SATOHAP LIDOCAINE HYDROCHLORIDE 4 PERCENT PAIN RELIEVING - lidocaine hydrochloride lotion
Sato Pharmaceutical Co., Ltd.

Satohap Lidocaine HCl 4% Pain Relieving Lotion

Active ingredients

Lidocaine hydrochloride 4%

Purpose

Lidocaine hydrochloride - Topical analgesic

Uses

For temporary relief of pain and itching

Warnings

For external use only

Flammable: Keep away from fire and flame

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

- avoid storing in direct sunlight
- store with lid tightly closed

Inactive ingredients alcohol, propylene glycol, sodium hydroxide, water

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lidocaine hydrochloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49873-618
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-618-01	1 in 1 CARTON	11/19/2018	
1		80 mL in 1 BOTTLE, WITH 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	11/19/2018	

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

Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical Co., Ltd.		715699133	manufacture(49873-618) , pack(49873-618) , label(49873-618)

Revised: 11/2023 Sato Pharmaceutical Co., Ltd.