TERRASIL COLD SORE TREATMENT - 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 0.5%, Benzalkonium Chloride 0.1%

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 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

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TERRASIL COLD SORE TREATMENT

allantoin, benzalkonium chloride ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:24909-109
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.5 g in 100 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 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:24909-109-14	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(24909-109) , label(24909-109)

Revised: 9/2012 Aidance Skincare & Topical Solutions, LLC