**SUNBURN RELIEF GEL- lidocaine hcl gel**
**Vi-Jon, Inc**

*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.*

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**Sunburn Relief Gel**
**005**

**Active ingredient**

Lidocaine HCl 0.5%

**Purpose**

External analgesic

**Uses**

for the temporary relief of pain and itching associated with

- minor burns
- sunburn
- minor cuts
- scrapes
- insect bites
- minor skin irritations

**Warnings**

**For external use only**

**When using this product** avoid contact with the eyes

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avoid contact with the eyes

**Do not use**

in large quantities, particularly over raw surfaces or blistered areas

**Stop use and ask a doctor if**

condition worsens, or if symptoms persist for more than 7 days or clean up and occur again within a few days

**Keep out of reach of children**

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

**Directions**

- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily

- children under 2 years of age: ask a doctor

**Inactive ingredients**

water, propylene glycol, glycerin, Aloe barbadensis leaf juice, triethanolamine, isopropyl alcohol, polysorbate 80, carbomer, diazolidinyl urea, menthol, disodium EDTA, blue 1, yellow 5

*This product is not manufactured or distributed by Bayer, distributor of Solarcaine Cool Aloe Burn Relief Formula

Manufactured by: Vi-Jon, Inc., St. Louis, MO 63114

Questions or comments? 1-888-593-0593

Made in the USA with US and foreign parts

005.001/005AB

**Principal Display Panel**

Mountain falls

*Compare to Solarcaine

with aloe vera

helps returned moisture to sunburned skin

with lidocaine HCl

doctor tested

SUNBURN RELIEF GEL

PAIN RELIEVING GEL

NET WT 8 OZ (226 g)


# SUNBURN RELIEF GEL

lidocaine hcl gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0869-0005 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **LIDOCAINE HYDROCHLORIDE** (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE HYDROCHLORIDE ANHYDROUS | 5.05 g in 1 g |

| Inactive Ingredients |
|---|

| Ingredient Name | Strength |
|---|---|
| **WATER** (UNII: 059QF0KO0R) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **TROLAMINE** (UNII: 9O3K93S3TK) | |
| **ISOPROPYL ALCOHOL** (UNII: ND2M416302) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **CARBOXYPOLYMETHYLENE** (UNII: 0A5MM307FC) | |
| **DIAZOLIDINYL UREA** (UNII: H5RIZ3MPW4) | |
| **MENTHOL** (UNII: L7T10EIP3A) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0869-0005-34 | 226 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 01/10/2017 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part348 | 01/10/2017 | |

## Labeler - Vi-Jon, Inc (790752542)

## Registrant - Vi-Jon, Inc (790752542)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Vi-Jon, Inc | | 790752542 | manufacture(0869-0005) |

Revised: 5/2020 Vi-Jon, Inc