

TOPICAL ANALGESIC- dermaline 3 in 1 roll on emulsion
Dermaline USA Corp

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.

Dermaline 3 in1 Roll On

Methyl Salicylate 15%

Topical Analgesic

Uses: For temporary relief of minor aches and pains of muscles and joints, such as simple backache, lumbago, arthritis, neuralgia, strains, bruises, and sprains

Warning: External use only. Keep out of reach of children. Avoid direct contact with eyes. In case of eye contact, flush thoroughly with water. Discontinue use if irritation occurs.

Do not use on wounds or damaged skin, with a bandage, with heating pad, over extensive areas of the body, on children under 16 years of age unless directed by a doctor. If pregnant or breast-feeding ask a health professional before use. In case of accidental ingestion, get medical help or contact a Poison Control center immediately.

Directions: Adult and children 16 years and older. Wash affected area with mild soap and warm water and rinse thoroughly. Apply a small amount of Dermaline Arnica Ointment to the affected area 1 to 3 times daily.

Camphor, Capsicum Extract, Carbomer, Deionized Water, DMDM hydantoin, Eucalyptus Oil, Isopropyl Alcohol, Menthol, Polysorbate 20, Propyleneglycol, Tocopherol Acetate, Triethanolamine, Tea Tree Oil

Store at room temperature. 15 - 30 degrees C (59-86 degrees F). Avoid excessive heat & humidity

Keep out of reach of children

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82165-107
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TRIETHANOLAMINE MYRISTATE (UNII: 68B0CQC306)	
TEA TREE OIL (UNII: VIF565UC2G)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
WATER (UNII: 059QF0KO0R)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
MENTHOL (UNII: L7T10EIP3A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CAPSICUM OLEORESIN (UNII: UW86K581WY)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82165-107-03	85.05 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	04/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/15/2022	

Labeler - Dermaline USA Corp (016069241)