**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.*

---

***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


sato
NDC 49873-619-01
For temporary relief of pain
SATOHAP®
LIDOCAINE 4%
MENTHOL 1%
Pain Relieving
Cream
Desensitize aggravated nerves
back, shoulders, neck
Unscented
CooL type
100 g (3.5 OZ)


# 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: 11/2018 Sato Pharmaceutical Co., Ltd.