SATOHAP- methyl salicylate, dl-camphor, l-menthol lotion Sato Pharmaceutical Co., Ltd.

Satohap Lotion

Active ingredients

dl-Camphor 5% l-Menthol 4% Methyl salicylate 10%

Purpose

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

Uses

temporarily relieves minor aches and pains of muscles and joints due to

■ backache ■ arthritis ■ strains ■ bruises ■ sprains

Warnings For external use only

Do not use

- on wounds
- on damaged or irritated skin

When using this product

- avoid contact with the eyes and mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

- excessive irritation develops
- condition worsens
- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- when using for pain of arthritis if:

- pain persist for more than 10 days
- redness is present
- in conditions affecting children under 12 years of age

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 2 years of age and over: apply to affected area not more than 3 to 4 times daily.
- children under 2 years of age: do not use, ask a doctor.

Inactive ingredients

edetate disodium, alcohol, propylene glycol, water



SATOHAP

methyl salicylate, dl-camphor, l-menthol lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49873-065	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 mL	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	5 g in 100 mL	
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	4 g in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
EDETATE DISODIUM (UNII: 7FLD91C86K)				
ALCOHOL (UNII: 3K9958V90M)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:49873- 065-01	1 in 1 CARTON	02/05/1991	
1		45 mL in 1 BOTTLE, WTH APPLICATOR; 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	02/05/1991		

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Sato Pharmaceutical Co., Ltd.		715699133	manufacture(49873-065) , label(49873-065) , pack(49873-065)	

Revised: 12/2023 Sato Pharmaceutical Co., Ltd.