CALM AND CORRECT SERUM WITH LIDOCAINE- lidocaine 3 percent liquid 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.

CALM and CORRECT PAIN RELIEF SERUM

Active Ingredient

Lidocaine 3%

Purpose

External Analgesic

Uses

Temporarily relieves pain and itching due to

- sunburn
- minor burns
- minor cuts
- minor skin irritations

Warnings

For external use only

Stop use and ask a doctor if

- Condition gets worse
- Symptoms persist for 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 2 years and older apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor

Inactive Ingredients:

Cyclopentasiloxane, Dihydroeugenol, Dimethicone, Dimethiconol, Dimethicone/Vinyl Dimethicone Crosspolymer, Helianthus Annuus (Sunflower) Seed Oil, Isoeugenyl Acetate, Petrolatum, Simmondsia Chinensis (Jojoba) Seed Oil, Squalane.

Manufactured in the U.S.A. for Dermamedics, LLC

Oklahoma City, OK 73112

www.dermamedics.com

1 800 990 6552

DERMAMEDICS

Calm & Correct

Pain Relief

Serum with

3 % Lidocaine

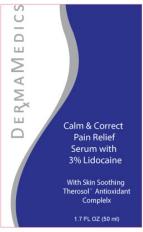
When using this product

Do not use in large quantities particularly over raw surfaces or blistered areas

Avoid contact with the eyes







	Facts
	Ingredient Purpose e 3.0% External Analgesic
	arily relieves pain and itching due to: m = minor burns = minor cuts = minor skin irritations
Warni For Ex	ngs ernal Use Only
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1	Manufactured in the U.S.A. for DermaMedics, LLC

107mmX76mm



lidocaine 3 percent liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76348-725

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	1.5 g in 50 mL

Inactive Ingredients			
Ingredient Name	Strength		
CYCLOMETHICONE 5 (UNII: OTHT5PCIOR)			
PETROLATUM (UNII: 4T6H12BN9U)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)			
ISOEUGENYL ACETATE (UNII: 9DF21GI8W6)			
JOJOBA OIL (UNII: 724GKU717M)			
DIHYDROEUGENOL (UNII: A3XE712277)			
SUNFLOWER OIL (UNII: 3W1JG795YI)			
SQUALANE (UNII: GW89575KF9)			

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:76348-725-01	1 in 1 BOX	08/02/2022			
1 NDC:76348-725-50	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M015	08/02/2022		

Labeler - Renu Laboratories, Inc. (945739449)

Establishment				
Name	Address	ID/FEI	Business Operations	
Renu Laboratories, Inc.		945739449	manufacture(76348-725)	

Revised: 4/2022 Renu Laboratories, Inc.