

**COMFORTCAINE- lidocaine hcl gel**  
**QS Key West Aloe, LLC**

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**Comfortcaine**

***Active Ingredients***

Lidocaine Hydrochloride (4% w/w)

***Purpose***

Topical Analgesic

***Uses***

• For the temporary relief of pain associated with minor burns, sunburn, scrapes, or minor skin irritations.

***Warnings***

- For external use only.
- Avoid contact with the eyes.
- ***Do not use*** in large quantities, particularly over raw surfaces or blistered areas.
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

***Keep out of reach of children***

- If accidentally ingested contact a physician or Poison Control Center immediately.

***Directions***

- Adults and children 2 years of age or older: Apply to affected area not more than 3 or 4 times daily. Children under 2 years of age: consult a physician.

***Inactive Ingredients:***

Aloe Barbadensis Leaf Extract, Water, Acrylates/c10-30 Alkyl Acrylate Crosspolymer, Phenoxyethanol, Sodium Hydroxide, Disodium EDTA, Caprylyl Glycol, Yellow No 5, FD&C Blue No 1.

***Other Information***

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

# Questions or comments?

1-800-445-2563

**COMFORTCAINE™**  
INSTANT SUNBURN RELIEF



**KEY WEST ALOE™**  
PURELY BY NATURE™

**COMFORTCAINE™**  
INSTANT SUNBURN RELIEF

**94%**  
PURE ALOE VERA  
+  
**4%**  
LIDOCAINE  
MAXIMUM STRENGTH

4 oz/113 mL



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**COMFORTCAINE™**  
INSTANT SUNBURN RELIEF

Delivers instant relief and soothing moisture to minor burns, sunburn, and insect bites. With maximum strength Lidocaine and 94% Pure Aloe Vera, Comfortcaine delivers relief every time.

**Drug Facts**

Active Ingredients	Purpose
Lidocaine Hydrochloride (4% w/w)	Topical Anesthetic

**Uses**

- For the temporary relief of pain associated with minor burns, sunburn, scrapes, or minor skin irritations.

**Warnings**

- For external use only.
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- Do not use in large quantities, particularly over raw surfaces or blistered areas.
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**Directions**

- Adults and children 2 years of age and older: Apply to affected area not more than 3 or 4 times daily. Children under 2 years of age: consult a physician.

**Inactive Ingredients:** Aloe Barbadensis Leaf Extract, Water, Acrylamide/CPD, Algin Acrylate Copolymer, Phenoxyethanol, Sodium Hydroxide, Disodium EDTA, Capryl Glycol, Yellow No. 5, Blue No. 1.

**Other Information**

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

**Questions or comments? 1-800-445-2563**



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INSTANT SUNBURN RELIEF

Delivers instant relief and soothing moisture to minor burns, sunburn, and insect bites. With maximum strength Lidocaine and 94% Pure Aloe Vera, Comfortcaine delivers relief every time.

Directions: Apply generously to clean irritated skin. For further cooling relief, refrigerate Comfortcaine. See Drug Facts for complete information.

Distributed by Key West Aloe  
Key West, FL 34901 USA  
888.452.7565  
keywestaloe.com  
Product ID: 201



COMFORTCAINE

## COMFORTCAINE

lidocaine hcl gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65008-005
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 132584PQMO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65008-005-04	1 in 1 CARTON	06/23/2023	
1		113 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	11/12/2004	

**Labeler** - QS Key West Aloe, LLC (969600555)

## Establishment

Name	Address	ID/FEI	Business Operations
Southeast Holdings Corp		080504027	manufacture(65008-005) , label(65008-005) , pack(65008-005)

Revised: 11/2025

QS Key West Aloe, LLC