

**ALOCANE EMERGENCY BURN- lidocaine hydrochloride gel**  
**Quest Products, LLC.**

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**Alocane<sup>®</sup> Emergency Burn Gel**

**Drug Facts**

**Active Ingredient**

Lidocaine HCL 4%

**Purpose**

Topical Analgesic

**Uses**

For the temporary relief of pain and itching associated with:

- Sunburn
- Minor Skin Irritation
- Minor Burns
- Cuts & Scrapes
- Insect Bites

**Warnings**

For external use only. Avoid contact with eyes.

**Keep out of reach of children.** In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

**Stop use and ask doctor:** if condition worsens, or if 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 care professional before use.

Do not use in large quantities, particularly over raw surfaces or blistered areas.

**Directions:**

**Adults and Children 2 years of age or older:**

- Clean the burn area with mild soap and water
- Gently apply over the burn or wound
- **Use on affected area not more than 3 to 4 times daily**

**Children under 2 years of age: Consult a doctor**

**Other Information**

Store at room temperature 15-30°C (59-86°F)

## Inactive Ingredients

1,3-Propanediol, Aloe Barbadensis (Aloe) Leaf Juice, Caprylyl Glycol, Chlorphenesin, Dimethyl Isosorbide, Hydroxyethyl Cellulose, Phenoxyethanol, Tocopheryl Acetate (Vitamin E), Water.

Distributed by:

Quest Products, LLC.

Pleasant Prairie, WI 53158

## PRINCIPAL DISPLAY PANEL - ALOCANE Burn Gel 2.5 fl oz tube

**4% Lidocaine**  
Maximum Strength

**ALOCANE**

| Drug Facts  |                    |
|---|--------------------|
| <b>Active Ingredient</b> .....  | <b>Purpose</b>     |
| Lidocaine HCL 4%.....   | Topical Anesthetic |
| <b>Uses:</b> For the temporary relief of pain and itching associated with: ■ Sunburn ■ Minor Burns ■ Minor Skin Irritation ■ Cuts and Scrapes   |                    |
| <b>Warnings:</b> For external use only. Avoid contact with eyes.  |                    |
| <b>Keep out of reach of children.</b> In case of accidental ingestion, get medical help or contact a Poison Control Center right away.  |                    |
| <b>Stop use and ask doctor:</b> If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.  |                    |
| <b>If pregnant or breast-feeding,</b> ask a health care professional before use.  |                    |
| Do not use in large quantities, particularly over raw surfaces or blistered areas.  |                    |
| <b>Directions:</b><br><b>Adults and children 2 years of age or older</b><br>■ Apply to affected area not more than 3 to 4 times daily.<br><b>Children under 2 years of age</b> consult a physician.                     |                    |
| <b>Other information:</b> Store at room temperature 15 - 30°C (59-86°F)   |                    |
| <b>Inactive Ingredients:</b><br>1,3-Propanediol, Aloe Vera Extract (X Decolorized), Caprylyl Glycol, Chlorphenesin, Dimethyl Isosorbide, Hydroxyethyl Cellulose, Phenoxyethanol, Tocopheryl Acetate (Vitamin E), Water. |                    |

**4% Lidocaine**  
Maximum Strength

**ALOCANE**

**4% Lidocaine**

**MAXIMUM STRENGTH**  
**ALOCANE**

**Emergency Burn Gel**

- Fast Pain and Itch Relief
- Assists the Healing process
- Soothing Aloe Gel & Vitamins
- Use on Sunburns & First Degree Burns with Vitamin E

Recommended by  
Physicians and Pharmacists

**Aloe**

Distributed by:  
Quest Products, LLC  
Pleasant Prairie, WI 53158  
Phone: 800.650.0113  
www.alocane.com

2.5 fl. oz (75ml)

## PRINCIPAL DISPLAY PANEL -- ALOCANE Burn Gel Pump

**4% Lidocaine**

| Drug Facts   |                                    |
|--|------------------------------------|
| <b>Active ingredient:</b> Lidocaine HCl, 4%  | <b>Purpose:</b> Topical Anesthetic |
| <b>Use:</b> For the temporary relief of pain and itching associated with:<br>• Minor Burns • Minor Skin Irritations • Cuts & Scrapes • Severe Itch • Insect Bites                                  |                                    |
| <b>Warnings:</b> For external use only. Avoid contact with eyes. Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center right away.   |                                    |
| Stop use and ask doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.   |                                    |
| If pregnant or breastfeeding, ask a health-care professional before use.   |                                    |
| Do not use in large quantities, particularly over sunburned or abraded areas.  |                                    |
| <b>Directions:</b> Adults and children 2 years of age or older<br>• Apply to affected area not more than 3 to 4 times daily<br>• Children under 2 years of age<br>• Consult a doctor or pharmacist |                                    |
| <b>Other information:</b> Store at room temperature 15-30°C (59-86°F)  |                                    |
| <b>Inactive ingredients:</b> 1,2-Propanediol, Aloe Vera Extract, Glycerin, Citric Acid, Chlorophyllin, Dimethyl Itaconate, Hydroxyethyl Cellulose, Phenylethanol, Tocopheryl Acetate, Water        |                                    |

**MAXIMUM STRENGTH**  
**ALOCANE<sup>®</sup>**  
**Emergency Burn Gel**

- Fast Pain and Itch Relief
- Assists the Healing process
- Use on Sunburns & First Degree Burns

with Vitamin E

THIS PACKAGE FOR NONSUNBURNED THOUGHT-YOUNG CHILDREN

Recommended by  
Physicians and Pharmacists

3.2 Fl Oz (94.6mL) Pump

**ALOCANE<sup>®</sup>**

ALOCANE<sup>®</sup> is recommended for First Degree Burns including:

Flame

Sun

Electricity

Heat

Light

Frictions

**Perfect for:**

- Backcountry • Desk Slips • Auto Slips
- Menstrual Cramps • Beauty Salons • Beaches
- Heat Related Work Environments

**PRINCIPAL DISPLAY PANEL - ALOCANE Burn Gel Single Use 45 Count**

**4% Lidocaine**

**MAXIMUM STRENGTH**

**ALOCANE<sup>®</sup>**

**Emergency Burn Gel**

- Use on Sunburns & First Degree Burns
- Soothing Aloe Gel & Vitamins

- Assists the Healing process
- Fast Pain and Itch Relief

with Vitamin E

Contents: 45 Single Use Packets - 0.12 Fl Oz (3.4mL)

**PRINCIPAL DISPLAY PANEL - ALOCANE Burn Spray 3.5 fl oz**

**4% Lidocaine**

**HOSPITAL  
GRADE**

# MAXIMUM STRENGTH ALOCANE<sup>®</sup>

## Emergency Burn Spray

- Fast Pain and Itch Relief
- Assists the Healing process
- Soothing Aloe Gel & Vitamins
- Use on Sunburns & First Degree Burns  
with Vitamin E

Recommended by  
Physicians and Pharmacists

**Aloe**

Net Wt  
3.5 Fl Oz (104mL)

**Drug Facts**

**Active Ingredient..... Purpose**  
Lidocaine HCL 4% ..... Topical Analgesic

**Uses:**  
For the temporary relief of pain and itching associated with: ■ Sunburn ■ Minor Burns ■ Minor Skin Irritation ■ Cuts and Scrapes

**Warnings:**  
For external use only. Avoid contact with eyes.  
**Keep out of reach of children.**  
Stop use and ask doctor if condition worsens, or if 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 care professional before use.

**Directions:**  
Adults and children 2 years of age or older  
Shake well. Apply to affected area not more than 3 to 4 times daily. Do not use in large quantities, particularly over raw surfaces or blistered areas. To apply to face, spray on palm or hand and gently apply.  
Children under 2 years of age consult a physician

**Other Information:** Store at 59°-86° F (15-30° C)

**Inactive Ingredients:** 1,3-Propanediol, Aloe Barbadosis (Aloe) Leaf Juice, Caprylyl Glycol, Chlorphenesin, Dimethyl Isosorbide, Hydroxyethyl Cellulose, Phenoxyethanol, Tocopheryl Acetate (Vitamin E), Water.



Distributed by:  
Quest Products, LLC  
Pharmaceutical Division  
www.alocane.com



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NDC #68229-201-08  
ALO\_LBL\_03258\_REV1\_10M21Y

## ALOCANE EMERGENCY BURN

lidocaine hydrochloride gel

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:68229-201 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength                 | Strength         |
|---|-----------------------------------|------------------|
| <b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE HYDROCHLORIDE ANHYDROUS | 4 g<br>in 100 mL |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>PROPANEDIOL</b> (UNII: 5965N8W85T)                               |          |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                            |          |
| <b>DIMETHYL ISOSORBIDE</b> (UNII: SA6A6V432S)                       |          |
| <b>HYDROXYETHYL CELLULOSE (5500 MPA.S AT 2%)</b> (UNII: M825OX60H9) |          |
| <b>PHENOXYETHANOL</b> (UNII: H1E492Z3T)                             |          |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                           |          |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                             |          |

**.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0)

**WATER** (UNII: 059QF0KO0R)

### Packaging

| #  | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|----|------------------|--|----------------------|--------------------|
| 1  | NDC:68229-201-02 | 1 in 1 CARTON  | 03/01/2019           |                    |
| 1  | NDC:68229-201-01 | 110 mL in 1 TUBE; Type 0: Not a Combination Product              |                      |                    |
| 2  | NDC:68229-201-03 | 110 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product     | 03/01/2020           |                    |
| 3  | NDC:68229-201-05 | 24 in 1 CARTON   | 03/01/2020           |                    |
| 3  | NDC:68229-201-04 | 3.4 mL in 1 PACKET; Type 0: Not a Combination Product            |                      |                    |
| 4  | NDC:68229-201-07 | 45 in 1 CARTON   | 03/01/2020           |                    |
| 4  | NDC:68229-201-06 | 3.4 mL in 1 PACKET; Type 0: Not a Combination Product            |                      |                    |
| 5  | NDC:68229-201-08 | 103.507 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 03/01/2020           |                    |
| 6  | NDC:68229-201-11 | 133.081 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 03/01/2020           |                    |
| 7  | NDC:68229-201-10 | 1 in 1 CARTON  | 03/01/2019           |                    |
| 7  | NDC:68229-201-09 | 118.294 mL in 1 TUBE; Type 0: Not a Combination Product          |                      |                    |
| 8  | NDC:68229-201-14 | 946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product      | 03/01/2019           | 12/31/2024         |
| 9  | NDC:68229-201-12 | 1 in 1 KIT   | 03/01/2019           | 09/30/2022         |
| 9  | NDC:68229-201-15 | 800 mL in 1 BAG; Type 0: Not a Combination Product               |                      |                    |
| 10 | NDC:68229-201-13 | 1 in 1 CARTON  | 03/01/2019           |                    |
| 10 | NDC:68229-201-15 | 800 mL in 1 BAG; Type 0: Not a Combination Product               |                      |                    |
| 11 | NDC:68229-201-18 | 1 in 1 CARTON  | 12/09/2021           |                    |
| 11 | NDC:68229-201-17 | 22 mL in 1 TUBE; Type 0: Not a Combination Product               |                      |                    |
| 12 | NDC:68229-201-16 | 124 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product     | 11/11/2022           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M017                                     | 03/01/2019           |                    |

**Labeler** - Quest Products, LLC. (075402441)

## Establishment

| Name          | Address | ID/FEI    | Business Operations    |
|---------------|---------|-----------|------------------------|
| Fill Tech USA |         | 926433855 | manufacture(68229-201) |

Revised: 11/2024

Quest Products, LLC.