TOPICAL ANALGESIC- dermaline arnica 3 in 1 ointment
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 Arnica 3 in 1

Active Ingredient(s)

Methyl Salicylate 15% . Purpose: Topical Analgesic

Purpose

Topical Analgesic

Use

For temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.

Warnings

For external use only. Avoid Contact with the eyes. Do not bandage tightly or apply to wounds or damaged costs.

Do not use

- On children under 16 years of age except on the advice of the physician.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case accidental ingestion, get medical help or contact a Poision Control Center right away.

Directions

Adults and children 16 years of age and older: Wash the affected area with mild soap and warm water and rinse thoroughly. Apply to affected area not more than 3 to 4 times daily.

Do not bandage tightly or apply to wounds or damaged skin. Children under 16 years of age; consult a doctor.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat

Inactive ingredients

Arnica, camphor, eucalyptus oil, D&C brown #486. Menthol, Mineral Oil, Paraffin Wax, Propylparaben, Tea Tree Oil, White Petrolatum

condition worsens, or if symptoms persist for more than 7 days or clear up and occur again with a few days.

Package Label - Principal Display Panel

2.5oz

TOPICAL ANALGESIC

dermaline arnica 3 in 1 ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82165-101
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 mg in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
WATER (UNII: 059QF0KO0R)	

ARNICA MONTANA (UNII: O80TY208ZW)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
MENTHOL (UNII: L7T10EIP3A)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
TEA TREE OIL (UNII: VIF565UC2G)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82165-101-02	70 g in 1 JAR; Type 0: Not a Combination Product	05/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/15/2021	

Labeler - Dermaline USA Corp (016069241)

Revised: 2/2023 Dermaline USA Corp