

SATOHAP COOL AND HOT PADS- camphor, capsaicin, menthol patch
Sato Pharmaceutical Co., Ltd.

Satohap Cool & Hot Pads - 5 pads in 1 pouch - (13cm by 8cm each pad)

Active ingredients

Camphor 3.1%

Capsaicin 0.025%

Menthol 6%

Purpose

External analgesic

External analgesic

External analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints due to:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only

Do not use

- on irritated or damaged skin
- on wounds

Ask a doctor or pharmacist before use if you have

- any concerns about using this product

When using this product

- avoid contact with the eyes or mucus membranes
- do not bandage tightly
- do not apply heat to the area in the form of heating pads, hot water bottles, or lamps (doing so increases the risk of serious burns)

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive irritation of the skin develops
- nausea, vomiting, abdominal discomfort, diarrhea, or skin rash occurs.
- you feel actual pain or experience blistering or burning after application (it is normal to feel a warming or cooling sensation)
- when using for pain or arthritis:
 - pain persists for more than 10 days
 - redness is present
- in conditions affecting children under 12 years of age

Report any unexpected side effects from the use of this product to the FDA MedWatch Program

Keep out of reach of children.

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

Directions

- Adults and children 4 years of age and older: remove polyethylene film and place adhesive pad over affected area.
- do not use more than 2 patches per day.
- Children under 4 years of age: Consult a doctor.

Other information

- keep pouch tightly closed
- keep product protected from heat

Inactive ingredients

carboxymethylcellulose sodium, dihydroxyaluminum aminoacetate, dried aluminum hydroxide gel, edetate disodium, emulsion of methyl acrylate and 2-ethylhexyl acrylate copolymer, glycerin, malic acid, partially neutralized polyacrylate, polysorbate 80, polyvinyl alcohol, sorbitol solution, talc, titanium dioxide, and water on a polyester fiber backing and covered with a polyethylene film.

Questions or comments?

- contact Sato Pharmaceutical Inc. 20695 S. Western Ave., Suite 240, Torrance, CA 90501
- you may also report serious side effects to this address

Satohap Cool and Hot Pads



医薬品表示

有効成分・分量 **配合目的**

メントール 外用鎮痛剤

カンפור 外用鎮痛剤

カプサイシン 外用鎮痛剤

効能 下記に示す痛止薬に相当する効能を有する。

用法・用量 大人及び小児に同様に貼る。貼る時は皮膚を清潔にし、貼る部位を乾燥させておく。貼る時は皮膚を清潔にし、貼る部位を乾燥させておく。

その他の情報 貼る時に皮膚が赤くなるのを避ける。

その他の成分 水酸化アルミニウム、ステアリン酸、ステアリン酸アルミニウム、ステアリン酸カルシウム、ステアリン酸マグネシウム、ステアリン酸亜鉛、ステアリン酸鉄、ステアリン酸銅、ステアリン酸ニッケル、ステアリン酸コバルト、ステアリン酸マンガン、ステアリン酸カルシウム、ステアリン酸マグネシウム、ステアリン酸亜鉛、ステアリン酸鉄、ステアリン酸銅、ステアリン酸ニッケル、ステアリン酸コバルト、ステアリン酸マンガン。

Manufactured by
SATO PHARMACEUTICAL CO., LTD.
1-5-27 MOTOMASAHAMINATO-KO, TOKYO, JAPAN

Reports of serious side effects associated
with use of this product can be sent to:
SATO PHARMACEUTICAL INC.
2002 S. Nimitz Ave., Suite 400, Torrance, CA 90503
TEL: (310) 781-0888 FAX: (310) 781-0877

Drug Facts (Content)
この商品の成分の呼び方
SATO PHARMACEUTICAL CO., LTD.
SATO PHARMACEUTICAL INC.
2002 S. Nimitz Ave., Suite 400, Torrance, CA 90503
TEL: (310) 781-0888 FAX: (310) 781-0877



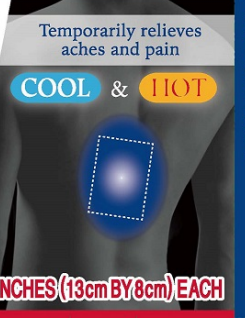
EXTERNAL ANALGESIC

Temporarily relieves aches and pain

COOL & HOT

Menthol Camphor

Capsaicin



5 PADS 5 1/8 BY 3 3/16 INCHES (13cm BY 8cm) EACH

SATOHAP COOL & HOT

LOT
EXP



SATOHAP COOL & HOT

1 R02.10.12 R 2L PAN286 PAN199 PAN288 PAN1235

5534
1150

SATOHAP COOL AND HOT PADS

camphor, capsaicin, menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49873-621
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	3.1 g in 100 g
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	6 g in 100 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.025 g in 100 g

Inactive Ingredients

Ingredient Name	Strength

ACRYLIC ACID/SODIUM ACRYLATE COPOLYMER (1:1; 600 MPA.S AT 0.2%) (UNII: M4PPW69Y4H)
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)
METHYL ACRYLATE (UNII: WC487PR91H)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)
SORBITOL (UNII: 506T60A25R)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)
WATER (UNII: 059QF0KO0R)
MALIC ACID (UNII: 817L1N4CKP)
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)
GLYCERIN (UNII: PDC6A3C0OX)
TALC (UNII: 7SEV7J4R1U)
EDETATE DISODIUM (UNII: 7FLD91C86K)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-621-01	1 in 1 BOX	12/18/2020	
1		5 in 1 POUCH		
1		9.36 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 Drug	M017	12/18/2020	

Labeler - Sato Pharmaceutical Co., Ltd. (690575642)

Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical Co., Ltd.		715699133	label(49873-621) , manufacture(49873-621) , pack(49873-621)

Establishment

Name	Address	ID/FEI	Business Operations
Fuji Seal, Inc.		718023935	label(49873-621) , pack(49873-621)