

TERRASIL FISSURES FORMULA- cocoa butter 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

Cocoa Butter 50%

Purpose

Skin Protectant

Uses

For the temporary relief of local itching and discomfort in the perianal area, associated with anorectal disorders. Temporarily forms a protective coating over inflamed tissues to help prevent drying of tissues. Temporarily protects irritated areas. Temporarily relieves burning.

Warnings

For external and/or intrarectal use only. When using this product do not exceed the recommended daily dosage unless directed by a doctor. **Stop use and ask a doctor if** - bleeding occurs - condition worsens or does not improve within 7 days. **If pregnant or breast-feeding**, ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or call a Poison Control Center right away.

Directions

Adults: If practical, cleanse the affected area before use. Apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement. Regular use provides continual therapy for relief of symptoms. Children under 12 years of age: ask a doctor.

Inactive Ingredients

beeswax (organic), bentonite (volcanic clay), calendula, chamomile, jojoba seed oil, magnesium oxide, peppermint oil, silver oxide, tea tree oil, zinc oxide.

PRINCIPAL DISPLAY PANEL - 14g Label

terrasil with Activated Minerals

Fissures Formula

Coats. Soothes. Protects.

Drug Facts	
Active Ingredients:	Purpose:
Cocoa Butter Ointment	Skin Protectant
<small>Uses: For the temporary relief of local itching and discomfort in the perianal area, associated with anorectal disorders. Temporarily protects irritated areas and relieves burning.</small>	
<small>Warnings: For external and/or intrarectal use only. When using this product do not exceed the recommended daily dosage unless directed by a doctor. Stop use and ask a doctor if: bleeding occurs - condition worsens or does not improve within 7 days. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, call poison control or seek medical help.</small>	



Drug Facts (continued)
<small>Directions: Adults: If fissured, cleanse the affected area before use. Apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement. Repeat use provides continued therapy in relief of symptoms. Children under 12 years of age: Ask a doctor. Store at room temperature. See other cautions.</small>
<small>Inactive ingredients: beeswax (organic), bentonite (volcanic clay), calendula, chamomile, jojoba seed oil, magnesium oxide, peppermint oil, silver oxide, tea tree oil, zinc oxide.</small>
<small>Questions? Call 422-7750 or www.aidance.com. Manufactured by Aidance Skincare. Copyright © 2014 Aidance Scientific, LLC. All rights reserved. TERRASIL is protected by numerous US and international patents granted and pending. Aidance™, Terrasil™ and Activated Minerals™ are trademarks of Aidance Skincare & Topical Solutions, LLC.</small>



TERRASIL FISSURES FORMULA

cocoa butter ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-118
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COCOA BUTTER (UNII: 512OYT1CRR) (COCOA BUTTER - UNII:512OYT1CRR)	COCOA BUTTER	50 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENTONITE (UNII: A3N5ZCN45C)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CHAMOMILE (UNII: FGL3685T2X)	
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:24909-118-14	14 g in 1 JAR		
2	NDC:24909-118-44	44 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	06/10/2014	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-118) , label(24909-118)

Revised: 6/2014

Aidance Skincare & Topical Solutions, LLC