

SALONPAS PAIN RELIEVING HOT-L- capsaicin, menthol 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.

Active ingredients

Capsicum extract 0.025% as Capsaicin

Menthol 1.25%

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
- remove 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, edetate disodium, gelatin, glycerin, magnesium aluminometasilicate, oleyl alcohol, polyacrylic acid, polyethylene glycol, polyvinyl alcohol, sodium polyacrylate, sorbitan monooleate, tartaric acid, titanium dioxide, water

Questions or comments?

Toll free **1-800-826-8861** www.salonpas.us

Principal Display Panel

LARGE

NDC#46581-890-03

for minor aches and pain relief

- Shoulder
- Upper Back
- Lower Back

Salonpas pain relieving GEL-PATCH HOT-L

Capsaicin 0.025%

Menthol 1.25%

LASTS UP TO 8 HOURS

Pain Relieving Ointment on a Breathable Cloth

STRETCHABLE

3 patches

3 15/16 X 7 7/8 (10cm X 20cm)

Hisamitsu

LARGE

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for minor aches
and pain relief

- Shoulder
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Salonpas®



pain relieving
Capsaicin 0.025%
Menthol 1.25% **GEL-PATCH**
HOT-L
Pain Relieving Ointment on a Breathable Cloth

STRETCHABLE

3 patches

3¹⁵/₁₆" × 7⁷/₁₆" (10cm × 20cm)

Hisamitsu®

SALONPAS PAIN RELIEVING HOT-L

capsaicin, menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46581-890
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
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALUMINUM SILICATE (UNII: T1FAD4SS2M)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
TARTARIC ACID (UNII: W4888119H)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46581-890-03	1 in 1 BOX		
1		3 in 1 POUCH		
1		20 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:46581-890-01	1 in 1 POUCH		
2		20 g in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:46581-890-99	1 in 1 POUCH		
3		20 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	05/01/2011	

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

Revised: 11/2015

Hisamitsu Pharmaceutical Co., Inc.