

TERRASIL SERIOUS FUNGAL TREATMENT- clotrimazole, thuja occidentalis

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.

Terrasil Serious Fungal Treatment

Active Ingredient

Ointment: Clotrimazole 1%

Cleansing Bar: Thuja Occidentalis 6X HPUS

The letters HPUS indicate the component(s) in this product is (are) officially monographed in the Homeopathic Pharmacopeia of the United States.

Purpose

Antifungal

Uses

Ointment: 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.

Cleansing Bar: For relief of most fungal skin infection symptoms.

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.

Directions

Ointment: Wash and dry affected skin. Apply a layer of ointment 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), cotton seed oil, jojoba seed oil, magnesium oxide, peppermint oil, silver oxide, tea tree oil, zinc oxide.

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

PRINCIPAL DISPLAY PANEL

SERIOUS FUNGAL TREATMENT 2 PRODUCT SYSTEM

All Natural

terrasil®

1> Anti-Fungal Ointment

2> Anti-Fungal Cleansing Bar

Cures most Fungal Infections, Athlete's Foot, Jock Itch, Tinea & Ringworm

SERIOUS FUNGAL TREATMENT	SERIOUS FUNGAL TREATMENT	SERIOUS FUNGAL TREATMENT	SERIOUS FUNGAL TREATMENT
<p>Doctor recommended: "Terrasil Anti-Fungal Treatment is very effective against typical tinea by eliminating fungus in less than a week - significantly faster than other topicals." — Dr. Brock Liden, DPM</p> <p>Doctor Brock Liden is a co-medical director at an Ohio hospital wound healing center and is a noted speaker at medical conferences.</p> <p>System Includes Anti-Fungal Ointment & Anti-Fungal Cleansing Bar</p> <p>Fast Acting Itch Relief Calms Inflammation Reduces Redness</p> <p>By using Activated Minerals® and our patented technology we created natural formulations that offer highly effective results and faster healing.</p> <p>6X FASTER terrasil® Anti-Fungal Ointment has more than 6X (on average) the fungal-fighting power of other products. - data on file</p> <p>Brand A: ~15% Brand B: ~15% terrasil® Anti-Fungal Ointment: ~75%</p> <p>Percent of Fungus Eliminated in the First 30 Minutes (results based on in vitro research - in vitro results do not always correlate to clinical results)</p>	<p>Drug Facts</p> <p>Active ingredient Ointment: Clotrimazole 1% Cleansing Bar: Thuja Occidentalis 6X HPUS</p> <p>Purpose Antifungal</p> <p>The letters HPUS indicate the component in this product is officially monographed in the Homeopathic Pharmacopeia of the United States.</p> <p>Uses Ointment: 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. Cleansing Bar: For relief of most fungal skin infection symptoms.</p> <p>Warnings For external use only. Do not use on children under two years of age unless directed by a physician. Avoid contact with eyes. If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a physician.</p> <p>Use our products risk-free for 90 days. 100% MONEY BACK GUARANTEE</p> <p>Questions? 401-432-7750 or www.aidance.com © Copyright 2014. All rights reserved. Made in USA by Aidance Skincare and distributed by Aidance Scientific. Protected by US and International patents granted and pending. Serious Fungal Treatment™, Aidance®, terrasil® and Activated Minerals® are trademarks and registered trademarks of Aidance Skincare and Topical Solutions LLC.</p>	<p>2 PRODUCT SYSTEM</p> <p>ALL NATURAL terrasil®</p> <p>1> Anti-Fungal Ointment 2> Anti-Fungal Cleansing Bar</p> <p>Cures Most Fungal Infections, Athlete's Foot, Jock Itch, Tinea & Ringworm</p> <p>6X FUNGAL FIGHTING POWER</p> <p>Kills Fungus Faster</p> <p>Box Contains Tube Net WT 0.5 OZ (14 g) + Cleansing Bar (75 g)</p> <p>DOCTOR RECOMMENDED</p>	<p>Drug Facts (continued)</p> <p>Directions Ointment: Wash and dry affected skin. Apply a layer of ointment 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.</p> <p>Inactive ingredients Ointment: beeswax (organic), bentonite (volcanic clay), cotton seed oil, jojoba seed oil, magnesium oxide, peppermint oil, silver oxide, tea tree oil, zinc oxide Cleansing Bar: beeswax (organic), bentonite (volcanic clay), coconut oil, glycerin, jojoba oil, lauric acid, lavender oil, magnesium oxide, palm acid, palm kernel acid, pentasodium pentetate, peppermint oil, propylene glycol, shea butter, silver oxide, sodium chloride, sodium citrate, sodium hydroxide, sodium laurate, SLES, SLS, sodium olivate, sodium palm kernelate, sodium palmitate, sodium stearate, sorbitol, stearic acid, tea tree oil, tetrasodium etidronate, titanium dioxide, water, zinc oxide</p> <p>Cleansing Bar is Homeopathic Medicine</p> <p>ALL NATURAL terrasil®</p> <p>NOT TESTED ON ANIMALS</p>

TERRASIL SERIOUS FUNGAL TREATMENT

clotrimazole, thuja occidentalis kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-155
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-155-25	1 in 1 PACKAGE; Type 1: Convenience Kit of Co-Package	01/01/2017	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	14 g
Part 2	1 CARTON	75 g

Part 1 of 2

TERRASIL SERIOUS ANTI-FUNGAL

clotrimazole ointment

Product Information

Item Code (Source)	NDC:24909-156
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
BENTONITE (UNII: A3N5ZCN45C)	
COTTONSEED OIL (UNII: H3E878020N)	
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:24909-156-14	14 g in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/01/2017	

Part 2 of 2

TERRASIL ANTI-FUNGAL CLEANSING BAR

thuja occidentalis soap

Product Information				
Item Code (Source)		NDC:24909-157		
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
THUJA OCCIDENTALIS WHOLE (UNII: 5HBV6WCE3N) (THUJA OCCIDENTALIS WHOLE - UNII:5HBV6WCE3N)		THUJA OCCIDENTALIS WHOLE	6 [hp_X] in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
BENTONITE (UNII: A3N5ZCN45C)				
COCONUT OIL (UNII: Q9L0O73W7L)				
GLYCERIN (UNII: PDC6A3C0OX)				
JOJOBA OIL (UNII: 724GKU717M)				
LAURIC ACID (UNII: 1160N9NU9U)				
LAVENDER OIL (UNII: ZBP1YXW0H8)				
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)				
PALM ACID (UNII: B6G0Y5Z616)				
PALM KERNEL ACID (UNII: 79P21R4317)				
PENTASODIUM PENTETATE (UNII: 961TOZ5L7T)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SHEA BUTTER (UNII: K49155WL9Y)				
SILVER OXIDE (UNII: 897WUN6G6T)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
SODIUM LAURATE (UNII: K146MR5EXO)				
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)				
SODIUM PALM KERNELATE (UNII: 6H91L1NXTW)				
SODIUM PALMATE (UNII: S0A6004K3Z)				
SODIUM STEARATE (UNII: QU7E2XA9TG)				
SORBITOL (UNII: 506T60A25R)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TEA TREE OIL (UNII: VIF565UC2G)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
ETIDRONATE TETRASODIUM (UNII: CZZ9T1T1X4)				
WATER (UNII: 059QF0KO0R)				
WHITE WAX (UNII: 7G1J5DA97F)				
ZINC OXIDE (UNII: SOI2LOH54Z)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-157-75	75 g in 1 CARTON; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/01/2017	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-155) , label(24909-155)

Revised: 1/2019

Aidance Skincare & Topical Solutions, LLC