# PRO NUMB- tattoo numbing spray spray Pro Numb Tattoo Numbing Spray LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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## **Pro Numb Tattoo Numbing Spray 120 mL**

## **Active Ingredient(s)**

Lidocaine HCI 5% Epinephrine HCI .01%

## **Purpose**

**Topical Anesthetic** 

#### Use

Temporarily takes away pain, itching, and swelling associated with anorectal disorders or pain-sensitive procedures.

## **Warnings**

External Use Only. Keep out of reach of children.

Do not use if you have • seizures or liver disease • if pregnant or breastfeeding • a known allergy or sensitivity occurs, discontinue use, and seek medical attention. If the condition intensifies or symptoms persist for more than seven days or clear up and occur again within a few days, Cease the use of this product and consult a doctor. Do not use in large quantities, Particularly over raw surfaces or blistered areas. Avoid contact with the eyes. If contact should occur, irrigate with large amounts of sterile saline and seek medical attention. Do not swallow, if swallowed, seek medical attention immediately.

When using this product, you may notice temporary whiting or redness of the skin where pro numb is applied.

Keep out of reach of children.

#### **Directions**

Sensitivity test encouraged before use. Spray a small amount on the broken area of the skin. Wait 60 seconds for the anesthetic to start working. Wash Pro Numb off completely before tattooing.

#### Other information

Store in a cool dark place or refrigerate and keep out of reach of children. Discard the item after the expiration date is due.

## **Inactive ingredients**

purified RO water, Paraben-DU, Disodium EDTA, Citric acid, Optiphen.

Call: (800) 865-4965

## **Package Label - Principal Display Panel**



Drug Fact- For Use by Licensed Tattoo artists onlyActive IngredientsPurposeLidocaine HCI5%Topical AnestheticEpinephrine HCI.01%Vasoconstriction

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Questions? Contact pro numb Distribution

Distributed by:
Pro Numb Tattoo numbing spray LLC
Melbourne, FL, 32907 (800) 865-4965
www.tattoonumbingsprays.com

120mL Spray NDC: 83389-111-11

#### **PRO NUMB**

tattoo numbing spray spray

	Inform	241212

Product Type HUMAN OTC DRUG Item Code (Source) NDC:83389-111

**Route of Administration** TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
<b>EPINEPHRINE HYDROCHLORIDE</b> (UNII: WBB0470038) (EPINEPHRINE - UNII:YKH83404BH)	EPINEPHRINE HYDROCHLORIDE	0.1 mg in 100 mL		
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	5 mg in 100 mL		

Inactive Ingredients		
Ingredient Name	Strength	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
WATER (UNII: 059QF0KO0R)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		

ı	Pac	Packaging			
	# 1	tem Code	Package Description	Marketing Start Date	Marketing End Date
			120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/12/2023	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		04/12/2023		

## **Labeler -** Pro Numb Tattoo Numbing Spray LLC (118964052)

Revised: 7/2023 Pro Numb Tattoo Numbing Spray LLC