METHYL SALICYLATE 25%- methyl salicylate cream
Oncora Pharma, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Uses

For the temporary relief of minor aches and pains of muscles and joints, associated with simpled backache, arthritis, strains, bruises and sprains.

For external use only.

When using this product
- Avoid contact with the eyes
- Do not bandage tightly

Stop use and ask a doctor if
- rash or irritation develops and lasts
- condition worsens
- if symptoms persist more than 7 days or clear up and occur again in a few days.

Keep out of reach of children

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

If pregnant or breast-feeding, ask a health professional before use.

Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.

Children under 2 years of age, consult a doctor.

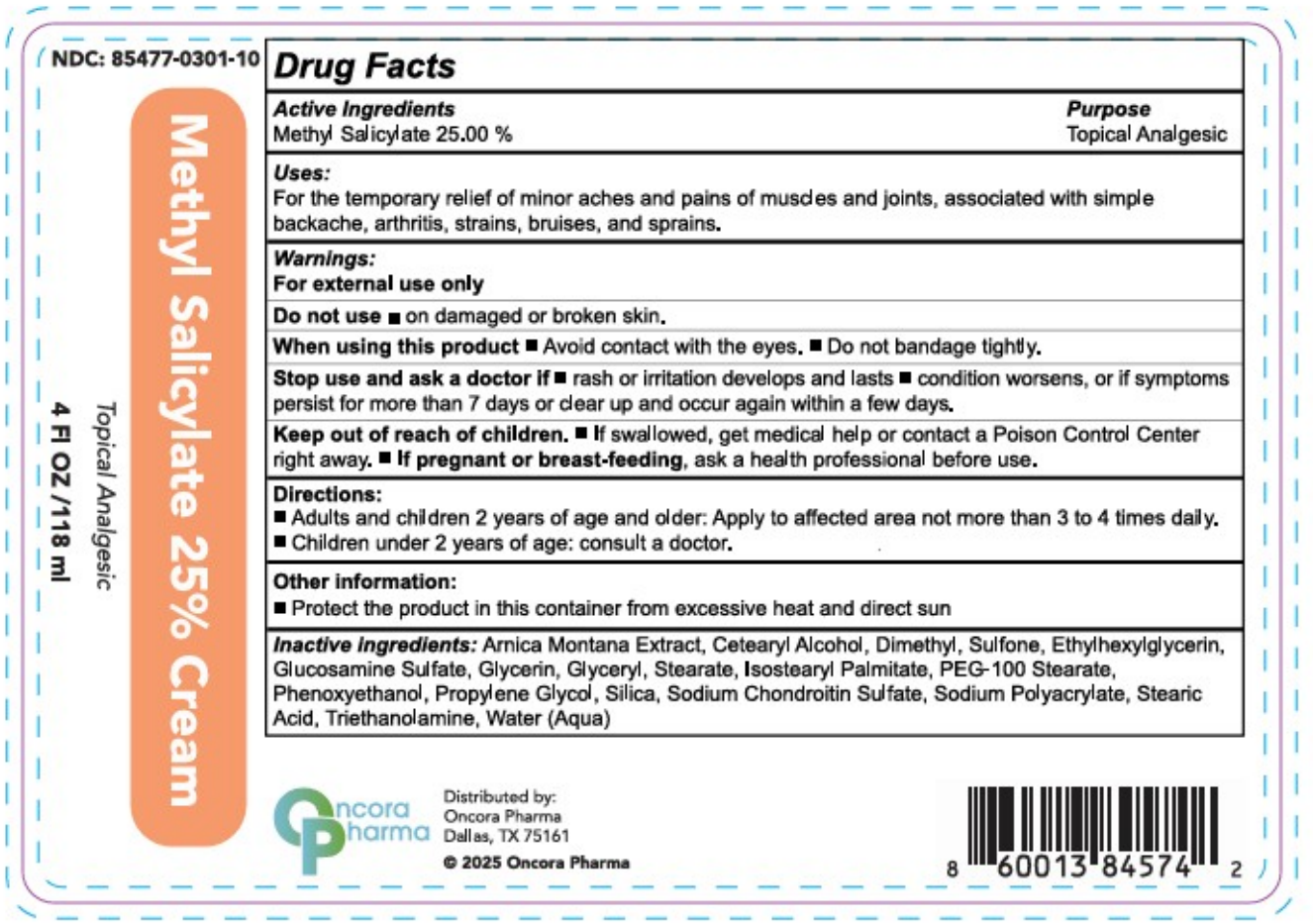
Protect the product in this container from excessive heat and direct sun.

Methyl Salicylate 25%

Arnica Montana Extract, Cetearly Alcohol, Dimethyl Sulfone, Ethylhexylglycerin, Glucosamine Sulfate, Glycerin, Glyceryl Stearate, Isostearyl Palmitate, PEG-100 Stearate, Phenoxyethanol, Propylene Glycol, Silica, Sodium Chondroitin Sulfate, Sodium Polyacrylate, Stearic Acid, Triethanolamine, Water

Purpose

Topical Analgesic



METHYL SALICYLATE 25%

methyl salicylate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:85477-301
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**
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
GLYCERYL STEARATE (UNII: 230OU9XXE4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ARNICA MONTANA (UNII: O80TY208ZW)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM CHONDROITIN SULFATE (PORCINE; 5500 MW) (UNII: H5BJH23Z9A)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	
ISOSTEARYL PALMITATE (UNII: 9EHU0R7ER1)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85477-301-10	118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/11/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/11/2025	

Labeler - Oncora Pharma, LLC (119482542)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source LLC		080354456	manufacture(85477-301)

Revised: 6/2025 Oncora Pharma, LLC