SATOHAP LIDOCAINE 4% MENTHOL 1% PAIN RELIEVING CREAM- lidocaine, menthol cream
Sato Pharmaceutical Co., Ltd.

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.

Satohap Lidocaine 4% Menthol 1% Cream

Active ingredients

Lidocaine 4%

Menthol 1%

Purpose

Lidocaine Topical analgesic

Menthol Topical analgesic

Uses

For temporary relief of pain

Warnings

For external use only

Do not use in large quantities, particularly over raw surfaces or blistered areas

When using this product avoid contact with the eyes

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
- a rash or irritation develops

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 older: apply to affected area not more than 3 to 4 times dailly
- children under 12 years of age: do not use, ask a doctor

Other information
- protect product from excessive moisture
- avoid storing in direct sunlight
- store with lid tightly closed

Inactive ingredients benzyl alcohol, butylene glycol, carbomer homopolymer (type C), isopropyl myristate, polyoxyl 40 hydrogenated castor oil, sodium hydroxide, water

Image

SATOHAP LIDOCAINE 4% MENTHOL 1% PAIN RELIEVING CREAM

lidocaine, menthol cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49873-619
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-619-01	1 in 1 CARTON	11/14/2018	
1		100 g in 1 TUBE; 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	11/14/2018	

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

Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical Co., Ltd.		715699133	pack(49873-619) , label(49873-619) , manufacture(49873-619)

Revised: 12/2022 Sato Pharmaceutical Co., Ltd.