NUMB GEL ANESTHETIC- lidocaine hcl gel
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.

NUMB Gel Anesthetic

Lidocaine HCl 4%

Topical anesthetic

Uses: For temporary relief of pain associated with minor skin procedures

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. • do not use on puncture wounds • for more than one week without consulting a doctor

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 or increase

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 the affected area up to 3 to 4 times a day

children under 2 years - ask a doctor

Inactive Ingredients: Aloe Barbadensis Leaf Powder, Benzyl Alcohol, Deionized Water, Disodium EDTA, Ethyl Alcohol SD 40B, Glycerin

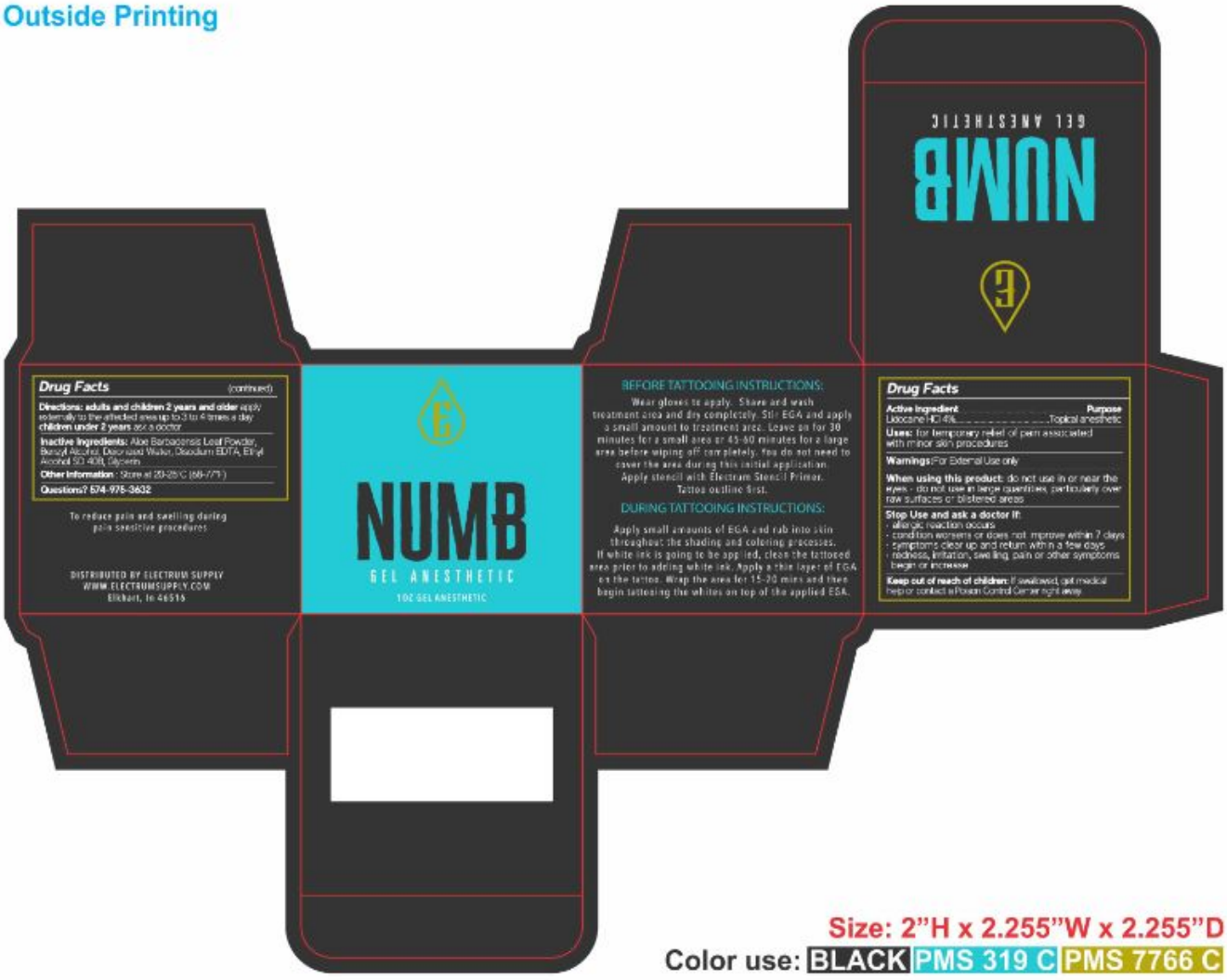
Store at 20 - 25 C (68 - 77 degrees F)

Questions? 574-975-3632

If pregnant or breast-feeding, ask a health professional before use.

JAR LABEL AND BOX ART

Outside Printing



Size: 2”H x 2.255”W x 2.255”D

Color use: BLACK PMS 319 C PMS 7766 C

NUMB GEL ANESTHETIC

lidocaine hcl gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76348-595
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	1.12 g in 28 g

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76348-595-02	1 in 1 BOX	11/20/2020	
1	NDC:76348-595-01	28 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	11/20/2020	

Labeler - RENU LABORATORIES, INC. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
RENU LABORATORIES, INC.		945739449	manufacture(76348-595)

Revised: 1/2022 RENU LABORATORIES, INC.