

TERRASIL THE FUNGAL SOLUTION KIT- clotrimazole
Aidance Scientific, Inc, DBA Aidance Skincare & Topical Solutions

Drug Facts

Active Ingredient

Clotrimazole 1%

Purpose

Antifungal

Uses

Ointment: Proven clinically effective in the treatment of athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis). For effective relief of itching, irritation, redness, scaling, cracking, burning, soreness, and discomfort which can accompany these conditions.

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 2 weeks, discontinue use and consult a physician. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Ointment: Wash and dry affected skin. Apply a layer of ointment over affected area twice daily or as directed by a doctor. Supervise children in the use of this product.

Cleansing Bar: Wash affected area daily. For best results use with terrasil® Antifungal ointment products.

Inactive Ingredients

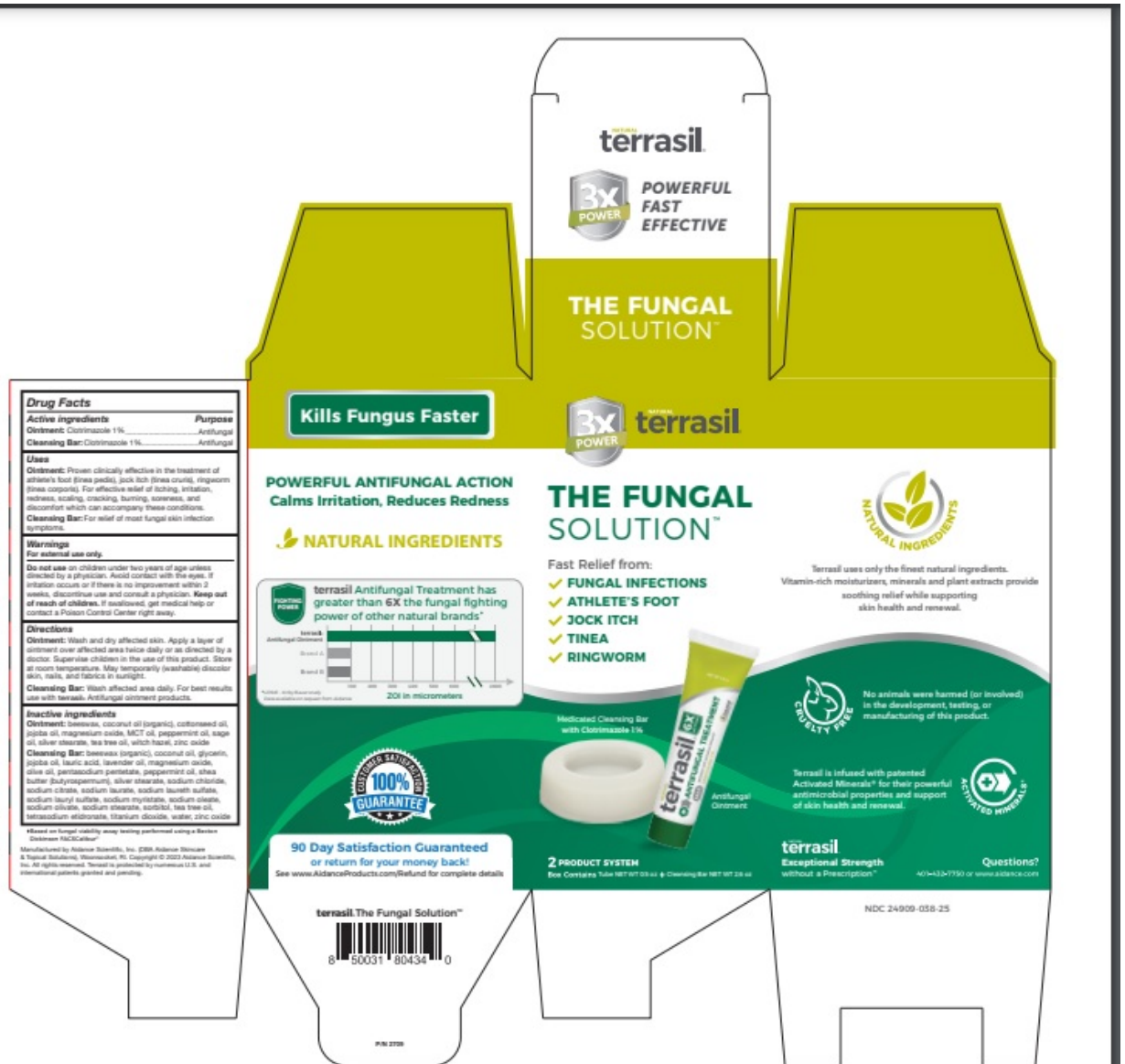
Ointment: beeswax, coconut oil (organic), cottonseed oil, jojoba oil, magnesium oxide, MCT oil, peppermint oil, sage oil, silver stearate, tea tree oil, witch hazel, zinc oxide

Cleansing Bar: beeswax (organic), coconut oil, glycerin, jojoba oil, lauric acid, lavender oil, magnesium oxide, olive oil, pentasodium pentetate, peppermint oil, shea butter (butyrospermum), silver stearate, sodium chloride, sodium citrate, sodium laurate, sodium laureth sulfate, sodium lauryl sulfate, sodium myristate, sodium oleate, sodium olivate, sodium stearate, sorbitol, tea tree oil, tetrasodium etidronate, titanium dioxide, water, zinc oxide

Other information

Store at room temperature. May temporarily (washable) discolor skin and fabrics in sunlight.

Product label



TERRASIL THE FUNGAL SOLUTION KIT

clotrimazole kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-038
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-038-01	1 in 1 KIT	10/02/2023	

Quantity of Parts

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

Part 1 of 2

TERRASIL ANTI-FUNGAL TREATMENT MAX

clotrimazole ointment

Product Information

Item Code (Source)	NDC:24909-106
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
YELLOW WAX (UNII: 2ZA36H0S2V)	
COCONUT OIL (UNII: Q9L0073W7L)	
COTTONSEED OIL (UNII: H3E878020N)	
JOJOBA OIL (UNII: 724GKU717M)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
PALM OIL (UNII: 5QUO05548Z)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SAGE OIL (UNII: U27K0H1H2O)	
SILVER STEARATE (UNII: 4H6PCL92ZN)	
TEA TREE OIL (UNII: VIF565UC2G)	
WITCH HAZEL (UNII: 101I4J0U34)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-106-15	14 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005		

Part 2 of 2

TERRASIL ANTIFUNGAL CLEANSING BAR

clotrimazole soap

Product Information

Item Code (Source)	NDC:24909-037
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
YELLOW WAX (UNII: 2ZA36H0S2V)	
COCONUT OIL (UNII: Q9L0073W7L)	
JOJOBA OIL (UNII: 724GKU717M)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAURIC ACID (UNII: 1160N9NU9U)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PENTASODIUM PENTETATE (UNII: 961TOZ5L7T)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SHEA BUTTER (UNII: K49155WL9Y)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM LAURATE (UNII: K146MR5EXO)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM MYRISTATE (UNII: 06BLC4V0IV)	
SODIUM OLEATE (UNII: 399SL044HN)	
SODIUM OLIVATE (UNII: ND5Y5M6ZUT)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SORBITOL (UNII: 506T60A25R)	
TEA TREE OIL (UNII: VIF565UC2G)	
ETIDRONATE TETRASODIUM (UNII: CZZ9T1T1X4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

ZINC OXIDE (UNII: SOI2LOH54Z)

SILVER STEARATE (UNII: 4H6PCL92ZN)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-037-75	75 g in 1 BOX; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	10/02/2023	

Labeler - Aidance Scientific, Inc, DBA Aidance Skincare & Topical Solutions (018950611)

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Scientific, Inc, DBA Aidance Skincare & Topical Solutions		018950611	manufacture(24909-038, 24909-106, 24909-037)

Revised: 11/2023

Aidance Scientific, Inc, DBA Aidance Skincare & Topical Solutions