TOPICAL ANALGESIC- dermaline arnica salve black 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 Salve Black

Active Ingredient(s)

Methyl Salicylate 5% Purpose: Topical Analgesic

Purpose

Topical Analgesic, Ointment

Use

For temporary relief 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 skin.

Do not use

Do not Use on children under 16 years of age except on the advice of a physician.

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.

Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children. In case accedental ingestion, get medical help or contact a Poison Control Center right away.

Directions

Apply to affected area not more than 3 to 4 times daily.

Other information

- Store at controlled room temperature 15-30C (59-86F)
- Do not expose to excessive heat

Inactive ingredients

Arnica, Camphor, D&C Brown #486, Menthol, Mineral Oil, Paraffin Wax, Propylparaben, White Petrolatum.

Package Label - Principal Display Panel

2.5oz

TOPICAL ANALGESIC

dermaline arnica salve black ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82165-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID -	METHYL SALICYLATE	5 mg in 100 g

UNII:O414PZ4LPZ)	METHYL SALICYLATE	5 mg in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
PARAFFIN (UNII: I9O0E3H2ZE)	
ARNICA MONTANA (UNII: O80TY208ZW)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
MENTHOL (UNII: L7T10EIP3A)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics			
Color	black	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:82165-102-02	70 g in 1 JAR; Type 0: Not a Combination Product	05/30/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/30/2021	

Labeler - Dermaline USA Corp (016069241)

Revised: 3/2023 Dermaline USA Corp