

METHYL SALICYLATE- methyl salicylate cream
PHARMACURE LLC

Active Ingredient

Purpose

Methyl Salicylate 25% (NSAID: Nonsteroidal anti-inflammatory drug)
Analgesic

Topical

Uses

Temporarily relieves mild to moderate aches & pains of muscles & joints associated with:

- strains • sprains • simple backache • arthritis • bruises

Warnings

For external use only

Stomach bleeding warning: This product contains an NSAID, which may cause stomach bleeding.

The chance is small but higher if you:

- are age 60 or older • have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product • take more or for a longer time than directed

Do not use

- on the face or rashes • on wounds or damaged skin • if allergic to aspirin or other NSAIDs
- with a heating pad • when sweating (such as from exercise or heat)
- right before or after heart surgery

Ask a doctor before use if

- you are allergic to topical products • the stomach bleeding warning applies to you
- you have high blood pressure, heart disease, or kidney disease • you are taking a diuretic

When using this product

- wash hands after applying or removing patch. Avoid contact with eyes. If eye contact occurs, rinse thoroughly with water.
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- stomach pain or upset gets worse or lasts • you feel faint, vomit blood, or have bloody or black stools

These are signs of stomach bleeding. • rash, itching or skin irritation develops

- condition worsens
- symptoms last for more than 3 days
- symptoms clear up and occur again within a few days

If pregnant or breast-feeding,

ask a doctor before use while breast-feeding and during the first 6 months of pregnancy. Do not use during the last 3 months of pregnancy because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. If put in mouth, get medical help or contact a Poison Control Center right away. Package not child resistant. Dispose of the used patches after folding sticky ends together.

Directions

- **Use only as directed**
- Adults and children 12 years of age and older: Apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: consult a physician

Other information

- Store at 20-25°C (68-77°F)
- Avoid storing product in direct sunlight
- Protect product from excessive moisture

Inactive ingredients

Aqua (deionized water), arnica montana (arnica) extract, boswellia serrata extract, cetearyl olivate, cetyl alcohol, dimethyl sulfone (MSM), ethylhexylglycerin, glycerin, glyceryl stearate, hemp, PEG-100 stearate, phenoxyethanol, polysorbate-20, resveratrol, sodium laurylglucosides hydroxypropylsulfonate, sorbital olivate, stearic acid

Product label

UNII:O414PZ4LPZ)

METRIL SALICILATE

250 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HEMP (UNII: TD1MUT01Q7)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
RESVERATROL (UNII: Q369O8926L)	
SODIUM LAURYLGLUCOSIDES HYDROXYPROPYLSULFONATE (UNII: Z6GFR7R72Y)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79643-004-01	100 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	05/01/2024	

Labeler - PHARMACURE LLC (055983858)

Revised: 5/2024

PHARMACURE LLC