

TERRASIL FLEX -PAIN RELIEF AND MUSCLE RUB MAX- 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.

Terrasil FLEX MAX Pain Relief & Muscle Rub

Active ingredient and purpose: Menthol 8% (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

Cotton seed oil, beeswax, sorbic acid (preservative), arnica oil, chamomile oil, jojoba seed oil, sage oil, olive oil, vegetable stearic acid (naturally sourced), magnesium oxide, silver oxide, zinc oxide

PRINCIPAL DISPLAY PANEL

Natural

terrasil® FLEX MAX

PAIN RELIEF & MUSCLE RUB OINTMENT

For Arthritis, Sore Muscles, Joint & Back Pain



TERRASIL FLEX -PAIN RELIEF AND MUSCLE RUB MAX

menthol ointment

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:24909-192

Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	8 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
COTTONSEED OIL (UNII: H3E878020N)				
WHITE WAX (UNII: 7G1J5DA97F)				
SORBIC ACID (UNII: X045WJ989B)				
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)				
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)				
JOJOBA OIL (UNII: 724GKU717M)				
SAGE OIL (UNII: U27K0H1H2O)				
OLIVE OIL (UNII: 6UYK2W1W1E)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)				
SILVER OXIDE (UNII: 897WUN6G6T)				
ZINC OXIDE (UNII: SOI2LOH54Z)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-192-44	44 g in 1 JAR; Type 0: Not a Combination Product	08/06/2019	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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(24909-192) , label(24909-192)