RESTORE LIDOCAINE PAIN RELIEF CREAM- lidocaine cream RENU LABORATORIES, 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.

Restore BY PURE RESEARCH Pain Relief Cream

Restore By Pure Research LIDOCAINE PAIN RELIEF CREAM

Lidocaine HCl 4%

Purpose

Topical anesthetic

Uses: to reduce pain or discomfort caused by skin irritations such as sunburn, insect bites, poison ivy, poison oak, poison sumac, and minor cuts, scratches or burns.

For External Use only

When using this product, do not use in or near the eyes

• do not use in large quantities, particularly over raw surfaces or blistered areas.

Stop Use and ask a doctor if:

- allergic reaction occurs
- condition worsens or does not improve within 7 days
- symptoms clear up and return within a few days
- redness, irritation, swelling, pain or other symptoms begin.

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

Directions: adults and children 2 years and older apply externally to the affected area up to 3 to 4 times a day

Children under 2 years, ask a doctor

May be applied under occlusive dressing

Store at 20 - 25° C

support@restoriden.com

Arnica Montana Extract, Capryl Glycol, Caprylic/Capric Triglycerides, Cetearyl Alcohol, Deionized Water, Emulsifying Wax NF, Ethylhexylglycerin, Glycerin, Hexylene Glycol, Hippophae Rhamnoides Fruit and Seed Oils, Phenoxyethanol, Polysorbate 20, Propylene Glycol, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hydroxide, Stearic Acid, Tetrasodium EDTA, Tocopherol

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RESTORE BOX





OTHER INFORMATION: Store at 68-77°F (20-25°C) Questions? support@restoriden.com

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Fruit and Seed Oils, Phenoxyethanol, Polysorbate 20, Propylene Glycol, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium

Hydroxide, Stearic Acid, Tetrasodium EDTA, Tocopherol.

lidocaine cream

Product Information							
Product Type	HUMAN OTC DRUG	ltem (Code (Source)	NDC:763	48-605		
Route of Administration	TOPICAL						
Active Ingredient/Active Moiety							
Ingredie	nt Name		Basis of Streng	yth	Strength		
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)		IE -	LIDOCAINE HYDROCHLORIDE ANHYDROUS		2.24 g in 56 g		

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Inactive Ingre	dients			
	Ingredient Name		Strength	
HEXYLENE GLYCOI	(UNII: KEH0A3F75J)			
HIPPOPHAE RHAMI	NOIDES SEED OIL (UNII: T53SBG6741)			
WATER (UNII: 059QI	FOKOOR)			
WHITE WAX (UNII:	7G1J5DA97F)			
MEDIUM-CHAIN TR	IGLYCERIDES (UNII: C9H2L21V7U)			
PROPYLENE GLYCO	DL (UNII: 6DC9Q167V3)			
JOJOBA OIL (UNII: 7	24GKU717M)			
CETOSTEARYL ALC	OHOL (UNII: 2DMT128M1S)			
ARNICA MONTANA	FLOWER (UNII: OZ0E5Y15PZ)			
CAPRYLYL GLYCOL	. (UNII: 00YIU5438U)			
ETHYLHEXYLGLYC	ERIN (UNII: 147D247K3P)			
STEARIC ACID (UNI	: 4ELV7Z65AP)			
TOCOPHEROL (UNI	: R0ZB2556P8)			
POLYSORBATE 20	(UNII: 7T1F30V5YH)			
HIPPOPHAE RHAMI	NOIDES FRUIT OIL (UNII: TA4JCF9S1J)			
GLYCERIN (UNII: PD	C6A3C0OX)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
EDETATE SODIUM (UNII: MP1J8420LU)				
Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:76348-605- 01	1 in 1 BOX	05/05/2021		
1 NDC:76348-605- 02	56 g in 1 JAR; Type 0: Not a Combination Product			

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph not pa	part348	05/05/2021	

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Labeler - RENU LABORATORIES, INC. (945739449)
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Establishment					
Name	Address	ID/FEI	Business Operations		
RENU LABORATORIES, INC.		945739449	manufacture(76348-605)		