

TERRASIL WOUND CARE - allantoin 0.5%, benzethonium chloride 0.5% 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%

Benzethonium Chloride 0.5%

Purpose

Allantoin - Skin Protectant

Benzethonium Chloride - Antiseptic

Uses

Temporarily protects minor cuts, scrapes, burns. Helps relieve chapped or cracked skin and lips. Helps protect from the drying effects of wind and cold weather. First aid to help decrease the risk of skin infection.

Warnings

For external use only. When using this product, do not get into eyes. Stop use and ask a doctor if condition worsens, symptoms last more than 7 days or clear up and occur again within a few days. Do not use on deep or puncture wounds, animal bites or serious burns.

Keep out of reach of children.

If swallowed, call poison control or seek medical help.

Directions

Wash and dry affected skin. Apply a thin layer of Terrasil. Cover affected area with a clean bandage. Repeat procedure 2-3 times daily until skin improves. Store at room temperature.

Inactive Ingredients

(Organic) Beeswax, Bentonite, Simmondsia Chinensis (Jojoba) Seed Oil, Magnesium Oxide, Peppermint Oil, Sage Oil, Silver Oxide, Zinc Oxide

Drug Facts Active Ingredients Purpose Allantoin 0.5% Skin Protectant Benzethonium Chloride 0.5% Antiseptic Uses: ■Temporarily protects minor cuts, scrapes, burns. ■ Helps relieve chapped or cracked skin and lips. ■ Helps protect from the drying effects of wind and cold weather. ■ First aid to help decrease the risk of skin infection. Warnings: For external use only. When using this product, do not get into eyes. Stop use and ask a doctor if condition worsens, symptoms last more than 7 days or clear up and occur again within a few days. Do not use on deep or puncture wounds, animal bites or serious burns.	 Wound Care Fast • Soothing • All-Natural with Activated Minerals™ Net Wt. 44 grams	Directions: Wash and dry affected skin. Apply a thin layer of Terrasil. Cover affected area with a clean bandage. Repeat procedure 2-3 times daily until skin improves. Store at room temperature. Inactive Ingredients: (organic) beeswax, bentonite, simmondsia chinensis (jojoba) seed oil, magnesium oxide, peppermint oil, sage oil, tea tree oil, silver oxide, zinc oxide Made in USA. Manufactured by Aidance Skincare. 977-4-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.  Keep out of reach of children. If swallowed, call poison control or seek medical help.
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allantoin 0.5%, benzethonium chloride 0.5% ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-115
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
Benzethonium Chloride (UNII: PH41D05744) (Benzethonium - UNII:1VU15B70BP)	Benzethonium Chloride	0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WHITE WAX (UNII: 7G1J5DA97F)	
BENTONITE (UNII: A3N5ZCN45C)	
JOJOBA OIL (UNII: 724GKU717M)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SAGE OIL (UNII: U27K0H1H2O)	
SILVER OXIDE (UNII: 897WUN6G6T)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-115-44	44 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part347	01/20/2012	

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

Establishment

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

Revised: 1/2012

Aidance Skincare & Topical Solutions, LLC