METHYL SALICYLATE- methyl salicylate patch 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)
- any patch from a pouch that has been open for 14 or more days 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

Adults 18 years and older:

- •Clean and dry affected area Only use one patch at a time
- Remove patch from backing film and apply to skin
- Apply one patch to the affected area and leave in place for up to 8 to 12 hours
- If pain lasts after using the first patch, a second patch may be applied for up to another 8 to 12 hours
- Do not use more than 2 patches per day Do not use for more than 3 days in a row
- The used patch should be removed from the skin when a new one is applied
- Children under 18 years of age: do not use: this product has not been shown to work in children

Other information

- Store at 20-25°C (68-77°F) Avoid storing product in direct sunlight
- Protect product from excessive moisture
- •Some individuals may not experience pain relief until several hours after applying the patch

Inactive ingredients

Adhesive, myrrh gum, zinc oxide.

Product label

DRUG FACTS

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INACTIVE INGREDIENTS:

Manufactured for: PHARMACURE

For questions or comments email info@pharmacure.info





METHYL SALICYLATE

methyl salicylate patch

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:79643-010

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength Strength

METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: 0414PZ4LPZ) METHYL SALICYLATE 25 g in 100 g

Inactive Ingredients					
Ingredient Name	Strength				
MYRRH (UNII: JC71GJ1F3L)					
ZINC OXIDE (UNII: SOI2LOH54Z)					

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:79643-010- 01	10 in 1 BOX	02/01/2025				
1		8 g in 1 PATCH; Type 0: Not a Combination Product					

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC Monograph Drug	M017	02/01/2025				

Labeler - PHARMACURE LLC (055983858)

Revised: 2/2025 PHARMACURE LLC