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

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### 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 wouds 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 beeding.
- rash, itching or skin irritaion 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

<u>Children under 18 years of age:</u> 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 inredients

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

### Questions or comments?

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

### **Principal Display Panel**

Hisamitsu

NDC#46581-680-20

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

20 pathces

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

Package not child resistant.

Keep our of reach of children.

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

disamitsu<sub>®</sub>

NDC#46581-680-20

for temporary relief of mild to moderate pain

- Arthritis
- Joint Pain
- Sprains
- Strains

# Salonpas<sub>®</sub> Arthritis Pain Patch



Menthol 3%
Methyl Salicylate 10%
Topical Analgesic

FDA APPROVED NON-PRESCRIPTION PAIN RELIEVING PATCH

**EFFECTIVENESS CONFIRMED IN CLINICAL TRIAL** 

PATCHES
23/4"×315/16" (7cm×10cm)

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

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### **Principal Display Panel**

NDC#46581-680-99

for temporary relief of mild to moderate pain

**Arthritis** 

Joint Pain

**Sprains** 

**Strains** 

### **HOW TO APPLY**

- 1 Peel the center film.
- 2 Place on affected area.
- 3 Slide the film upward.
- 4 Slide the other film downward.

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

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.

**IAPAN SAGA TOSU** 

MADE IN JAPAN

Distributed by

Hisamitsu America, Inc.

Florham Park, NJ 07932

FREE SAMPLE

NOT FOR RE-SALE







film upward.

film downward.

# Salonds Arthritis Pain Patch



Menthol 3% **Methyl Salicylate 10% Topical Analgesic** 

FDA APPROVED NON-PRESCRIPTION PAIN RELIEVING PATCH

IVENESS CONFIRMED IN CLINICAL TRIAL

**PATCH** 

 $2\frac{3}{4}$ " $\times 3\frac{15}{16}$ " (7cm $\times 10$ cm)

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

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

Manufactured by Hisamitsu Pharmaceutical Co., Inc. Hisamitsu America, Inc. JAPAN SAGA TOSU MADE IN JAPAN

Distributed by Florham Park, NJ 07932

**FREE SAMPLE NOT FOR RE-SALE** 

## **SALONPAS ARTHRITIS PAIN**

menthol, methyl salicylate patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46581- 680
Route of Administration	TOPICAL, PERCUTANEOUS, TRANS DERMAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	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: T1FAD4SS2M)			
MINERAL OIL (UNII: T5L8T28FGP)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:46581-680- 15	3 in 1 BOX	06/01/2008			
1		5 in 1 POUCH; Type 0: Not a Combination Product				
2	NDC:46581-680- 05	1 in 1 BOX	05/01/2008			
2		5 in 1 POUCH; Type 0: Not a Combination Product				
3	NDC:46581-680- 20	4 in 1 BOX	11/01/2022			
3		5 in 1 POUCH; Type 0: Not a Combination Product				
4	NDC:46581-680- 03	3 in 1 POUCH; Type 0: Not a Combination Product	09/01/2008			
5	NDC:46581-680- 01	1 in 1 POUCH; Type 0: Not a Combination Product	05/01/2008			
6	NDC:46581-680- 99	1 in 1 POUCH; Type 0: Not a Combination Product	05/01/2008			

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)

Revised: 11/2022 Hisamitsu Pharmaceutical Co., Inc.