

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.

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

<p>Drug Facts</p> <p>Active Ingredients Purpose Allantoin 1.0% Skin Protectant Lidocaine 1.0% Topical Anesthetic</p> <p>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.</p> <p>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.</p>	 <p>Fast • Powerful • All-Natural</p> <p>Net Wt. 14 grams</p>	<p>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.</p> <p>Inactive Ingredients: (organic) beeswax, bentonite, magnesium oxide, palmarosa oil, 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> 
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allantoin 1.0%, lidocaine 1.0% ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Allantoin (UNII: 344S277G0Z) (Allanto in - UNII:344S277G0Z)	Allanto 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 OXIDE (UNII: 3A3U0GI71G)	
PALMAROSA OIL (UNII: 0J3G3O53ST)	
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:24909-110-14	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	02/01/2012	

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

Establishment

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