# SALONPAS PAIN RELIEVING HOT- capsaicin patch His amits u 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





## **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.

Salonpas pain relieving PATCH HOT Pain Relieving Ointment on a Breathable Cloth 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

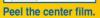
Distributed by Hisamitsu America, Inc. Torrance, CA 90503 Cut open easily by hand

#### FREE SAMPLE **NOT FOR RE-SALE**

for minor ache

- Shoulder Neck
- Leg
- Back









Place on affected area.



Slide the film forward.



Slide the other film backward.

# Salondas



# pain relieving **PATCH HOT**

Pain Relieving Ointment on a Breathable Cloth Capsaicin 0.025%

STRETCHABLE & FLEXIBLE

2¾"×3¹⁵⁄₁₅"(7cm×10cm)

dusamitsu<sub>®</sub>

Manufactured by Hisamitsu Pharmaceutical Co., Inc. **MADE IN JAPAN** 

Hisamitsu America, Inc. Torrance, CA 90503

## 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**

ı	0	J			
I	I	ngredient Name		Basis of Strength	Strength
I	CAPSICUM (UNII: 00UK7646FG	) (CAPSICUM - UNII:00UK7646FG)	(	CAPSAICIN	0.025 g in 100 g

# **Inactive Ingredients**

mactive ingredients			
Ingredient Name	Strength		
Aluminum silicate (UNII: T1FAD4SS2M)			
Butylated hydroxytoluene (UNII: 1P9 D0 Z171K)			
Mineral oil (UNII: T5L8T28FGP)			

# Packaging

#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:46581-730-05	1 in 1 BOX	0 1/0 1/20 12		
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	0 1/0 1/20 12		
2		1.05 g in 1 PATCH; Type 0: Not a Combination Product			
3	NDC:46581-730-99	1 in 1 POUCH	0 1/0 1/20 12		
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	0 1/0 1/20 12	

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

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

Revised: 12/2019 Hisamitsu Pharmaceutical Co., Inc.