

TERRASIL ANTI-FUNGAL TREATMENT - clotrimazole 1.0% 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.

Drug Facts

Active Ingredient

Clotrimazole 1.0%

Purpose

Antifungal

Uses

- Cures most fungal skin infections, including ringworm 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, call poison control or seek medical help.

Directions

Wash and dry affected skin. Apply a thin layer of Terrasil 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.

Inactive Ingredients

(Organic) Beeswax, Bentonite, Magnesium Oxide, Peppermint Oil, Silver Oxide, Simmondsia Chinensis (Jojoba) Seed Oil, Tea Tree Oil, Zinc Oxide

Drug Facts Active Ingredients Purpose Clotrimazole 1% Antifungal Uses: •Cures most fungal skin infections, including ringworm 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.	 terrasil TM MA _{AX} Anti-Fungal Treatment Fast. Powerful. All-Natural. Net Wt. 44 grams	Directions: Wash and dry affected skin. Apply a thin layer of Terrasil 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. Inactive Ingredients: (organic) beeswax, bentonite, magnesium oxide, peppermint oil, silver oxide, simmondsia chinensis (jojoba) seed oil, tea tree oil, zinc oxide Made in USA. Manufactured by Aidance Skincare. 877-4-AIDANCE www.aidance.com Protected by US and international patents granted and pending. Terrasil TM and Activated Minerals TM are trademarks of Aidance Skincare and Topical Solutions LLC.  Keep out of reach of children. If swallowed, call poison control or seek medical help.
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Place holder text

TERRASIL ANTI-FUNGAL TREATMENT clotrimazole 1.0% ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-107
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1.0 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENTONITE (UNII: A3N5ZCN45C)	
JOJOBA OIL (UNII: 724GKU717M)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SILVER OXIDE (UNII: 897WUN6G6T)	
TEA TREE OIL (UNII: VIF565UC2G)	
WHITE WAX (UNII: 7G1J5DA97F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-107-44	44 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/26/2012	

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

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture, label

Revised: 1/2012

Aidance Skincare & Topical Solutions, LLC