

# TERRASIL ITCH, RASH AND PAIN RELIEF - allantoin, lidocaine 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.*

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**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 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

(Organic) Beeswax, Bentonite, Eucalyptus Citriodora Oil, Magnesium Oxide, Peppermint Oil, Silver Oxide, Simmondsia Chinensis (Jojoba) Seed Oil, Zinc Oxide.

## PRINCIPAL DISPLAY PANEL - 44g Label

<p><b>Drug Facts</b></p> <table border="0"><tr><td>Active Ingredients .....</td><td>Purpose</td></tr><tr><td>Allantoin 0.5% .....</td><td>Skin Protectant</td></tr><tr><td>Lidocaine HCl 0.5% .....</td><td>Topical Anesthetic</td></tr></table> <p><b>Uses:</b> For temporary protection and relief of pain and itching associated with minor skin irritations, rashes, eczema and/or insect bites.</p> <p><b>Warnings:</b> 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. <b>Keep out of reach of children.</b> If swallowed, consult physician. Do not bandage tightly. <b>If pregnant or breast feeding,</b> contact physician prior to use.</p>	Active Ingredients .....	Purpose	Allantoin 0.5% .....	Skin Protectant	Lidocaine HCl 0.5% .....	Topical Anesthetic		<p><b>Drug Facts (continued)</b></p> <p><b>Directions:</b> Apply directly to affected area. Do not use more than four times per day. Store at room temperature.</p> <p><b>Inactive ingredients:</b> (organic) beeswax, bentonite, eucalyptus citriodora oil, magnesium oxide, peppermint oil, silver oxide, simmondsia chinensis (jojoba) seed oil, zinc oxide</p> <p>Made in USA. Manufactured by Aidance Skincare, 877-4-AIDANCE www.aidance.com Protected by US and international patents granted and pending. Terrasil™ and Activated Minerals™ are trademarks of Aidance Skincare and Topical Solutions LLC.</p>	<p>AidanceSkincare.com 0 187451 000048</p> 
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# TERRASIL ITCH, RASH AND PAIN RELIEF

allantoin, lidocaine ointment

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:24909-123
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
Allantoin (UNII: 344S277G0Z) (Allantoin - UNII:344S277G0Z)	Allantoin	0.5 g in 100 g
Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	Lidocaine Hydrochloride	0.5 g in 100 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
BENTONITE (UNII: A3N5ZCN45C)	
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

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:24909-123-14	14 g in 1 JAR		
2	NDC:24909-123-44	44 g in 1 JAR		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part347	09/07/2012	

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

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-123) , label(24909-123)