

TERRASIL SKIN REPAIR MAX- allantoin, benzethonium 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 Ingredients

Allantoin 1%

Benzethonium Chloride 0.2%

Purpose

Allantoin - Skin Protectant

Benzethonium Chloride - Antiseptic

Uses

- Helps protect skin and supports healing of skin lesions, ulcers, sores, blisters, cracked or damaged skin and lips.
- Helps relieve minor skin irritation and itching due to rashes.
- Topical antiseptic 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

bentonite, cedarwood himalayan oil, cera alba (organic beeswax), magnesium oxide, peppermint oil, silver oxide, simmondsia chinensis (jojoba) seed oil, tea tree oil, zinc oxide

PRINCIPAL DISPLAY PANEL - 44g Label

<p>Drug Facts</p> <p>Active Ingredients Purpose Allantoin 1.0% Skin Protectant Benzethonium Chloride 0.2% Antiseptic</p> <p>Uses: •Helps protect skin and supports healing of skin lesions, ulcers, sores, blisters, cracked or damaged skin and lips. •Helps relieve minor skin irritation and itching due to rashes. •Topical antiseptic to help decrease the risk of skin infection.</p> <p>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.</p>		<p>Drug Facts (continued)</p> <p>Keep out of reach of children. If swallowed, call poison control or seek medical help.</p> <p>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.</p> <p>Inactive ingredients: bentonite, cedarwood himalayan oil, cera alba (organic beeswax), magnesium oxide, peppermint oil, silver oxide, simmondsia chinensis (jojoba) seed oil, tea tree oil, zinc oxide</p> <p><small>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.</small></p>
--	---	---

TERRASIL SKIN REPAIR MAX

allantoin, benzethonium chloride ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-132
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
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENTONITE (UNII: A3N5ZCN45C)	
CEDRUS DEODARA WOOD OIL (UNII: 01O086PVD0)	
JOJOBA OIL (UNII: 724GKU717M)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SILVER OXIDE (UNII: 897WUN6G6T)	
TEA TREE OIL (UNII: VIF565UC2G)	
WHITE WAX (UNII: 7G1J5DA97F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-132-14	14 g in 1 JAR		
2	NDC:24909-132-44	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	09/07/2012	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-132) , label(24909-132)

Revised: 9/2012

Aidance Skincare & Topical Solutions, LLC