

## TERRASIL FLEX PAIN RELIEF AND MUSCLE RUB- 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.*

### Terrasil FLEX Pain Relief & Muscle Rub

**Active ingredient and purpose:** Menthol 4% (Topical Analgesic)

#### Uses

Temporarily relieves minor aches and pains of muscles and joints associated with simple backaches, arthritis, strains and bruises.

#### Warnings

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

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

#### Directions

Adults & 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.

#### Inactive Ingredients

Purified water, emulsifying wax, shea butter, cotton seed oil, sorbic acid (preservative), chamomile oil, jojoba oil, sage oil, vitamin B oil, olive oil, vegetable stearic acid (naturally sourced), magnesium oxide, silver oxide, zinc oxide

### PRINCIPAL DISPLAY PANEL

Natural  
terrasil® FLEX  
PAIN RELIEF & MUSCLE RUB CREAM  
For Arthritis, Sore Muscles, Joint & Back Pain



**TERRASIL FLEX PAIN RELIEF AND MUSCLE RUB**  
menthol cream

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:24909-191	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	4 g in 100 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
WATER (UNII: 059QF0KO0R)				
CETYL STEARATE (UNII: 06RI5UQA7L)				
SHEA BUTTER (UNII: K49155WL9Y)				
COTTONSEED OIL (UNII: H3E878020N)				
SORBIC ACID (UNII: X045WJ989B)				
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)				
JOJOBA OIL (UNII: 724GKU717M)				
SAGE OIL (UNII: U27K0H1H2O)				
PANTHENOL (UNII: WV9CM0O67Z)				
OLIVE OIL (UNII: 6UYK2W1W1E)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)				
SILVER OXIDE (UNII: 897WUN6G6T)				
ZINC OXIDE (UNII: SOI2LOH54Z)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:24909-191-44	44 g in 1 JAR; Type 0: Not a Combination Product	08/06/2019	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part348	08/06/2019		

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

### Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-191) , label(24909-191)