TERRASIL FOOT AND NAIL ANTI-FUNGAL- clotrimazole cream 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%

Purpose

Antifungal

Uses

Cures most athlete's foot and toe area fungal infections. 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 2 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 cream 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

bentonite clay, distilled water, eucalyptus citriodora oil, jojoba seed oil, silver oxide, tea tree oil, zinc oxide.

Questions?401-432-7750 or www.Aidance.com

PRINCIPAL DISPLAY PANEL - 25g Bottle

ALL NATURAL

terrasil

THE END OF SUFFERING SKIN

DRUG FACTS

Active Ingredient: Clotrimazole 1% Purpose: Antifungal Uses: Cures most athlete's foot and toe area fungal infections. 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 2 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 cream 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: bentonite clay, distilled water, eucalyptus citriodora oil, jojoba seed oil, silver oxide, tea tree oil, zinc oxide.

Questions? 401-432-7750 or www.aidance.com.
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CREAM

FDA Registered

NET WT 25g

TERRASIL FOOT AND NAIL ANTI-FUNGAL

clotrimazole cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-125
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)			
EUCALYPTUS OIL (UNII: 2R04ONi662)			
JOJOBA OIL (UNII: 724GKU717M)			
SILVER OXIDE (UNII: 897WUN6G6T)			
TEA TREE OIL (UNII: VIF565UC2G)			

WATER (UNII: 059QF0KO0R)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:24909-125-25	25 g in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	06/26/2014	

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

Establishment			
Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-125), label(24909-125)

Revised: 6/2014

Aidance Skincare & Topical Solutions, LLC