METHYL SALICYLATE 40 PERCENT- methyl salicylate cream Alexso, Inc

Methyl Salicylate 40 Percent Cream

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Drug Facts

Active ingredient

Methyl Salicylate 40%

Purpose

Topical analgesic

Uses

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

Warnings

For external use only.

When using this product

- Avoid contact with the eyes
- Do not use in large quantities, particularly over raw surfaces or blistered areas
- Do not apply to wounds or damaged skin
- Do not bandage

Stop use and ask a doctor if

- allergic reaction occurs
- condition worsens or does not improve within 7 days
- symptoms clear up and return within a few days
- redness, irritation, swelling, pain or other symptoms begin or increase

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

Adults and children 2 years and older: apply externally to the affected area up to 3 to 4 times a day

Children under 2 years of age: consult a doctor

Other information

- May be applied under occlusive dressing.
- Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). See USP Controlled Room Temperature.

Inactive ingredients

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Cetearyl Alcohol, Chondroitin Sulfate, Ethylhexylglycerin, Glucosamine Sulfate, Glycerin, Glyceryl Stearate, C13-14 Isoparaffin, Isostearyl Palmitate, Laureth-7, Methylsulfonylmethane (MSM), PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Polysorbate-20, Propylene Glycol, Sodium Polyacrylate, Stearic Acid, Triethanolamine

Methyl Salicylate 40% Cream

NDC: 50488-6040-6

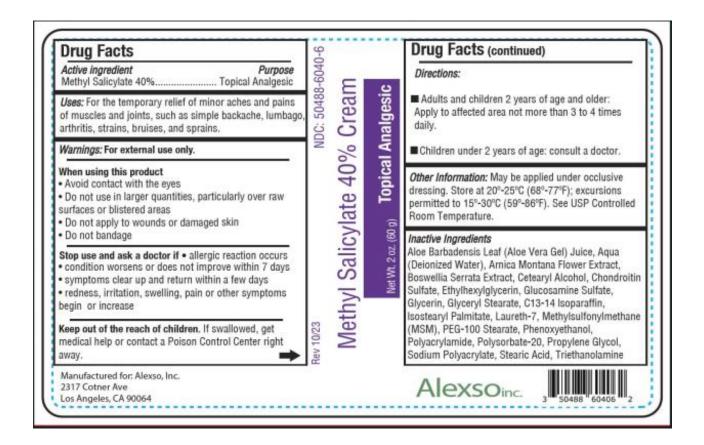
60 gram

Manufactured for: Alexso, Inc 2317 Cotner Ave Los Angeles, CA 90064

PRINCIPAL DISPLAY PANEL

NDC 50488-6040-6 Methyl Salicylate 40% Cream Net Wt. 2 oz. 60 g

Rev 10/23



METHYL SALICYLATE 40 PERCENT

methyl salicylate cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50488-6040	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety Ingredient Name METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: 0414PZ4LPZ) Basis of Strength METHYL SALICYLATE 400 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
WATER (UNII: 059QF0KO0R)		
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)		
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)		
GLYCERIN (UNII: PDC6A3C0OX)		
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)		
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)		

ISOSTEARYL PALMITATE (UNII: 9EHU0R7ER1)	
LAURETH-7 (UNII: Z95S6G8201)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 903K93S3TK)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50488- 6040-6	60 g in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2023		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	10/01/2023		

Labeler - Alexso, Inc (963338061)

Revised: 10/2023 Alexso, Inc