

SALONPAS ARTHRITIS PAIN- menthol, methyl salicylate patch
Hisamitsu Pharmaceutical Co., Inc.

Active ingredients (in each patch)

Menthol 3%

Methyl salicylate 10% (NSAID : nonsteroidal anti-inflammatory drug)

Purpose

Topical analgesic

Uses

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

- arthritis
- sprains
- strains
- bruises
- simple backache

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 are taking a diuretic
- you have high blood pressure, heart disease, or kidney disease

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 health professional before use. It is especially important not to use methyl salicylate at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor 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:

- only use one patch at a time
- clean and dry affected area
- remove patch from backing film and apply to skin (see illustration)
- 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 degrees Celsius (68-77 degrees Fahrenheit)
- 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

alicyclic saturated hydrocarbon resin, baking cloth, film, mineral oil, polyisobutylene, polyisobutylene 1,200,000, styrene-isoprene-styrene block copolymer, synthetic aluminum silicate

Questions or comments?

Toll free **1-87-SALONPAS** www.salonpas.us

Principal Display Panel

Hisamitsu

NDC#46581-685-09

LARGE

3 15/16" X 5 1/2"

for temporary relief of mild to moderate pain

Arthritis

Joint Pain

Sprains

Strains

Salonpas

Arthritis Pain Patch

APPLY FOR 8-12 HOURS

Menthol 3%

Methyl Salicylate 10%

Topical Analgesic

FDA APPROVED NON-PRESCRIPTION PAIN RELIEVING PATCH
EFFECTIVENESS CONFIRMED IN CLINICAL TRIAL

9 patches

3 15/16" X 5 1/2"(10cm X 14cm)

Package not child resistant.

Keep out of reach of children.

* DO NOT USE MORE THAN ONE SALONPAS PATCH AT A TIME. SEE DIRECTIONS.

LARGE

3¹⁵/₁₆" X 5¹/₂"

Hisamitsu®

NDC#46581-685-09

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- Arthritis
- Joint Pain
- Sprains
- Strains

Salonpas®

Arthritis Pain Patch

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SALONPAS ARTHRITIS PAIN

menthol, methyl salicylate patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46581-685
Route of Administration	TOPICAL, PERCUTANEOUS, TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	63 mg
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	210 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM SILICATE (UNII: T1FAD4SS2M)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46581-685-09	3 in 1 BOX	11/01/2022	
1		3 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022029	11/01/2022	

Labeler - Hisamitsu Pharmaceutical Co., Inc. (690539713)

Revised: 11/2022

Hisamitsu Pharmaceutical Co., Inc.