

## **TERRASILMED INFECTION CONTROL AND PROTECTION-**

**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 0.5%  
Benzethonium Chloride 0.1%

#### **Purpose**

Skin Protectant  
First Aid Antiseptic

#### **Uses**

Helps protect skin and supports healing of minor cuts, scrapes, burns and wounds, including pressure sores, diabetic ulcers and cracked skin. 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, consult a physician.

#### **Directions**

Wash and dry affected skin. Apply a thin layer of product. Cover affected area with a clean bandage. Repeat procedure as directed by healthcare provider or daily until affected area improves. Store at room temperature. May stain fabrics.

#### **Inactive ingredients**

Beeswax, MCT (coconut oil), Petrolatum, Silver Stearate, Sorbic Acid

#### **Questions?**

## Product label

<div><div>TERRASILMED INFECTION CONTROL AND PROTECTION</div><div>allantoin,benzethonium chloride ointment</div></div>			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-025
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ALLANTOIN</b> (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.5 g in 100 g
<b>BENZETHONIUM CHLORIDE</b> (UNII: PH41D05744) (BENZ ETHONIUM - UNII:1VU15B70BP)	BENZ ETHONIUM CHLORIDE	0.1 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>SILVER STEARATE</b> (UNII: 4H6PCL92ZN)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-025-50	50 g in 1 TUBE; Type 0: Not a Combination Product	05/08/2023	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/08/2023	

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

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-025)

Revised: 5/2023

Aidance Skincare &amp; Topical Solutions, LLC