**BIKINI ZONE MEDICATED CREME- lidocaine cream**
**CCA Industries, Inc.**

*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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**Bikini Zone Medicated CREME**

**Drug Facts**

**Active Ingredient**

LIDOCAINE 2.00%

**Purpose**

topical analgesic/anesthetic

**Use**

temporarily relieves pain and itching associated with minor skin irritation.

**Warnings**

**For external use only.**

**Avoid contact with eyes**

**Do not use**

- in large quantities, particularly over raw surfaces or blistered areas.
- before any hair removal process that involves heat or lasers

**Stop use and ask a doctor if**

- Condition worsens
- Symptoms last for more than 7 days or clear up and occur again within a few days.
- redness is present
- irritation develops

**Keep out of reach of children**

In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

**Directions**

**adults and children 12 years and older**

- see top of cap to open tube

- immediately after hair removal, apply sparingly to areas affected
- repeat as necessary, but no more than 4 times daily
- continue to apply as a part of your hair removal routine, whether you use a razor, wax or depilatory.
- children under 2 years: ask a doctor

***Other information***

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

**Inactive Ingredients**

aloe barbadensis gel, benzyl alcohol, camphor, cetearyl alcohol, cyclohexasiloxane, cyclopentasiloxane, disodium edta, diazolidinyl urea, fragrance, glyceryl dilaurate, glyceryl stearate, hexylene glycol, lactic acid, menthol, methylparaben, octyldodecanol, peg-40 stearate, peg-100 stearate, polyquaternium-37, ppg-1 trideceth-6, propylene glycol dicaprylate/dicaprate, propylene glycol, propylparaben, salicylic acid, sd alcohol 23a, sodium hydroxide, water (aqua).

**Questions or Comments?**

Call 1-800-595-6230

**Package Labeling:**


# BIKINI ZONE MEDICATED CREME

lidocaine cream

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:61543-1601 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **LIDOCAINE** (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 2 g in 100 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **BENZYL ALCOHOL** (UNII: LKG8494WBH) | |
| **CAMPHOR (NATURAL)** (UNII: N20HL7Q941) | |

| | |
|---|---|
| **CETOSTEARYL ALCOHOL** (UNII: 2DMT128M1S) | |
| **CYCLOMETHICONE 6** (UNII: XHK3U310BA) | |
| **CYCLOMETHICONE 5** (UNII: 0THT5PCI0R) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **DIAZOLIDINYL UREA** (UNII: H5RIZ3MPW4) | |
| **GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4) | |
| **HEXYLENE GLYCOL** (UNII: KEH0A3F75J) | |
| **LACTIC ACID** (UNII: 33X04XA5AT) | |
| **MENTHOL** (UNII: L7T10EIP3A) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **OCTYLDODECANOL** (UNII: 461N1O614Y) | |
| **POLYOXYL 100 STEARATE** (UNII: YD01N1999R) | |
| **PROPYLENE GLYCOL DICAPRYLATE** (UNII: 581437HWX2) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **SALICYLIC ACID** (UNII: O414PZ4LPZ) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |
| **WATER** (UNII: 059QF0KO0R) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:61543-1601-1 | 1 in 1 BOX | 03/15/2019 | |
| **1** | | 28 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part333B | 06/03/2010 | |

## Labeler - CCA Industries, Inc. (106771041)

Revised: 12/2022 CCA Industries, Inc.