

METHYL SALICYLATE- methyl salicylate patch
PHARMACURE, INC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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,

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

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

DRUG FACTS

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INACTIVE INGREDIENTS:
Adhesive, Myrrh Gum, Zinc Oxide.

Manufactured for:

PHARMACURE
For questions or comments
email info@pharmacure.info

METHYL SALICYLATE 10% PATCH

EXTERNAL ANALGESIC
PAIN RELIEF

NDC# 79643-003-01
10 PATCHES

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)	

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 not final	part348	02/17/2023	

Labeler - PHARMACURE, INC. (055983858)

Revised: 3/2023

PHARMACURE, INC.