

TERRASILMED BURN CARE- allantoin,menthol 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%
Menthol 0.15%

Purpose

Skin Protectant
Topical Analgesic

Uses

Helps protect skin and provide temporary relief of pain and itching due to minor burns, sunburn, and skin irritations.

Warnings

For external use only

When using this product, do not get into eyes. Do not apply to open wounds or damaged skin. If symptoms persist for more than seven days discontinue use and consult physician.

If pregnant or breastfeeding, contact physician prior to use.

Keep out of reach of children. If swallowed, consult a physician.

Directions

Apply directly to affected area. Do not use more than 4 times per day. Do not bandage damaged skin. Store at room temperature. May stain fabrics.

Inactive ingredients

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

Questions?

401-432-7750 or www.aidance.com

Product label

NATURAL
TerrasilMed™
BURN CARE OINTMENT

Allantoin 0.5% / Menthol 0.15%

Net Wt 1.7 oz (50 g)

97%
 NATURAL

CLINICALLY TESTED†

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 Scientific, Inc. All rights reserved. TerrasilMed™,
 is protected by numerous U.S. and International
 patents granted and pending. Aidance® and
 TerrasilMed™ are a registered trademark and
 trademark of Aidance Scientific, Inc.
 † Clinically tested refers to the active ingredients.



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PN 2778

TERRASILMED BURN CARE

allantoin,menthol ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-027
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
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
COCONUT OIL (UNII: Q9L0073W7L)	
PETROLATUM (UNII: 4T6H12BN9U)	
SILVER STEARATE (UNII: 4H6PCL92ZN)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-027-50	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	part348	05/08/2023	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-027)

Revised: 5/2023

Aidance Skincare & Topical Solutions, LLC