

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.

Active ingredient

Lidocaine - 3.9%

Purpose

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 a doctor if condition worsens or symptoms last more than 7 days or clear up and occur again within 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 3-4 times daily.

Children under 5 years of age: ask a doctor.

Inactive ingredients

Aloe Barbados 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[®]

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

Active ingredient	Purpose
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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61566-279
Route of Administration	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)
METHYLPARABEN (UNII: A2I8C7HI9T)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
PROPYLPARABEN (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:61566-279-04	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 - Derma Care Research Labs (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs		116817470	manufacture(61566-279)