

METHYL SALICYLATE 25 PERCENT- methyl salicylate cream
Alexso, Inc

Methyl Salicylate 25_Percent Pump Cream

Methyl Salicylate 25% Pump Bottle Cream

Drug Facts

Active ingredient

Methyl Salicylate 25%

Purpose

Topical analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints, such as simple backache, lumbago, arthritis, neuralgia, 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 | apply externally to the affected area up

years and older	to 3 to 4 times a day
children under 2 years	ask 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

Aqua (Deionized Water), Arnica Montana Flower Extract, Indian Frankincense, Chondroitin Sulfate, Ethylhexylglycerin, Glucosamine Sulfate, Glycerin, Glyceryl Monostearate, Cetostearyl Alcohol, Aloe Vera Leaf, C13-14 Isoparaffin, Isostearyl Palmitate, Trolamine, Laureth-7, PEG-100 Stearate, Phenoxyethanol, Propylene Glycol, Stearic Acid.

Methyl Salicylate 25% Pump Bottle Cream

NDC: 50488-1016-5

50 mL



Manufactured for:
Alexso, Inc
Los Angeles, CA 90064

Tel: 888.495.6078

PRINCIPAL DISPLAY PANEL

NDC 50488-1016-5
Methyl Salicylate 25% Pump Bottle Cream
50 mL

Rev 05/24

Drug Facts		Rev 05/24 Methyl Salicylate 25% Pump Bottle Cream NDC: 50488-1016-5 50 mL	Drug Facts (continued)	
Active Ingredient Methyl Salicylate 25%.....	Purpose Topical Analgesic		Directions	
Uses: For the temporary relief of minor aches and pains of muscles and joints, such as simple backache, lumbago, arthritis, neuralgia, strains, bruises, and sprains.			adults and children 2 years and older	apply externally to the affected area up to 3 to 4 times a day
Warnings: For external use only.			children under 2 years	ask a doctor
When using this product <ul style="list-style-type: none"> • Avoid contact with the eyes • Do not use in larger quantities, particularly over raw surfaces or blistered areas • Do not apply to wounds or damaged skin • Do not bandage 		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.		
Stop use and ask a doctor if <ul style="list-style-type: none"> • 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 		Inactive ingredients Aqua (Deionized Water), Arnica Montana Flower Extract, Indian Frankincense, Chondroitin Sulfate, Ethylhexylglycerin, Glucosamine Sulfate, Glycerin, Glycerol Monostearate, Cetostearyl Alcohol, Aloe Vera Leaf, C13-14 Isoparaffin, Isostearyl Palmitate, Trolamine, Laureth-7, PEG-100 Stearate, Phenoxyethanol, Propylene Glycol, Stearic Acid.		
Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		 		
Manufactured for: Alexso, Inc. Los Angeles, CA 90064		Tel: 888.495.6078		

METHYL SALICYLATE 25 PERCENT

methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50488-1016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	250 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
ISOSTEARYL PALMITATE (UNII: 9EHU0R7ER1)	
TROLAMINE (UNII: 9O3K93S3TK)	

LAURETH-7 (UNII: Z95S6G8201)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50488-1016-5	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	05/01/2024	

Labeler - Alexso, Inc (963338061)

Revised: 5/2024

Alexso, Inc