FLANAX- methyl salicylate, menthol, capsaicin liniment Belmora LLC

FLANAX® LINIMENT

Drug Facts

Active Ingredients

Methyl Salicylate 28% Menthol 10% Capsaicin 0.003%

Purpose

Topical Analgesic

Uses:

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

Warnings:

For external use only. Do not use if you are allergic to any of the active or inactive ingredients. Do not use: on wounds damaged, broken, or irritated skin. With a heating pad. Immediately before or after taking a bath or shower. Stop use and ask a doctor if: Condition worsens. Symptoms persist for more than 7 days or clear up and occur again within a few days. Skin irritation occurs. When using this product, do not: heat, microwave, add to hot water or any container with heating water. May cause splattering and result in burns. Avoid contact with lips, eyes, nose, and any mucous membranes at all times. Do not bandage.

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

Directions:

Adults and children 12 years of age and older: Apply to affected area not more than 3-4 times daily. A temporary burning may be felt when applied, but usually disappears with continued use. Wash hands thoroughly after use to avoid spreading liniment to the eyes or other sensitive areas of the body. If applying liniment to the hands wait 30 minutes before washing hands. Initial pain relief is usually noted within 1-2 weeks. If condition does not improve in 4 weeks discontinue use of this product. Children under 12 years of age: consult doctor before use.

Other Information:

Store at room temperature 20° to 25°C (68° to 77°F).

Inactive Ingredients:

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Boswellia Serrata Gum Extract, Cetearyl Alcohol, Ethyl Alcohol, Ethylhexylglycerin, Gaultheria Procumbens (Wintergreen) Leaf Extract, Glycerin, Glyceryl Stearate, Isopropyl Palmitate, PEG-100 Stearate, Phenoxyethanol, Polysorbate 60, Propylene Glycol, Salix Alba (Willow) Bark Extract, Stearyl Alcohol, Triethanolamine, Water

Analgesic, Anesthetic and Anti-inflammatory Muscular Liniment Triple Action Pain Relief

Questions/Comments:

Distributed by Belmora LLC 3033 Wilson Blvd. Suite 700 Arlington, VA 22201 1-888-779-2877

WWW.FLANAXUSA.COM

Packaging







Guestlons/Comments: Preguntas/Comentarios? Distributed by Belmas LLC

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Olva Información: Guárdelo a una temperatura de 20° a 25°C (68° a 77°F).

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Datos Sobre el Medicamento

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THE FLANAX HAMENTO

DRUG FACTS LABEL

Drug Facts

Active Ingredients **Purpose** Methyl Salicylate 28%......Topical Analgesic Menthol 10%......Topical Analgesic Capsalcin 0.003%......Topical Analgesic

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FLANAX

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27854-499	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: 0414PZ 4LPZ)	METHYL SALICYLATE	28 g in 100 g		
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 g in 100 g		
CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM)	CAPSAICIN	0.003 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S AT 0.5%) (UNII: YY2HMJ9NZF)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ALCOHOL (UNII: 3K9958V90M)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GAULTHERIA PROCUMBENS LEAF (UNII: 2125M16OWN)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
PEG-100 MONOSTEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TROLAMINE (UNII: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:27854-499- 01	1 in 1 CARTON	08/01/2024		
1		28.35 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information				
Marketing	Application Number or Monograph Citation	Marketing Start	Marketing End	
Category		Date	Date	

Labeler - Belmora LLC (112753244)

Revised: 8/2024 Belmora LLC