# TERRASIL COLD SORE TREATMENT MAX- allantoin 1.0%, lidocaine 1.0% 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 Ingredient**

Allantoin 1.0%, Lidocaine 1.0%

#### Purpose

Allantoin - Skin Protectant Lidocaine - Topical Anesthetic

#### Uses

Treats fever blisters and cold sores on the face or lips.
For the temporary relief of pain and itching.
Relieves dryness and softens cold sores and fever blisters.
Softens crusts (scabs) which may be associated with cold sores and fever blisters.

#### Warnings

For external use only. Do not use in or near the eyes. Avoid applying directly inside your mouth. Do not share this product with anyone. This may spread infection. Stop use and ask a doctor if: your cold sore gets worse or the cold sore is not healed within 10 days.

#### Keep out of reach of children.

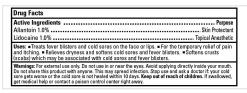
If swallowed, get medical help or contact a poison control center right away.

#### **Directions**

Adults and children 12 years or over: Wash hands before and after applying Terrasil. Apply to affected area on face or lips at the first sign of cold sore/fever blister (tingle). Early treatment ensures the best results. Rub in gently but completely. Use 3-5 times a day until healed. Children under 12 years: ask a doctor. Store at room temperature.

#### **Inactive Ingredients**

(organic) beeswax, bentonite, magnesium oxide, palmarosa oil, peppermint oil, silver oxide, simmondsia chinensis (jojoba) seed oil, zinc oxide





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### TERRASIL COLD SORE TREATMENT MAX

allantoin 1.0%, lidocaine 1.0% ointment

Product Type Howan of C Drog Rem Code (Source) NDC.24909-110	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-110
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Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Allantoin (UNII: 344S277G0Z) (Allantoin - UNII:344S277G0Z)	Alla nto in	1 g in 100 g		
Lidocaine (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)	Lidocaine	1 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
BENTONITE (UNII: A3N5ZCN45C)			
JOJOBA OIL (UNII: 724GKU717M)			
MAGNESIUM O XIDE (UNII: 3A3U0 GI71G)			
PALMAROSA OIL (UNII: 0J3G3O53ST)			
PEPPERMINT OIL (UNII: AV092KU4JH)			
SILVER OXIDE (UNII: 897WUN6G6T)			
WHITE WAX (UNII: 7G1J5DA97F)			
ZINC OXIDE (UNII: SOI2LOH54Z)			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-110-14	14 g in 1 JAR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	0 2/0 1/20 12	

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

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture, label	

Revised: 2/2012 Aidance Skincare & Topical Solutions, LLC