

SATOGESIC- dl-camphor, l-menthol, methyl salicylate patch
Sato Pharmaceutical Co., Ltd.

Satogessic Medicated Adhesive Pads

Active ingredients

dl-Camphor 0.5%
l-Menthol 0.4%
Methyl salicylate 0.8%

Purpose

dl-Camphor External analgesic
l-Menthol External analgesic
Methyl salicylate External analgesic

Uses temporary relieves 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 irritated, broken, or damaged skin ■ on wounds ■ otherwise than as directed

When using this product

■ avoid contact with the eyes or mucous membranes ■ do not bandage the area tightly and do not apply local heat (heating pads, lamps, hot water in bags or bottles) because doing so can increase 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

■ 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

■ you experience pain, swelling, or blistering of the skin (this product should not cause pain or skin damage)

Warning - Rare cases of serious burns have been reported to occur on the skin where

OTC external analgesics were applied. Read and follow all directions and warnings on this label.

Keep out of reach of children to avoid accidental poisoning. If swallowed, get medical

help or contact a Poison Control Center right away.

Directions

■ Strip off the polyethylene film and place adhesive pad over affected area. ■ Change pad 1 or 2 times a day

■ Not for children under 4 years.

Other Information

■ keep pouch tightly closed until ready to use ■ store at room temperature (20° to 25°C or 68° to 77°F)

Inactive ingredients

carbomer 940, carboxymethylcellulose sodium, dried aluminum hydroxide gel, edetate disodium, glycerin, malic acid, methacrylic acid and n-butyl acrylate copolymer, partially hydrolyzed polyvinyl alcohol, partially neutralized polyacrylate, PEG 60 hydrogenated castor oil, sorbitol, titanium dioxide, water.



SATOGESIC

dl-camphor, l-menthol, methyl salicylate patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49873-060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	5 mg
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	4 mg
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	8 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	

POLYVINYL ALCOHOL (UNII: 532B59J990)
SORBITOL (UNII: 506T60A25R)
GLYCERIN (UNII: PDC6A3C0OX)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
EDETATE DISODIUM (UNII: 7FLD91C86K)
MALIC ACID (UNII: 817L1N4CKP)
WATER (UNII: 059QF0KO0R)
POLYOXYL 60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)
ALGELDRATE (UNII: 03J11K103C)
BUTYL ACRYLATE/METHACRYLIC ACID COPOLYMER (2% METHACRYLIC ACID) (UNII: Q984S31CYH)
CARBOMER 940 (UNII: 4Q93RCW27E)
ACRYLIC ACID/SODIUM ACRYLATE COPOLYMER (1:1; 600 MPA.S AT 0.2%) (UNII: M4PPW69Y4H)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-060-01	1 in 1 CARTON	12/03/1990	
1		5 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:49873-060-02	1 in 1 CARTON	12/03/1990	
2		5 in 1 POUCH; 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	12/03/1990	

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

Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical Co., Ltd.		715699133	manufacture(49873-060) , label(49873-060) , pack(49873-060)

Establishment

Name	Address	ID/FEI	Business Operations
Fuji Seal, Inc.		718023935	pack(49873-060) , label(49873-060)

Revised: 11/2023

Sato Pharmaceutical Co., Ltd.