

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

*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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**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™**  
PERFECT BY NATURE™

**COMFORTCAINE™**  
INSTANT SUNBURN RELIEF

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

4 oz / 113 mL

**INSTANT RELIEF**  
SUNBURN  
MINOR BURNS  
MINOR CUTS  
MINOR SKIN IRRITATIONS  
SCRAPES  
INSECT BITES

**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.
- 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 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 Barbados Leaf Extract, Water, Acrylates/C10-18 Alkyl Acrylate Copolymer, Phenoxyethanol, Sodium Hydroxide, Disodium EDTA, Caprylyl 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

Distributed by Key West Aloe  
Key West, FL • Made in U.S.A.  
1-800-445-2563  
KeyWestAloe.com  
Product ID: 2001

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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.

**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 / Made in U.S.A.  
800-445-2563  
KeyWestAloe.com  
Product ID: 201



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**COMFORTCAINE**  
lidocaine hcl gel

## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 132584PQMO)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part348	11/12/2004	

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