

ALOE VERA GEL- lidocaine hcl gel
Valu Merchandisers, CO.

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.

Sunburn Relief with Aloe
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

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 clear 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

Proudly distributed by: Valu Merchandisers, Co.

5000 Kansas Ave, Kansas City, KS 66106

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005.001/005AB

Principal display panel

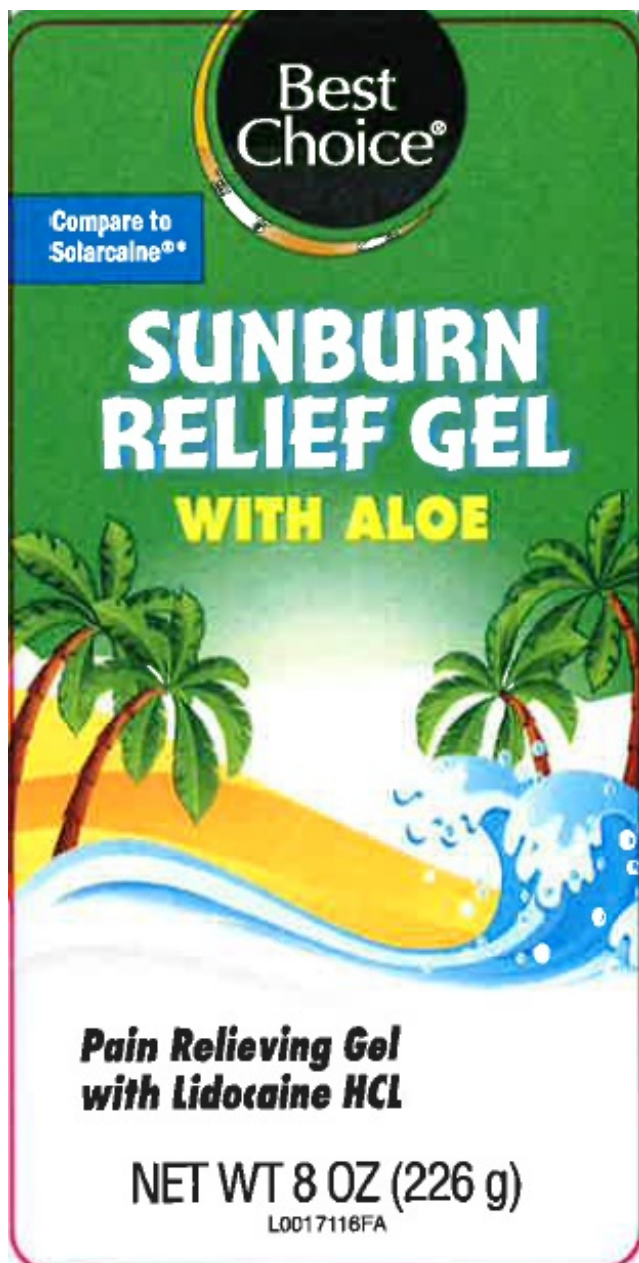
Best Choice

Sunburn Relief Gel with Aloe

Pain Relieving Gel With Lidocaine HCL

Compare to Solarcaine*

NET WT 8 OZ (226 g)



ALOE VERA GEL

lidocaine hcl gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63941-005 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------------|--------------|
| LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE HYDROCHLORIDE ANHYDROUS | 2.5 g in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| water (UNII: 059QF0K00R) | |
| 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 ANHYDROUS (UNII: 8NLQ36F6MM) | |
| 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:63941-005-34 | 226 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/14/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 08/14/2017 | |

Labeler - Valu Merchandisers, CO. (868703513)

Registrant - Vi-Jon (790752542)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| Vi-Jon | | 790752542 | manufacture(63941-005) |

Revised: 5/2020

Valu Merchandisers, CO.