TERRASIL SERIOUS TINEA 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 Tinea 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: Clears up tinea fungal infections including tinea corporis, tinea crursis, and tinea pedis. For effective relief of itching, scaling, cracking, burning, discoloration, soreness, irritation, discomfort, redness and chafing associated with fungal skin infections.

Cleansing Bar: For most fungal infection.

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. Massage oinment in to affected skin. Reapply up to 4 times daily. 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)*, cedarwood oil, cotton seed oil, jojoba seed oil, magnesium oxide, peppermint oil, sage oil, silver oxide, vegetable stearic acid (naturally sourced), 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 palmate, sodium stearate, sorbitol, stearic acid, tea tree oil, tetrasodium etidronate, titanium dioxide, water, zinc oxide.

PRINCIPAL DISPLAY PANEL

SERIOUS TINEA TREATMENT 2 PRODUCT SYSTEM

All Natural terrasil®

- 1> Anti-Tinea Ointment
- 2> Anti-Fungal Cleansing Bar



TERRASIL SERIOUS TINEA TREATMENT

clotrimazole, thuja occidentalis kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:24909-170

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-170- 25	1 in 1 PACKAGE, COMBINATION; Type 1: Convenience Kit of Co-Package	0 1/0 1/20 17	

Quan	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 TINEA TREATMENT

clotrimazole ointment

Product Information

Item Code (Source) NDC:24909-178

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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	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)

JUNIPERUS VIRGINIANA OIL (UNII: PAD4FN7P2G)

COTTONSEED OIL (UNII: H3E878020N)

JOJOBA OIL (UNII: 724GKU717M)

MAGNESIUM OXIDE (UNII: 3A3U0GI71G)

PEPPERMINT OIL (UNII: AV092KU4JH)

SAGE OIL (UNII: U27K0H1H2O)

SILVER OXIDE (UNII: 897WUN6G6T)

STEARIC ACID (UNII: 4ELV7Z65AP)

WHITE WAX (UNII: 7G1J5DA97F)

ZINC OXIDE (UNII: SOLZOH54Z)

Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:24909-178-14 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	0 1/0 1/20 17		

Part 2 of 2

TERRASIL ANTI-FUNGAL CLEANSING BAR

thuja occidentalis soap

Product Information		
Item Code (Source)	NDC:24909-176	
Route of Administration	TOPICAL	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
THUJA O CCIDENTALIS WHOLE (UNII: 5HBV6 WCE3N) (THUJA OCCIDENTALIS WHOLE - UNII:5HBV6 WCE3N)	THUJA OCCIDENTALIS WHOLE	6 [hp_X] in 1 g		

NTONITE (UNII: A3N5ZCN45C) CONUT OIL (UNII: Q9L0O73W7L) CYCERIN (UNII: PDC6A3C0OX) JOBA OIL (UNII: 724GKU717M) URIC ACID (UNII: 1160N9NU9U) CYCENDER OIL (UNII: ZBPIYXW0HB) ACNESIUM OXIDE (UNII: 3A3U0G171G) LIM ACID (UNII: B6G0 Y5Z616) LIM ACID (UNII: B6G0 Y5Z616) LIM ACID (UNII: PDP21R4317) NTASODIUM PENTETATE (UNII: 961TOZ5L7T) PPERMINT OIL (UNII: AV092KU4JH) OPYLENE GLYCOL (UNII: 6DC9Q167V3) EAB BUTTER (UNII: K49155WL9 Y) LVER OXIDE (UNII: 48915WL9 Y) LVER OXIDE (UNII: 487WUN6G6T) EDIUM CHLORIDE (UNII: 451W47KQ8 X) EDIUM CHRATE (UNII: K46MR5EXO) EDIUM LAURATE (UNII: K146MR5EXO) EDIUM LAURATE (UNII: S99SL044HN) EDIUM PALM KERNELATE (UNII: 6H91L1NXTW) EDIUM PALMATE (UNII: Q07E2XA9TG) ERBITOL (UNII: 906760A25R) EARIC ACID (UNII: 45EV7Z65AP) A TREE OIL (UNII: 41FFX89V2JP) ATER (UNII: 059QF0KOOR)	Strength
JOBA OIL (UNII: 724GKU717M) JURIC ACID (UNII: 1160N9NU9U) JURIC ACID (UNII: 28P1YXW0H8) JURIC ACID (UNII: 28P1YXW0H8) JURIC ACID (UNII: 383U0GI71G) LM ACID (UNII: 86G0Y5Z616) LM ACID (UNII: 86G0Y5Z616) LM KERNEL ACID (UNII: 99P21R4317) NTASODIUM PENTETATE (UNII: 961T0Z5L7T) PPERMINT OIL (UNII: AV092KU4JH) OPYLENE GLYCOL (UNII: 6DC9Q167V3) JURIC AB BUTTER (UNII: 849155WL9Y) LVER OXIDE (UNII: 897WUN6G6T) JURIC CHORIDE (UNII: 451W47IQ8 X) JURIC CHORIDE (UNII: 1273Q2JULR) JURIC CHORIDE (UNII: 55X04QC32I) JURIC LAURATE (UNII: K146MR5EXO) JURIC LAURATE (UNII: 399SL04HN) JURIC LAURATE (UNII: 399SL04HN) JURIC MALMATE (UNII: 50A6004K3Z) JURIC MALMATE (UNII: 506T60A25R) EARIC ACID (UNII: 4ELV7Z65AP) JA TREE OIL (UNII: VIF565UC2G) JURONATE TETRASODIUM (UNII: CZZ9TITIX4) TANIUM DIOXIDE (UNII: 15FIX9V2JP)	
JOBA OIL (UNII: 724GKU717M) JURIC ACID (UNII: 1160 N9 NU9 U) JURIC ACID (UNII: 1160 N9 NU9 U) JURIC ACID (UNII: 3B71YXW0 H8) JURIC ACID (UNII: 3B300 GI71G) LM ACID (UNII: 86G0 Y5Z6 16) LM ACID (UNII: 86G0 Y5Z6 16) LM KERNEL ACID (UNII: 79 P21R4317) NTASODIUM PENTETATE (UNII: 961TOZ5L7T) PPERMINT OIL (UNII: AV092KU4JH) OPYLENE GLYCOL (UNII: 6DC9Q 167V3) JURIC BURTER (UNII: 849 155WL9 Y) LVER OXIDE (UNII: 897WUN6G6T) JURIC CHORIDE (UNII: 451W471Q8 X) JURIC CHORIDE (UNII: 1273Q2JULR) JURIC CHORIDE (UNII: 55X04QC32) JURIC LAURATE (UNII: 8146 MR5EXO) JURIC LAURATE (UNII: 399SL044HN) JURIC MALURETH SULFATE (UNII: 6H91L1NXTW) JURIC MALURETH SULFATE (UNII: 6H91L1NXTW) JURIC MALURET (UNII: 50660 A25R) EARIC ACID (UNII: 4ELV7Z65AP) JA TREE OIL (UNII: VIF565UC2G) JURO NATE TETRASODIUM (UNII: CZZ9T1T1X4) TANIUM DIOXIDE (UNII: 15FIX9 V2JP)	
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• /	
HITE WAX (UNII: 7G1J5DA97F)	

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:24909-176-75	75 g in 1 CARTON; Type 1: Convenience Kit of Co-Packag	e			
Marketing Inf	ormation				
Marketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved homeopat	nic	0 1/0 1/20 17			
Marketing Information					
Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part333C	0 1/0 1/20 17			

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-170), label(24909-170)	

Revised: 1/2019 Aidance Skincare & Topical Solutions, LLC