

TERRASIL BACK PAIN CREAM- menthol cream
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

Menthol 4%

Purpose

Topical Analgesic

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with simple back ache.

Warnings

For external use only.

Do not use on wounds or damaged skin and avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Keep out of reach of children.

If swallowed consult a physician.

Directions

Adults and children 12 years of age and older. Apply to affected area not more than 3 to 4 times daily. Children under 12 years of age - consult a physician. May stain fabrics.

Inactive Ingredients

Chamomile oil, cotton seed oil, emulsifying wax, jojoba oil, magnesium oxide, olive oil, purified water, sage oil, shea butter, silver stearate, sorbic acid (preservative), vitamin B oil, zinc oxide.

401-432-7750 or www.aidance.com

Product label



Shown @ 200% for clarity

Drug Facts

Active ingredient and purpose: Menthol 4% (Topical Analgesic). **Uses:** Temporarily relieves minor aches and pains of muscles and joints associated with simple back ache.
Warnings: For external use only. Do not use on wounds or damaged skin and avoid contact with eyes. If contact occurs, rinse thoroughly with water. **Keep out of reach of children.** If swallowed, consult a physician. **Directions:** Adults and children 12 years of age and older. Apply to affected area not more than 3 to 4 times daily. Children under 12 years of age - consult a physician. May stain fabrics. **Inactive ingredients:** Chamomile oil, cotton seed oil, emulsifying wax, jojoba oil, magnesium oxide, olive oil, purified water, sage oil, shea butter, silver stearate, sorbic acid (preservative), vitamin B oil, zinc oxide

terrasil® Back Pain Cream is your all-natural solution for relief with a proven FDA listed active ingredient, natural moisturizers, and our patented **Activated Minerals®**. Together they provide fast, safe and effective pain relief and support healthy skin. ***3X Action - Menthol + Soothing Oils + Activated Minerals®**. 90-day satisfaction guarantee. Made in the USA.
Questions? 401-432-7750 or learn more at www.aidance.com
Manufactured by Aidance Scientific, Inc. (DBA Aidance Skincare & Topical Solutions), Woonsocket, RI. Copyright © 2021 Aidance Scientific, Inc. All rights reserved. Terrasil is protected by numerous U.S. and international patents granted and pending. Aidance®, Terrasil® and Activated Minerals® are registered trademarks of Aidance Scientific, Inc.



TERRASIL BACK PAIN CREAM

menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-199
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL, UNSPECIFIED FORM	4 g in 100 g
Inactive Ingredients			
Ingredient Name			Strength
COTTONSEED OIL (UNII: H3E878020N)			
JOJOBA OIL (UNII: 724GKU717M)			
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)			
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)			
OLIVE OIL (UNII: 6UYK2W1W1E)			
WATER (UNII: 059QF0KO0R)			
SAGE OIL (UNII: U27K0H1H2O)			

SHEA BUTTER (UNII: K49155WL9Y)

ZINC OXIDE (UNII: SOI2LOH54Z)

SORBIC ACID (UNII: X045WJ989B)

SILVER OXIDE (UNII: 897WJN6G6T)

PANTHENOL (UNII: WW9CM0O67Z)

CETYL STEARATE (UNII: 06RI5UQA7L)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-199-01	44 g in 1 JAR; Type 0: Not a Combination Product	07/28/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/28/2021	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Scientific, Inc, DBA Aidance Skincare & Topical Solutions		018950611	manufacture(24909-199) , label(24909-199)

Revised: 8/2021

Aidance Skincare & Topical Solutions, LLC