#### METHYL SALICYLATE- methyl salicylate cream Preferred Pharmaceuticals 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.

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Methyl Salicylate Cream Methyl Salicylate 25% Cream Alexso, Inc

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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**

<del>_</del>	apply externally to the affected area up to 3 to 4
older	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: 68788-7925-1

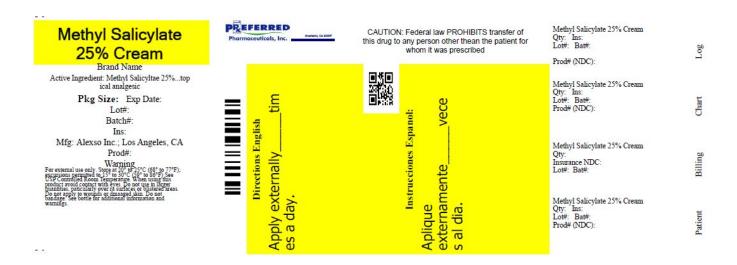
#### 120 grams

Manufactured for: Alexso, Inc Los Angeles, CA 90064

#### PRINCIPAL DISPLAY PANEL

NDC 68788-7925-1 Methyl Salicylate 25% Cream 120 grams

Relabeled By: Preferred Pharmaceuticals Inc.



## **METHYL SALICYLATE**

methyl salicylate cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-7925(NDC:50488-1015)	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	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: 2300U9XXE4)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
ISOSTEARYL PALMITATE (UNII: 9EHU0R7ER1)	
<b>LAURETH-7</b> (UNII: Z95S6G8201)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 903K93S3TK)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	

# SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L) POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)

P	Packaging			
# Item Code Package Description		Marketing Start Date	Marketing End Date	
1	NDC:68788- 7925-1	120 g in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/13/2021	
	part546	08/13/2021	

# Labeler - Preferred Pharmaceuticals Inc. (791119022)

# **Registrant - Preferred Pharmaceuticals Inc. (791119022)**

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-7925)	

Revised: 8/2023 Preferred Pharmaceuticals Inc.