PRO PLUS- lidocaine hcl, tetracaine hcl cream
Dermal Source, Inc.

Drug Facts - For use by licensed professionals only.

Active Ingredients (in each cc)	***Purpose***
Lidocaine HCl 5%	Topical Anesthetic
Tetracaine HCl 1%	Topical Anesthetic

Uses: External Use Only on Intact Skin. Temporarily relieves pain due to tattooing or other pain sensitive procedures.

Warnings: Keep out of children's reach.
Keep out of eyes and mouth. In case of accidental contact with eyes, rinse immediately with copious amounts of eyewash. Seek care by an eye care physician. If accidentally swallowed, get medical help immediately.

Do not use:

- If you have a history of severe liver disease or impairment.
- If you have a known allergy or sensitivity to any of the components of this product. If sensitivity occurs, discontinue use and seek medical attention as needed. If condition worsens or does not improve in seven days, or clears up and occurs again within a few days, discontinue use of this product and consult a doctor. Do not use in large quantities, particularly over raw surfaces or blistered areas.
- If pregnant or nursing.

Directions: Sensitivity test advised prior to use.

Apply sparingly to affected area for 15-30 minutes or until anesthetic effect occurs. Remove and cleanse skin. Repeat as needed up to three times a day.

Inactive Ingredients: Purified Water, Glycerol Monostearate, Petrolatum, Stearic Acid, Cetyl Alcohol, Hydroxyethylcelluose, Triethanolamine, PEG 100 Stearate, Propyl Paraben, Methyl Paraben, and BHT.

Other information: Discard after expiration date. Store in cool, dark place.

Questions? Contact distributor on product label.

PRINCIPAL DISPLAY PANEL

PREMIUM

PRO PLUS

Topical Anesthetic for use before a pain sensitive procedure

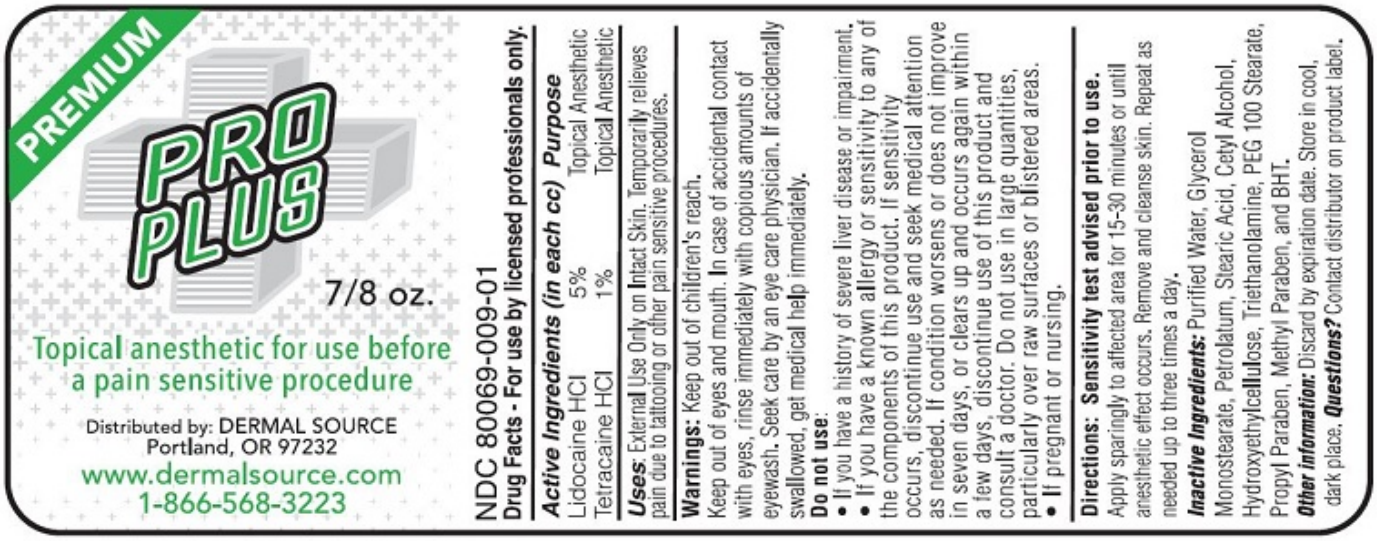
7/8 oz.

Distributed by: DERMAL SOURCE
Portland, OR 97232

www.dermalsource.com
1-866-568-3223

NDC 80069-009-01

NDC Drug Facts - For use by licensed professionals only.



PRO PLUS
lidocaine hcl, tetracaine hcl cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80069-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	Lidocaine Hydrochloride Anhydrous	50 mg in 29.5735 mL
Tetracaine Hydrochloride (UNII: 5NF5D4OPCI) (Tetracaine - UNII:0619F35CGV)	Tetracaine Hydrochloride	10 mg in 29.5735 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Petrolatum (UNII: 4T6H12BN9U)	
Hydroxyethyl Cellulose, Unspecified (UNII: T4V6TWG28D)	
Trolamine (UNII: 9O3K93S3TK)	
Peg-100 Stearate (UNII: YD01N1999R)	
Propylparaben (UNII: Z8IX2SC1OH)	
Methylparaben (UNII: A2I8C7HI9T)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80069-009-01	25.8768 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	04/10/2021	

Labeler - Dermal Source, Inc. (183535629)

Establishment

Name	Address	ID/FEI	Business Operations
HTO Nevada, Inc. (dba Kirkman)		117115846	manufacture(80069-009)

Revised: 10/2023 Dermal Source, Inc.