

TERRASIL COLD SORE TREATMENT MAX- allantoin, benzalkonium chloride 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%, Benzalkonium Chloride 0.13%

Purpose

Allantoin - Skin Protectant

Benzalkonium Chloride - Cold sore / fever blister treatment; Topical Antiseptic

Uses

- To treat cold sores / fever blisters.
- To help guard against infection.

Warnings

For external use only.

Do not use in the eyes over large areas of the body if you are allergic to any ingredient in this product longer than one week unless directed by doctor

Stop use and ask doctor if condition persists or worsens symptoms persist for more than 7 days.

Ask a doctor if used to treat deep or puncture wounds, animal bites or serious burns you are pregnant or nursing.

When using this product you may feel a brief stinging sensation when you apply it. The stinging should go away in a short time.

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. Do not use more than 3 times a day. Children under 12 years: ask a doctor. Store at room temperature.

Inactive Ingredients

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

PRINCIPAL DISPLAY PANEL - 14g Label

<p>Drug Facts</p> <p>Active Ingredients..... Purpose Allantoin 1%..... Skin Protectant Benzalkonium Chloride 0.13%..... Cold sore / fever blister treatment; Topical Antiseptic</p> <p>Uses: •To treat cold sores / fever blisters. •To help guard against infection.</p> <p>Warnings: For external use only. Do not use in the eyes or over large areas of the body. If you are allergic to any ingredient in this product longer than one week unless directed by doctor. Stop use and ask doctor if condition persists or worsens. Symptoms persist for more than 7 days. Ask a doctor if used to treat deep or puncture wounds, animal bites or serious burns. If you are pregnant or nursing. When using this product you may feel a brief stinging sensation when you apply it. The stinging should go away in a short time. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.</p>		<p>Drug Facts (continued)</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. Do not use more than 3 times a day. Children under 12 years: ask a doctor. Store at room temperature.</p> <p>Inactive ingredients: bentonite, cera alba (organic beeswax), magnesium oxide, palmarosa oil, peppermint oil, silver oxide, simmondsia chinensis (jojoba) seed oil, zinc oxide</p> <p>Other information: The ingredients in toothpaste, soft drinks and fruit juices can deactivate the active ingredient. For best results, avoid using these items for one hour after applying.</p> <p><small>Made in USA. Manufactured by Aidance Skincare, 817 J. 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.</small></p>
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TERRASIL COLD SORE TREATMENT MAX

allantoin, benzalkonium chloride ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:249 09-108
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	1 g in 100 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 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:24909-108-14	14 g in 1 JAR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/07/2012	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-108) , label(24909-108)

Revised: 9/2012

Aidance Skincare & Topical Solutions, LLC