TERRASIL RAPID-CLEAR ANTI-FUNGAL- clotrimazole 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 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

Ointment: 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. May stain fabrics.

Cleansing Bar: Wash affected area daily.

Inactive Ingredients

Ointment: beeswax (organic), bentonite (volcanic clay), jojoba seed oil, magnesium oxide, peppermint oil, silver oxide, tea tree oil, zinc oxide.

Cleansing Bar: beeswax, bentonite clay, coconut oil, glycerin, jojoba seed oil, lauric acid, lavender oil, magnesium oxide, olive oil, palm acid, palm kernel acid, pentasodium pentetate, peppermint oil, propylene glycol, purified water, silver oxide, sodium stearate, sorbitol, shea butter, sodium laureth sulphate (SLES), stearic acid, sodium chloride, sodium palmate, sodium palm kernelate, sorbitol, tea tree oil, titanium dioxide, tetrasodium etidronate, zinc oxide.

PRINCIPAL DISPLAY PANEL - BOX

Anti-Fungal

- Cures Most Fungal and Tinea Infections
- Athlete's Foot, Jock Itch and Ringworm
- Irritation, Burning and Discoloration

All Natural

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RAPID-CLEAR ANTI-FUNGAL OINTMENT

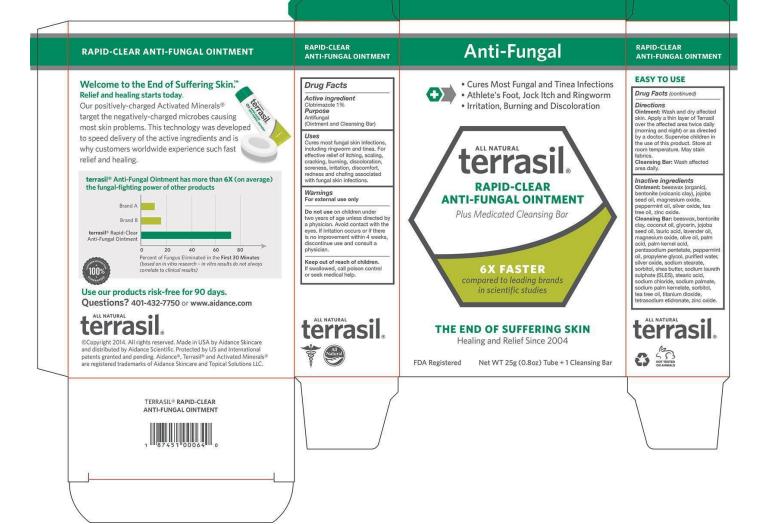
Plus Medicated Cleansing Bar

6X FASTER

compared to leading brands in scientific studies

THE END OF SUFFERING SKIN

Healing and Relief Since 2004



AIDANCE SCIENTIFIC

and speeds healing

Patented system targets infection

TERRASIL RAPID-CLEAR ANTI-FUNGAL

clotrimazole kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:24909-165

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# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:24909-165-25	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	25 g
Part 2	1 CARTON	75 g

Part 1 of 2

TERRASIL RAPID-CLEAR ANTI-FUNGAL

clotrimazole ointment

Product Information

Item Code (Source) NDC:24909-175

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients				
Ingredient Name	Strength			
BENTONITE (UNII: A3N5ZCN45C)				
JOJOBA OIL (UNII: 724GKU717M)				
MAGNESIUM O XIDE (UNII: 3A3U0 GI71G)				
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:24909-175-25	25 g in 1 TUBE		

Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC monograph finalpart333C04/18/2014

Part 2 of 2

TERRASIL ANTI-FUNGAL MEDICATED CLEANSING BAR

clotrimazole soap

Product Information		
Item Code (Source)	NDC:24909-185	
Route of Administration	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
BENTO NITE (UNII: A3N5ZCN45C)	
COCONUT OIL (UNII: Q9L0O73W7L)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
JOJOBA OIL (UNII: 724GKU717M)	
LAURIC ACID (UNII: 1160 N9 NU9 U)	
LAVENDER O IL (UNII: ZBP1YXW0H8)	
MAGNESIUM O XIDE (UNII: 3A3U0 GI71G)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PALM ACID (UNII: B6G0Y5Z616)	
PALM KERNEL ACID (UNII: 79 P21R4317)	
PENTASODIUM PENTETATE (UNII: 961TOZ5L7T)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILVER OXIDE (UNII: 897WUN6G6T)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SHEA BUTTER (UNII: K49 155WL9 Y)	
SODIUM LAURETH SULFATE (UNII: BPV390 UAP0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PALMATE (UNII: S0A6004K3Z)	
SODIUM PALM KERNELATE (UNII: 6 H9 1L1NXTW)	
SORBITOL (UNII: 506T60A25R)	
TEA TREE OIL (UNII: VIF565UC2G)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
ETIDRO NATE TETRASO DIUM (UNII: CZZ9T1T1X4)	
WATER (UNII: 059QF0KO0R)	
WHITE WAX (UNII: 7G1J5DA97F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Pac	kaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 N	DC:24909-185-75	75 g in 1 CARTON		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part333C	04/18/2014				
Marketing Info	Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part333C	04/18/2014				

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

Establishment					
Name	Address	ID/FEI	Business Operations		
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-165), label(24909-165)		

Revised: 4/2014

Aidance Skincare & Topical Solutions, LLC