

BURN RELIEF PROFESSIONAL BIO-KOOL- lidocaine - 4% 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.

Drug Facts

Lidocaine - 4.0%

Topical Pain Reliever

Uses

Temporarily relieves pain due to: sunburns, burns, insect bites, and itching.

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

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.

Aloe Barbadensis Leaf Juice, Glycerol, 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, Fragrance.

Bio-Kool[®]

Professional Burn Relief

**MAXIMUM STRENGTH
LIDOCAINE 4.0%**

STOPS PAIN FAST

Zinc, Vitamin C & Aloe

THE VACATION SAVER

ORIGINAL FORMULA
NEW SAFETY PACKAGE



CEO
Dan Perkins



SATISFACTION
GUARANTEE

NET WT. 4 OZ. (113 g)

Recommended by Dermatologists

Drug Facts

Active ingredient	Purpose
Lidocaine 4.0%	Topical pain reliever

Uses Temporarily relieves pain due to:
• sunburns • 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 Barbadensis Leaf Juice, Glycerol, 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, Fragrance.



DISTRIBUTED BY: KOOL-DOWN, INC
2706 SOUTH RIDGEWOOD AVE
SOUTH DAYTONA, FL 32119
www.kooldown.com
KEEP OUT OF EXTREME HEAT

BURN RELIEF PROFESSIONAL BIO-KOOL

lidocaine - 4% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61566-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61566-201-04	113 g in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/15/2013	

Labeler - Kool-Down Inc. (146580548)

Registrant - Derma Care Research Labs (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs		116817470	manufacture(61566-201)