

SALONPAS PAIN RELIEF- 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:

- 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 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#46581-670-05

for temporary relief of mild to moderate pain

Sore Muscle

Sprains

Backache

Joint Pain

Salonpas

Pain Relief 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

5 PATCHES

2 3/4" X 3 15/16" (7cm X 10cm)

Package not child resistant.

Keep out of reach of children.

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

for temporary relief of mild to moderate pain



- Sore Muscle
- Sprains
- Backache
- Joint Pain

Salonpas[®]

Pain Relief Patch

Menthol 3%
Methyl Salicylate 10%
Topical Analgesic



FDA APPROVED NON-PRESCRIPTION PAIN RELIEVING PATCH

EFFECTIVENESS CONFIRMED IN CLINICAL TRIAL

5 PATCHES
2³/₄" × 3¹⁵/₁₆" (7cm × 10cm)

*Package not child resistant.
Keep out of reach of children.*

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

Principal Display Panel

Hisamitsu

FREE SAMPLE

NOT FOR RE-SALE

minty scent

NDC#46581-670-99

for temporary relief of mild to moderate pain

Sore Muscle

Sprains

Backache

Joint Pain

1 Peel the center film.

2 Place on affected area.

3 Slide the film forward.

4 Slide the other film backward.

Salonpas

Pain Relief 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

1 patch

2 3/4" X 3 15/16" (7cm X 10cm)

Package not child resistant.

Keep out of reach of children.

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

Manufactured by

Hisamitsu Pharmaceutical Co., Inc.

JAPAN SAGA TOSU

MADE IN JAPAN

Distributed by

Hisamitsu America, Inc.
Florham Park, NJ 07932

Hisamitsu[®]

NDC#46581-670-99

for temporary relief of mild to moderate pain

- Sore Muscle
- Sprains
- Backache
- Joint Pain

HOW TO APPLY



Peel the center film.



Place on affected area.



Slide the film backward.



Slide the other film forward.

Salonpas[®]

Pain Relief Patch

Menthol 3%
Methyl Salicylate 10%
Topical Analgesic



1 PATCH
2³/₄" × 3¹⁵/₁₆" (7cm × 10cm)

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

Package not child resistant.
Keep out of reach of children.

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

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JAPAN SAGA TOSU
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Florham Park, NJ 07932

**FREE SAMPLE
NOT FOR RE-SALE**

Principal Display Panel

Hisamitsu

NDC#46581-670-06

for temporary relief of mild to moderate pain

Sore Muscle

Sprains

Backache

Joint Pain

BONUS PACK!

ONE FREE PATCH

Salonpas

Pain Relief 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

6 patches

2 3/4" X 3 15/16" (7cm X 10cm)

Package not child resistant.

Keep out of reach of children.

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

Hisamitsu®

NDC#46581-670-06

*for temporary
relief of mild to
moderate pain*



**BONUS PACK!
ONE FREE PATCH**

- Sore Muscle
- Sprains
- Backache
- Joint Pain

Salonpas[®]

Pain Relief Patch

Menthol 3%
Methyl Salicylate 10%
Topical Analgesic



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

6 ~~5~~ **PATCHES**
2³/₄" × 3¹⁵/₁₆" (7cm × 10cm)

*Package not child resistant.
Keep out of reach of children.*

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

SALONPAS PAIN RELIEF

menthol, methyl salicylate patch

Product Information

Product Type

HUMAN OTC DRUG

**Item Code
(Source)**

NDC:46581-
670

Route of AdministrationTOPICAL, PERCUTANEOUS,
TRANSDERMAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	31.5 mg
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	105 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM SILICATE (UNII: T1FAD4S52M)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46581-670-15	3 in 1 BOX	06/26/2008	
1		5 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:46581-670-20	4 in 1 BOX	02/01/2020	
2		5 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:46581-670-06	2 in 1 BOX	12/31/2013	
3		3 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:46581-670-05	1 in 1 BOX	05/22/2008	
4		5 in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:46581-670-03	3 in 1 POUCH; Type 0: Not a Combination Product	09/26/2008	
6	NDC:46581-670-01	1 in 1 POUCH; Type 0: Not a Combination Product	07/06/2011	
7	NDC:46581-670-99	1 in 1 POUCH; Type 0: Not a Combination Product	07/06/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022029	04/25/2008	

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

