

## **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.*

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### **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 cruris, 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 ointment 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.



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

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: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	01/01/2017	

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 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 OLEATE (UNII: 399SL044HN)	
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)	
ETIDRONATE TETRASODIUM (UNII: CZZ9T1T1X4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
WHITE WAX (UNII: 7G1J5DA97F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-176-75	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(24909-170) , label(24909-170)