METHYL SALICYLATE- methyl salicylate patch PHARMACURE LLC

Active Ingredient Purpose

Methyl Salicylate 10% (NSAID: Nonsteroidal anti-inflammatory drug) Topical Analgesic

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,

after folding sticky ends together.

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

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

Inactive ingredients

Adhesive, myrrh gum, zinc oxide.

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

Product label





METHYL SALICYLATE

methyl salicylate patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79643-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: O414PZ4LPZ)	METHYL SALICYLATE	100 mg in 1000 mg

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:79643-003- 01	2 in 1 BOX	02/17/2023		
1		5 in 1 POUCH			
1		1000 mg 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	02/17/2023	

Labeler - PHARMACURE LLC (055983858)

Revised: 5/2024 PHARMACURE LLC