TERRASIL ITCH, RASH AND PAIN RELIEF- allantoin, lidocaine 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%, Lidocaine HCL 0.5%

Purpose

Allantoin - Skin Protectant

Lidocaine HCL - 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 pregnant or breast feeding, contact physician prior to use.

Keep out of reach of children.

If swallowed, consult physician.

Directions

Ointment: Apply directly to affected area. Do not use more than four times per day. Store at room temperature. May stain fabrics.

Cleansing Bar: Wash affected area daily.

Inactive Ingredients

Ointment: beeswax (organic), bentonite (volcanic clay), eucalyptus citriodora oil, jojoba seed oil, magnesium oxide, peppermint oil, silver oxide, zinc oxide.

Cleansing Bar: beeswax, bentonite clay, coconut oil, eucalyptus oil, glycerin, jojoba seed oil, lauric acid, lavender oil, magnesium oxide, olive oil, palm acid, palm kernel acid, pentasodium pentetate, peppermint oil, propylene glycol, purified water, silver oxide, sodium stearate, sorbitol, shea butter, sodium laureth sulphate (SLES), stearic acid, sodium chloride, sodium palmate, sodium palm kernelate, sorbitol, titanium dioxide, tetrasodium etidronate, zinc oxide.

PRINCIPAL DISPLAY PANEL - BOX

Itch, Rash & Pain

- Penetrating Pain and Intense Itching
- Eczema, Dermatitis, Insect Bites
- Rashes and Red Irritated Skin

All Natural

terrasil

ITCH, RASH & PAIN RELIEF OINTMENT

Plus Medicated Cleansing Bar

FAST & EFFECTIVE

itch and pain relief

THE END OF SUFFERING SKIN



TERRASIL ITCH, RASH AND PAIN RELIEF

allantoin, lidocaine kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:24909-163

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	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:24909-163-25	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Quan	Quality of Farts				
Part #	Package Quantity	Total Product Quantity			
Part 1	1 TUBE	25 g			
Part 2	1 CARTON	75 g			

Part 1 of 2

TERRASIL ITCH, RASH AND PAIN RELIEF

allantoin, lidocaine ointment

Product Information

Item Code (Source) NDC:24909-173

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLANTO IN (UNII: 344S277G0 Z) (ALLANTOIN - UNII:344S277G0 Z)	ALLANTOIN	0.5 g in 100 g
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength	
BENTONITE (UNII: A3N5ZCN45C)		
EUCALYPTUS OIL (UNII: 2R04ONI662)		
JOJOBA OIL (UNII: 724GKU717M)		
MAGNESIUM O XIDE (UNII: 3A3U0 GI71G)		
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:24909-173-25	25 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/18/2014	

Part 2 of 2

TERRASIL ITCH, RASH AND PAIN RELIEF MEDICATED CLEANSING BAR

lidocaine soap

Product Information	
Item Code (Source)	NDC:24909-183
Route of Administration	TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98 PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
BENTONITE (UNII: A3N5ZCN45C)			
COCONUT OIL (UNII: Q9L0O73W7L)			
EUCALYPTUS OIL (UNII: 2R04ONI662)			
GLYCERIN (UNII: PDC6A3C0OX)			
JOJOBA OIL (UNII: 724GKU717M)			
LAURIC ACID (UNII: 1160 N9 NU9 U)			
LAVENDER O IL (UNII: ZBP1YXW0H8)			
MAGNESIUM O XIDE (UNII: 3A3U0 GI71G)			
OLIVE OIL (UNII: 6UYK2W1W1E)			
PALM ACID (UNII: B6G0Y5Z616)			
PALM KERNEL ACID (UNII: 79 P21R4317)			
PENTASO DIUM PENTETATE (UNII: 961TOZ5L7T)			
PEPPERMINT OIL (UNII: AV092KU4JH)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SILVER OXIDE (UNII: 897WUN6G6T)			
SODIUM STEARATE (UNII: QU7E2XA9TG)			

SHEA BUTTER (UNII: K49 155WL9 Y)	
SODIUM LAURETH SULFATE (UNII: BPV390 UAP0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PALMATE (UNII: S0A6004K3Z)	
SODIUM PALM KERNELATE (UNII: 6 H9 1L1NXTW)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
ETIDRO NATE TETRASO DIUM (UNII: CZZ9 T1T1X4)	
WATER (UNII: 059QF0KO0R)	
WHITE WAX (UNII: 7G1J5DA97F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Pa	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1		75 g in 1 CARTON				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	04/18/2014			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part347	04/18/2014			

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

Establishment								
Name	Address	ID/FEI	Business Operations					
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-163), label(24909-163)					

Revised: 4/2014

Aidance Skincare & Topical Solutions, LLC