

RESTORIDEN LIDOCAINE 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.

Restoriden Lidocaine Pain Relief Cream

Restoriden Nutrition 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

PRODUCT LABEL

Topical anesthetic cream with Vitamin E

Restoriden 2oz / 57g

MADE IN USA

LIDOCAINE PAIN RELIEF CREAM

Fast acting
Long lasting
Expertly formulated

MANUFACTURED FOR: RESTORIDEN & Liberty Square #0203 Boston, MA 02109

NDC 76348-583-02

Peel Back for Drug Facts

Drug Facts

Active Ingredient: Lidocaine HCl 4% Purpose: Topical anesthetic

Use: 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.

Warnings: 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

Drug Facts (continued)

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

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

Other Information: May be applied under occlusive dressing - Store at 20-25°C (68-77°F)
Questions? support@restoriden.com

MANUFACTURED FOR: RESTORIDEN & Liberty Square #0203 Boston, MA 02109

AND PRODUCT BOX

Card Box
2.5 x 2.5 x 2.375 (inch)

OUR STORY
We created Restoriden with the sole purpose of creating high quality, affordable products for consumers.
We are a small business based in Massachusetts and we strive very hard to make sure our customers get the quality they deserve.
If for any reason you are not happy with any of our products, please contact us at support@restoriden.com
We will be sure to make things right within 24 hours of you contacting us.

Restoriden 2oz / 57g

LIDOCAINE PAIN RELIEF CREAM

CHILD RESISTANT PACKAGING

Fast acting Expertly formulated
Long lasting
Topical anesthetic cream with Vitamin E

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NDC 76348-583-02

RESTORIDEN LIDOCAINE CREAM
lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-583
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2.24 g in 56 g

Inactive Ingredients

Ingredient Name	Strength
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)	
WATER (UNII: 059QF0K00R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
HIPPOPHAE RHAMNOIDES FRUIT OIL (UNII: TA4JCF9S1J)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE SODIUM (UNII: MP1J8420LU)	
WHITE WAX (UNII: 7G1J5DA97F)	
JOJOBA OIL (UNII: 724GKU717M)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-583-01	1 in 1 BOX	10/20/2020	
1	NDC:76348-583-02	56 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/20/2020	

Establishment

Name	Address	ID/FEI	Business Operations
RENU LABORATORIES, INC.		945739449	manufacture(76348-583)

Revised: 10/2020

RENU LABORATORIES, INC.