

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.

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: 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 25% Cream

Brand Name

Active Ingredient: Methyl Salicylate 25%...topical analgesic

Pkg Size: Exp Date:

Lot#:

Batch#:

Ins:

Mfg: Alexso Inc., Los Angeles, CA

Prod#:

Warning

For external use only. Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F). See USP Controlled Room Temperature. When using this product avoid contact with 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. See bottle for additional information and warnings.



CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed

Methyl Salicylate 25% Cream

Qty: Ins:
Lot#: Bat#:

Prod# (NDC):

Methyl Salicylate 25% Cream

Qty: Ins:

Lot#: Bat#:

Prod# (NDC):

Methyl Salicylate 25% Cream

Qty: Ins:

Insurance NDC:

Lot#: Bat#:

Methyl Salicylate 25% Cream

Qty: Ins:

Lot#: Bat#:

Prod# (NDC):

Log

Chart

Billing

Patient



Directions English

Apply externally _____ times a day.



Instrucciones Espanol:

Aplique externamente _____ veces al dia.

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	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: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	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment

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

Revised: 8/2023

Preferred Pharmaceuticals Inc.