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, particularity 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.



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.

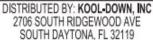
Stop use and ask doctor if . condition gets worse symptoms last more than 7 days
symptoms clear up and occur

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.



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

Basis of Strength Strength **Ingredient Name** LIDO CAINE (UNII: 98 PI200987) (LIDO CAINE - UNII: 98 PI200987) LIDOCAINE 4 g in 100 g

Inactive Ingredients Strength **Ingredient Name** ALOE (UNII: V5VD430 YW9) GLYCERIN (UNII: PDC6A3C0OX) STEARIC ACID (UNII: 4ELV7Z65AP) GLYCERYL STEARATE SE (UNII: FCZ5MH785I) ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS) DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8 X02B) CERESIN (UNII: Q1LS2UJO3A) POLYSORBATE 80 (UNII: 6OZP39ZG8H)

CARBO XYPO LYMETHYLENE (UNII: 0 A5MM307FC)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
ALLANTO IN (UNII: 344S277G0Z)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZO LIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE SO DIUM (UNII: MP1J8420LU)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALMOND OIL (UNII: 66 YXD4DKO9)	

ı	Packaging						
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
ı	1 NDC:61566-201-04	113 g in 1 BOTTLE; Type 0: Not a Combination Product	0 1/15/20 13				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part348	0 1/15/20 13				

Labeler - Kool-Down Inc. (146580548)

Registrant - Derma Care Research Labs (116817470)

Establishment						
Name	Address	ID/FEI	Business Operations			
Derrma Care Research Labs		116817470	manufacture (6 156 6 - 20 1)			

Revised: 2/2019 Kool-Down Inc.