

SATOHAP LIDOCAINE 4% MENTHOL 1% PAIN RELIEVING CREAM- lidocaine, menthol cream

Sato Pharmaceutical Co., Ltd.

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 daily
- 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



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 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 Drug	M017	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: 12/2024

Sato Pharmaceutical Co., Ltd.