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, 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 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 that 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.



Drug Facts

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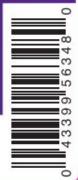
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DISTRIBUTED BY: KOOL-DOWN, INC 2706 SOUTH RIDGEWOOD AVE SOUTH DAYTONA, FL 32119

www.kooldown.com KEEP OUT OF EXTREME HEAT



BURN RELIEF EXTRA STRENGTH KOOL-DOWN

lidocaine - 3.9% cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61566-279

TOPICAL Route of Administration

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name Strength 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: 6 OZP39 ZG8 H)

CARBO XYPO LYMETHYLENE (UNII: 0 A5MM30 7FC)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
ALLANTO IN (UNII: 344S277G0 Z)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE SO DIUM (UNII: MP1J8420LU)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALMOND OIL (UNII: 66 YXD4DKO9)	
CANOLA OIL (UNII: 331KBJ17RK)	

ı	Packaging						
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
ı	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)				

Revised: 2/2019 Kool-Down Inc