

**TERRASIL ITCH, RASH AND PAIN RELIEF MAXIMUM STRENGTH- allantoin,
menthol ointment**

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 Itch, Rash and Pain Relief Maximum Strength

Active Ingredients

Allantoin 0.5%, Menthol 0.15%

Purpose

Allantoin - Skin Protectant

Menthol - Topical Anesthetic

Uses

For temporary relief and protection from pain and itching associated with minor skin irritations, rashes, eczema and/or insect bites.

Warnings

For external use only. Avoid contact with eyes. Do not apply to open wounds or damaged skin. If symptoms persist for more than seven days, discontinue use and consult physician. **If pregnant or breast feeding**, contact physician prior to use.

Keep out of reach of children. If swallowed, consult physician.

Directions

Apply directly to affected area. Do not use more than 4 times per day. Do not bandage damaged skin. Store at room temperature. May stain fabrics.

Inactive Ingredients

beeswax (organic), bentonite (volcanic clay)**, cotton seed oil, eucalyptus citriodora oil, jojoba seed oil, magnesium oxide, peppermint oil, silver oxide, vegetable stearic acid (naturally sourced), zinc oxide.

**may contain this ingredient.

PRINCIPAL DISPLAY PANEL

All Natural

terrasil®

ITCH, RASH & PAIN RELIEF OINTMENT

MAXIMUM STRENGTH

with Activated Minerals®

ALL NATURAL

terrasiil®



NET WT 50 g

  **ITCH, RASH & PAIN
RELIEF OINTMENT**
MAXIMUM STRENGTH

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DRUG FACTS

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***3X Action** Targeted delivery, fast relief, calms irritation.

******may contain this ingredient.

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TERRASIL ITCH, RASH AND PAIN RELIEF MAXIMUM STRENGTH

allantoin, menthol ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-160
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.5 in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENTONITE (UNII: A3N5ZCN45C)	
COTTONSEED OIL (UNII: H3E878020N)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
JOJOBA OIL (UNII: 724GKU717M)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
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:24909-160-50	50 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2017	
2	NDC:24909-160-14	14 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/01/2017	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-160) , label(24909-160)

Revised: 1/2019

Aidance Skincare & Topical Solutions, LLC