

**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> <b>Adults and children 2 years of age or older</b> ■ Apply to affected area not more than 3 to 4 times daily. <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> 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**

**ALOCANE** Emergency Burn Gel is a water-based formula that quickly absorbs deep into the layers of skin.

**ALOCANE** relieves pain by the use of 4% Lidocaine Hydrochloride. Four percent is the maximum percentage of Lidocaine Hydrochloride topical anesthetic allowed by the US FDA (United States Food & Drug Administration) for use in OTC (Over-The-Counter) products.

Apply **ALOCANE** Emergency Burn Gel generously to the burned area. Repeat application of **ALOCANE** as often as necessary (no more than four times daily) to further extinguish pain and lessen the overall damage done.

**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: • 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 • Apply to affected area not more than 3 to 4 times daily • Children under 2 years of age • Use Caution in Anesthetized Patients	
<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 YOUTH/ 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 Barbadensis (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

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

ALOCANE EMERGENCY BURN			
lidocaine hydrochloride gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68229-201
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 mL
Inactive Ingredients			
	Ingredient Name	Strength	
	PROPANEDIOL (UNII: 5965N8W85T)		
	ALOE VERA LEAF (UNII: ZY81Z83H0X)		
	DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)		
	HYDROXYETHYL CELLULOSE (5500 MPA.S AT 2%) (UNII: M825OX60H9)		
	PHENOXYETHANOL (UNII: H1E492Z3T)		
	CAPRYLYL GLYCOL (UNII: 00YIU5438U)		
	CHLORPHENESIN (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: 11/2023

Quest Products, LLC.