

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

SATOHAP Cool & Hot - 5 pads in 1 pouch - (10cm BY 7cm 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 of 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.

SATOHAP COOL & HOT 10cm BY 7cm



SATOHAP COOL AND HOT

camphor, capsaicin, menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49873-622
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.025 g in 100 g
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

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUNO)	
MALIC ACID (UNII: 817L1N4CKP)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
TALC (UNII: 7SEV7J4R1U)	
ACRYLIC ACID/SODIUM ACRYLATE COPOLYMER (1:1; 600 MPA.S AT 0.2%) (UNII: M4PPW69Y4H)	
METHYL ACRYLATE (UNII: WC487PR91H)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-622-01	1 in 1 BOX	09/01/2024	
1		5 in 1 POUCH		
1		6.3 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	09/01/2024	

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

Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceuticals Co., Ltd.		715699133	manufacture(49873-622) , pack(49873-622) , label(49873-622)

Establishment

Name	Address	ID/FEI	Business Operations
Fuji Seal, Inc.		718023935	label(49873-622) , pack(49873-622)

Revised: 9/2024

Sato Pharmaceuticals Co., Ltd.