

SALONPAS PAIN RELIEVING HOT- capsaicin patch
Hisamitsu Pharmaceutical Co., 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.

Drug Facts

Active ingredient

Capsicum extract 0.025% as Capsaicin

Purpose

Topical analgesic

Uses

For temporary relief of minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only

Do not use

- on wounds or damaged skin.
- with a heating pad.
- if you are allergic to any ingredients of this product.

When using this product

- do not use otherwise than as directed.
- avoid contact with the eyes, mucous membranes or rashes.
- do not bandage tightly.
- discontinue use at least 1 hour before a bath or shower.
- do not use immediately after a bath or shower.

Stop use and ask a doctor if

- rash, itching or excessive skin irritation develops.
- conditions worsen.
- symptoms persist for more than 7 days.
- symptoms clear up and occur again within a few days.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age and over:

- clean and dry affected area.
- peel film from patch and apply to the skin. (see illustration.)
- apply to affected area not more than 3 to 4 times daily.
- remove patch from the skin after at most 8 hours' application.

Children under 12 years of age: consult a doctor.

Other information

- avoid storing product in direct sunlight.
- protect product from excessive moisture.

Inactive ingredients

aluminum silicate, butylated hydroxytoluene, hydrogenated rosin glycerol ester, maleated rosin glycerin ester, mineral oil, polyisobutylene, polyisobutylene 1,200,000, styrene-isoprene-styrene block copolymer

Questions or comments?

Toll free **1-800-826-8861**, Weekdays, 9AM to 5PM (PST) www.salonpas.us

Principal Display Panel

NDC#46581-730-05

for minor aches and pain relief

- Shoulder
- Neck
- Leg
- Back

Salonpas pain relieving PATCH HOT
Pain Relieving Ointment on a Breathable Cloth
LASTS UP TO 8 HOURS
Capsaicin 0.025%

STRETCHABLE and FLEXIBLE

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

Hisamitsu

NDC#46581-730-05

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and pain relief**



- **Shoulder**
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Salonpas®

pain relieving PATCH **HOT**

Pain Relieving Ointment on a Breathable Cloth
Capsaicin 0.025%



STRETCHABLE & FLEXIBLE

5 patches

2³/₄" × 3¹⁵/₁₆" (7cm × 10cm)

Hisamitsu®

Principal Display Panel

Cut open easily by hand

FREE SAMPLE NOT FOR RE-SALE

NDC#46581-730-99

for minor aches and pain relief

- Shoulder
- Neck
- Leg
- Back

1 Peel the center film.

2 Place on affected area.

3 Slide the film forward.

4 Slide the other film backward.

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Capsaicin 0.025%

LASTS UP TO 8 HOURS

STRETCHABLE AND FLEXIBLE

1 patch

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

Hisamitsu

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

Distributed by
Hisamitsu America, Inc.
Torrance, CA 90503

Cut open easily by hand

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SALONPAS PAIN RELIEVING HOT

capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46581-730
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSICUM (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)	CAPSAICIN	0.025 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Aluminum silicate (UNII: T1FAD4SS2M)	
Butylated hydroxytoluene (UNII: 1P9D0Z171K)	
Mineral oil (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46581-730-05	1 in 1 BOX	01/01/2012	
1		5 in 1 POUCH		
1		1.05 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:46581-730-01	1 in 1 POUCH	01/01/2012	
2		1.05 g in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:46581-730-99	1 in 1 POUCH	01/01/2012	
3		1.05 g 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	01/01/2012	

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

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