METHYL SALICYLATE 25% CREAM- methyl salicylate 25% cream Forreal Pharmaceuticals LLC

Methyl Salicylate Cream

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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

	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

Aloe vera leaf, Glycerine, Arnica Montana Flower, Indian Frankincense, Cetostearyl Alcohol, Ethylhexylglycerin, Glucosamine Sulfate, Glyceryl Monostearate, C13-14 Isoparaffin, Isosteryl Palmitate, Trolamine, Stearic Acid, Propylene Glycol, Laureth-7, Peg-100 Stearate, Water, Phenoxyethanol

Methyl Salicylate 25% Cream

NDC: 81877-721-01

120 grams

Manufactured for: Forreal Pharmaceuticals, LLC Royal Oak, MI 48067

PRINCIPAL DISPLAY PANEL

NDC: 81877-721-01

Methyl Salicylate 25% Cream

120 grams

Manufactured For:

Forreal Pharmaceuticals, LLC Royal Oak, MI 48067 Questions or Comments Please call 877-367-3250 NDC: 81877-721-01

Methyl Salicylate 25%

120 grams

Manufactured For: Forreal Pharmaceuticals, LLC Royal Oak, MI 48067 Questions or Comments Please call 877-367-3250

Drug Facts	
Active ingredient	Purpose
Methyl Salicylate 25%	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 larger 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 the reach of children.

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

- 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

Glyceryl Monostearate, C13-14 Isoparaffin, Isostearyl Palmitate, Trolamine, Stearic Acid, Propylene Glycol, Laureth-7,

Peg-100 Stearate, Water, Phenoxyethanol



81877 07211

METHYL SALICYLATE 25% CREAM

methyl salicylate 25% cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81877-721

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)

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 ALOE VERA LEAF (UNII: ZY81Z83H0X) ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ) INDIAN FRANKINCENSE (UNII: 4PW41QCO2M) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)

GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
ISOSTEARYL PALMITATE (UNII: 9EHU0R7ER1)	
TROLAMINE (UNII: 903K93S3TK)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
LAURETH-7 (UNII: Z95S6G8201)	
PEG-100 STEARATE (UNII: YD01N1999R)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

ı	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
:	NDC:81877-721-	120 g in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2024		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	part348	04/15/2024		

Labeler - Forreal Pharmaceuticals LLC (118029197)

Revised: 5/2024 Forreal Pharmaceuticals LLC