

**BURN RELIEF EXTRA STRENGTH KOOL-DOWN- lidocaine - 3.9% cream**  
**Kool-Down 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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**Active ingredient**

Lidocaine - 3.9%

**Purpose**

Topical Pain Reliever

**Keep Out of Reach of Children**

If swallowed, get medical help or contact a Poison Control Center right away.

**Uses**

Temporarily relieves pain due to:

- burns
- insect bites
- itching

**Warnings**

**For external use only.**

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

**When using this product** keep out of eyes, use only as directed.

**Stop use and ask a doctor if**

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days.

**Directions**

Adults and children 5 years of age and older: apply to affected area not more than 3-4 times daily.  
Children under 5 years of age: ask a doctor.

**Inactive ingredients**

Aloe Barbadensis Leaf Juice

Glycerin

Stearic Acid

Glyceryl Stearate SE

Isopropyl Myristate

Ethoxydiglycol

Ozokerite

Polysorbate 80

Carbomer

Zinc Oxide

Allantoin

Ascorbic Acid

Methylparaben

Diazolidinyl Urea

Propylparaben

Triethanolamine

Tetrasodium EDTA

Tocopheryl Acetate

Prunus Amygdalus Dulcis (Sweet Almond) Oil

Canola Oil

Fragrance

# Kool-Down<sup>®</sup>

## Burn Relief

**EXTRA STRENGTH  
LIDOCAINE**

STOPS PAIN FAST

Pure Aloe Vera

**THE VACATION SAVER**

ORIGINAL FORMULA  
NEW SAFETY PACKAGE



CEO  
Dan Perkins



SATISFACTION  
GUARANTEE

NET WT. 4 OZ. (113 g)

Recommended by Pharmacist

**Drug Facts**

<b>Active ingredient</b>	<b>Purpose</b>
Lidocaine 3.9%.....	Topical pain reliever

**Uses** Temporarily relieves pain due to:

- burns • insect bites • itching

**Warnings**

**For external use only.**

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

**When using this product** • keep out of eyes  
• use only as directed.

**Stop use and ask doctor if** • condition gets worse • symptoms last more than 7 days • symptoms clear up and occur again in a few days.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions** • adults and children 5 years of age and older: apply to affected area not more than 3 to 4 times daily  
• children under 5 years of age: ask a doctor.

**Inactive ingredients** Aloe Barbadosis Leaf Juice, Glycerin, Stearic Acid, Glyceryl Stearate SE, Isopropyl Myristate, Ethoxydiglycol, Ozokerite, Polysorbate 80, Carbomer, Zinc Oxide, Allantoin, Ascorbic Acid, Methylparaben, Diazolidinyl Urea, Propylparaben, Triethanolamine, Tetrasodium EDTA, Tocopheryl Acetate, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Canola Oil, Fragrance.

DISTRIBUTED BY: **KOOL-DOWN, INC**  
2706 SOUTH RIDGEWOOD AVE  
SOUTH DAYTONA, FL 32119

**www.kooldown.com**  
KEEP OUT OF EXTREME HEAT



0 43399 56348 0

## BURN RELIEF EXTRA STRENGTH KOOL-DOWN

lidocaine - 3.9% cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61566-117
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	3.9 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
ALOE (UNII: V5VD430YW9)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
CERESIN (UNII: Q1LS2UJO3A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)
ZINC OXIDE (UNII: SOI2LOH54Z)
ALLANTOIN (UNII: 344S277G0Z)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
METHYL PARABEN (UNII: A2I8C7HI9T)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
TROLAMINE (UNII: 9O3K93S3TK)
EDETATE SODIUM (UNII: MP1J8420LU)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ALMOND OIL (UNII: 66YXD4DKO9)
CANOLA OIL (UNII: 331KBJ17RK)

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61566-117-04	113 g in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2013	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/15/2013	

**Labeler** - Kool-Down Inc (146580548)

**Registrant** - CGI Packaging, LLC (080691099)

**Establishment**

Name	Address	ID/FEI	Business Operations
CGI Packaging, LLC		080691099	manufacture(61566-117)