MICOCILEN
undecylenic acid cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70570-0198
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Undecylenic Acid (UNII: K3D86KJ24N) (Undecylenic Acid - UNII:K3D86KJ24N)	Undecylenic Acid	150 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Tricaprylin (UNII: 6P92858988)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
Phenol (UNII: 339NCG44TV)	
Salicylic Acid (UNII: O414PZ4LPZ)	
Tea Tree Oil (UNII: VIF565UC2G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70570-0198-1	1 in 1 CARTON	02/01/2015	
1		29.5 mL in 1 TUBE; 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	02/01/2015	

Labeler - Arymar Inc. (021650273)

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Arymar Inc.