

LIDOCAINE PAIN RELIEVING CREME- lidocaine hydrochloride cream
SOTAC PHARMACEUTICALS PRIVATE LIMITED

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.

Lidocaine Pain Relieving Creme- Careone

Lidocaine Pain Relieving Creme

Drug Facts

Active ingredient

Lidocaine HCl 4%

Purpose

Topical anesthetic

Uses

temporarily relieves minor pain

Warnings

For external use only

Do not use

- on large areas of the body or on cut, irritated or swollen skin
- on puncture wounds
- for more than one week without consulting a doctor

When using this product

- use only as directed. Read and follow all directions and warnings on this carton.
- do not allow contact with the eyes
- do not bandage or apply local heat (such as heating pads) to the area of use

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children and pets.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children over 12 years:

- apply a thin layer to affected area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period

children 12 years and younger: ask a doctor


Inactive ingredients

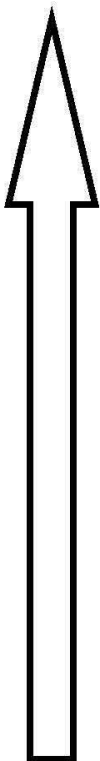
Butylated hydroxyl toluene, cetostearyl alcohol, cetomacrogol 1000, cetyl alcohol, disodium EDTA, disodium hydrogen phosphate, light liquid paraffin, propylene glycol, sorbic acid, transquitol P, white petroleum jelly

Keep Carton As It Contains Important Information

Close cap tightly between uses.

Outer Label

| CareOne Pain Relieving Cream 4% Lidocaine 4.7 Oz | | | |
|---|--|--|----------------------------|
| Active Ingredient Lidocaine HCl 4%..... Topical Anesthetic | | | |
| BATCH NO. | | QUANTITY | 18X4 (X 133 g) =72 Bottles |
| MFG. DATE | 05/2018 | SHIPPER NO. | out of 30 |
| EXP. DATE | 04/2020 | GROSS WT. | kg. |
| | | NET WT. | 11.500 kg. |
| WARNING: KEEP OUT OF REACH OF CHILDREN AND PETS. FOR EXTERNAL USE ONLY. | | STORE AT CONTROLLED TEMPERATURE OF 59°F to 86° F (15 to 30 °C) | |
| CONFORMANCE WITH THE F.D & C ACT AND REGULATIONS THERE UNDER | | PROTECT FROM DIRECT SUNLIGHT / MOISTURE / FREEZING | |
| MANUFACTURED BY: SOTAC PHARMACEUTICALS PVT LTD PLOT NO. PF-21, SANAND GIDC-II, CHARAL INDUSTRIAL ESTATE, TALUKA-SANAND, DISTRICT-AHMEDABAD 382 110. INDIA | | | |
| Lic#GUJ/DRUGS/G/25/2169 | | | |
| SHIPPED TO: VELOCITY PHARMA LLC 226/B SHERWOOD AVE, FARMINGDALE , NY-11735 | | | |
| NDC No | 76168-205-32 | | |
| Barcode No. |  | | |



| LIDOCAINE PAIN RELIEVING CREME | | | |
|---------------------------------------|----------------|---------------------------|---------------|
| lidocaine hydrochloride cream | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72351-004 |

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------------|-----------------|
| LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98P200987) | LIDOCAINE HYDROCHLORIDE ANHYDROUS | 4 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| CETETH-2 (UNII: 7H8VAM7778) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU) | |
| LIGHT MINERAL OIL (UNII: N6K5787QVP) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SORBIC ACID (UNII: X045WJ989B) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72351-004-00 | 72 in 1 CASE | 05/31/2018 | |
| 1 | | 133.24 g in 1 BOTTLE; 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 | 03/03/2017 | |

Labeler - SOTAC PHARMACEUTICALS PRIVATE LIMITED (876894019)

Revised: 5/2018

SOTAC PHARMACEUTICALS PRIVATE LIMITED