

METHYL SALICYLATE- methyl salicylate cream

Alexso, Inc

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.

Methyl Salicylate Cream

Methyl Salicylate 25% Cream

Alexso, Inc

Methyl Salicylate 25% 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 years and older	apply externally to the affected area up 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, 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, Propylene Glycol, Sodium Polyacrylate, Stearic Acid, Triethanolamine

Methyl Salicylate 25% Cream

NDC: 50488-1015-5

50 grams**Methyl Salicylate 25% Cream**

NDC: 50488-1015-1

120 grams

Manufactured for:
Alexso, Inc
Los Angeles, CA 90064

PRINCIPAL DISPLAY PANEL

NDC 50488-1015-1
Methyl Salicylate 25% Cream
120 grams

NDC: 50488-1015-1

Methyl Salicylate 25% Cream

120 grams

Manufactured for: Alexco, Inc.
2317 Cotner Avenue Los Angeles, CA 90064
Tel: 888.495.6078

Drug Facts

Active ingredient Purpose
Methyl Salicylate 25%Topical analgesic

Uses

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Drug Facts (continued)

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

ask a doctor

Other Information

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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, Propylene Glycol, Sodium Polyacrylate, Stearic Acid, Triethanolamine.



Principal Display Panel

NDC 50488-1015-5
Methyl Salicylate 25% Cream
50 grams

Drug Facts		Rev 06/21 Methyl Salicylate 25% Cream 50 gram NDC: 50488-1015-5	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		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.		
<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 		Inactive ingredients		
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		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, Methylsulfonylethane (MSM), PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Propylene Glycol, Sodium Polyacrylate, Stearic Acid, Triethanolamine.		
Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		 Alexso inc. 3 50488 10155 4		
Manufactured for: Alexso, Inc. Los Angeles, CA 90064				

METHYL SALICYLATE

methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50488-1015
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 g

Inactive Ingredients

Ingredient Name	Strength
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: 230OU9XXE4)	

C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
ISOSTEARYL PALMITATE (UNII: 9EHU0R7ER1)
LAURETH-7 (UNII: Z95S6G8201)
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)
PEG-100 STEARATE (UNII: YD01N1999R)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
STEARIC ACID (UNII: 4ELV7Z65AP)
TROLAMINE (UNII: 9O3K93S3TK)
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50488-1015-1	120 g in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2019	
2	NDC:50488-1015-5	50 g in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/01/2019	

Labeler - Alexso, Inc (963338061)