

TERRASIL ITCH, RASH AND PAIN RELIEF- 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.

Drug Facts

Active Ingredients

Allantoin 0.5%, Menthol 0.15%

Purpose

Allantoin - Skin Protectant

Menthol - Topical Anesthetic

Uses

For temporary protection and relief of 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 swallowed, consult physician. Do not bandage tightly. **If pregnant or breast feeding,** contact physician prior to use.

Keep out of reach of children.

If swallowed, consult physician.

Directions

Apply directly to effected area. Do not use more than four times per day. Store at room temperature.

Inactive Ingredients

bentonite, cera alba (organic beeswax), cotton seed oil, eucalyptus citriodora oil, magnesium oxide, peppermint oil, silver oxide, simmondsia chinensis (jojoba) seed oil, zinc oxide.

PRINCIPAL DISPLAY PANEL - 44g Label

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ALL NATURAL
terrasil MAX STRENGTH
ITCH, RASH & PAIN RELIEF
FDA Registered Net WT 44 grams

Drug Facts (continued)
Directions: Apply directly to affected area. Do not use more than four times per day. Store at room temperature.

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AIDANCE SCIENTIFIC
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TERRASIL ITCH, RASH AND PAIN RELIEF

allantoin, menthol ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-154
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Allantoin (UNII: 344S277G0Z) (Allantoin - UNII:344S277G0Z)	Allantoin	0.5 g 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)	
WHITE WAX (UNII: 7G1J5DA97F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-154-14	14 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:24909-154-44	44 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/16/2015	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-154) , label(24909-154)