BLUE GEL ANESTHETIC- lidocaine hcl, tetracaine hcl, racepinephrine hcl gel
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
Racepinephrine HCl 0.01%	Vasoconstrictor

Uses: External Use Only. Temporarily relieves pain and swelling due to tattooing, permanent makeup or other pain sensitive procedures.

Warnings: Avoid contact with eyes.
Do not swallow. Keep out of children's reach.
Do not use if you have

- A history of severe liver disease or impairment
- A known allergy or sensitivity to any of the components of this product.

If sensitivity occurs, consult a doctor if condition worsens or does not improve in seven days, or clears up and occurs again within a few days. Do not use in large quantities, particularly over raw surfaces or blistered areas.

Do not use if pregnant or nursing. 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.

When using this product

- You may notice temporary blanching, skin irritation or sensitivity of the skin where gel is applied
- You may not have pain - avoid sources of heat or injury
- You may have delayed swelling after drug is dissipated

Directions: Sensitivity test advised prior to use.

Apply sparingly to broken skin and cover with occlusive dressing. Product is ineffective when applied to intact skin. Wait until anesthetic effect occurs (2-5 minutes). Remove product before continuing with your procedure.

Inactive Ingredients: Purified Water, Ethoxydiglycol, Propylene Glycol, Hydroxyethylcellulose, Sodium Metabisulfite, L-Epinephrine, Diazolidinyl Urea, Disodium EDTA, Methyl Paraben, Propyl Paraben, Sodium Citrate, Citric Acid, FD&C

Yellow 5, and FD&C Blue 1.

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

Questions? Contact distributor on product label for further questions.

PRINCIPAL DISPLAY PANEL

NEW & IMPROVED

BLUE
GEL
ANESTHETIC

To reduce pain and swelling during pain sensitive procedures.

1 oz.

Distributed by: DERMAL SOURCE
Portland, OR 97232

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

BLUE GEL ANESTHETIC

lidocaine hcl, tetracaine hcl, racepinephrine hcl gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80069-013

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 1 g
Tetracaine Hydrochloride (UNII: 5NF5D4OPCI) (Tetracaine - UNII:0619F35CGV)	Tetracaine Hydrochloride	10 mg in 1 g
Racepinephrine Hydrochloride (UNII: 336096P2WE) (Racepinephrine - UNII:GR0L9S3J0F)	Racepinephrine	0.1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Diethylene Glycol Monoethyl Ether (UNII: A1A1I8X02B)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Hydroxyethyl Cellulose, Unspecified (UNII: T4V6TWG28D)	
Sodium Metabisulfite (UNII: 4VON5FNS3C)	
Epinephrine Hydrochloride (UNII: WBB047OO38)	
Diazolidinyl Urea (UNII: H5RIZ3MPW4)	
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Sodium Citrate, Unspecified Form (UNII: 1Q73Q2JULR)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Fd&C Yellow No. 5 (UNII: I753WB2F1M)	
Fd&C Blue No. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80069-013-01	28.3495 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/07/2022	11/24/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	06/07/2022	11/24/2024

Labeler - Dermal Source, Inc. (183535629)

Establishment

Name	Address	ID/FEI	Business Operations
HTO Nevada, Inc. (dba Kirkman)		117115846	manufacture(80069-013)