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.

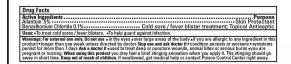
If swallowed, get medical help or contact a poison control center right away.

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





Drug Facts (continued)

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Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:24909-109

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength ALLANTO IN (UNII: 344S277G0Z) (ALLANTO IN - UNII:344S277G0Z) BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - BENZALKONIUM 0.1 g in 100 g UNII:7N6 JUD5X6 Y) CHLO RIDE 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)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:24909-109-14	14 g in 1 JAR		

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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