

**TERRASILMED ANTIFUNGAL- clotrimazole ointment**  
**Aidance Skincare & Topical Solutions, LLC**

*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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**Drug Facts**

<b>Active Ingredients</b>	<b>Purpose</b>
Clotrimazole 1.0%	Antifungal

***Uses***

Treats most fungal skin infections, including ringworm, athlete's foot, jock itch and tinea. For effective relief of itching, scaling, cracking, burning, discoloration, soreness, irritation, discomfort, redness and chafing associated with fungal skin infections.

***Warnings***

**For external use only**

**Do not use** on children under two years of age unless directed by a physician. Avoid contact with the eyes. If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a physician.

**Keep out of reach of children.** If swallowed, consult a physician.

***Directions***

Wash and dry affected skin. Apply a thin layer of product over the affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this product. Store at room temperature. May stain fabrics.

***Inactive ingredients***

Beeswax, MCT (coconut oil), Petrolatum, Silver Stearate, Sorbic Acid

**Questions?**

401-432-7750 or [www.aidance.com](http://www.aidance.com)

**Product label**

NATURAL  
**TerrasilMed™**  
 ANTIFUNGAL OINTMENT

Clotrimazole 1.0%

Net Wt 1.7 oz (50 g)

99.99%  
 FUNGAL KILL\*

CLINICALLY TESTED†

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 \*Based on USP91 study performed using Kirby-Bauer protocol.  
 †Clinically tested refers to the active ingredient.



PN 2776

**TERRASILMED ANTIFUNGAL**

clotrimazole ointment

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:24909-026
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)		CLOTRIMAZOLE	1 g in 100 g

  

Inactive Ingredients	
Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
COCONUT OIL (UNII: Q9L0O73W7L)	
PETROLATUM (UNII: 4T6H12BN9U)	
SILVER STEARATE (UNII: 4H6PCL92ZN)	
SORBIC ACID (UNII: X045WJ989B)	

  

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-026-50	50 g in 1 TUBE; Type 0: Not a Combination Product	05/08/2023	

  

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	05/08/2023	

**Labeler** - Aidance Skincare & Topical Solutions, LLC (018950611)

### Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-026)

Revised: 5/2023

Aidance Skincare & Topical Solutions, LLC