LIDODOSE- lidocaine hydrochloride gel
Gensco Laboratories, LLC

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.

LidoDose Topical Anesthetic

Dosage and Administration

Adults and children 2 years of age and older: Apply using a gloved hand. Swirl the applicator tip prior to removing swab from the pouch and apply to area 3-5 minutes prior to procedure not more than 4 times daily.

Children under 2 years of age: consult a physician.

Usage

Pain relief

Warning: for external use only.

Methemoglobinemia

Cases of methemoglobinemia have been reported in association with local anesthetic use. Although all patients are at risk for methemoglobinemia, patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, infants under 6 months of age, and concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing clinical manifestations of the condition. If local anesthetics must be used in these patients, close monitoring for symptoms and signs of methemoglobinemia is recommended.

Signs and symptoms of methemoglobinemia may occur immediately or may be delayed some hours after exposure and are characterized by a cyanotic skin discoloration and abnormal coloration of the blood. Methemoglobin levels may continue to rise; therefore, immediate treatment is required to avert more serious central nervous system and cardiovascular adverse effects, including seizures, coma, arrhythmias, and death. Discontinue LidoDose and any other oxidizing agents. Depending on the severity of the symptoms, patients may respond to supportive care, i.e., oxygen therapy, hydration. More severe symptoms may require treatment with methylene blue, exchange transfusion, or hyperbaric oxygen.

Avoid contact with eyes.

Stop use and consult a physician if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days. Do not use in large

quantities, particularly over raw surfaces or blistered areas.

DRUG INTERACTIONS

Patients that are administered local anesthetics may be at increased risk of developing methemoglobinemia when concurrently exposed to the following oxidizing agents:

Class	Examples
Nitrates/Nitrites	nitroglycerin, nitroprusside, nitric oxide, nitrous oxide
Local anesthetics	benzocaine, lidocaine, bupivacaine, inepivacaine, tetracaine, prilocaine, procaine, articaine, ropivacaine
Antineoplastic agents	cyclophosphamide, flutamide, rasburicase, ifosfamide, hydroxyurea
Antibiotics	dapsone, sulfonamides, nitrofurantoin, para¬aminosalicylic acid
Antimalarials	chloroquine, primaquine
Anticonvulsants	phenytoin, sodium valproate, phenobarbital
Other drugs	acetaminophen, metoclopramide, sulfa drugs (i.e., sulfasalazine), quinine

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Storage

Store between 68 and 77 F (20 - 25 C), with allowed excursions between 59 and 86 F (15 - 30 C). Protect from freezing. (See USP Controlled Room Temperature).

PATIENT COUNSELING INFORMATION

Inform patients that use of local anesthetics may cause methemoglobinemia, a serious condition that must be treated promptly. Advise patients or caregivers to stop use and seek immediate medical attention if they or someone in their care experience the following signs or symptoms: pale, gray, or blue colored skin (cyanosis); headache; rapid heart rate; shortness of breath; lightheadedness; or fatigue.

Active Ingredients:

Lidocaine Hydrochloride 3%

Purpose:

Anesthetic

Inactive Ingredients:

Aqua (Deionized Water), Carbomer, Isopropyl Alcohol, Petrolatum, Polysorbate-20,

Triethanolamine

Please see product insert for additional information.

LIDO DOSE

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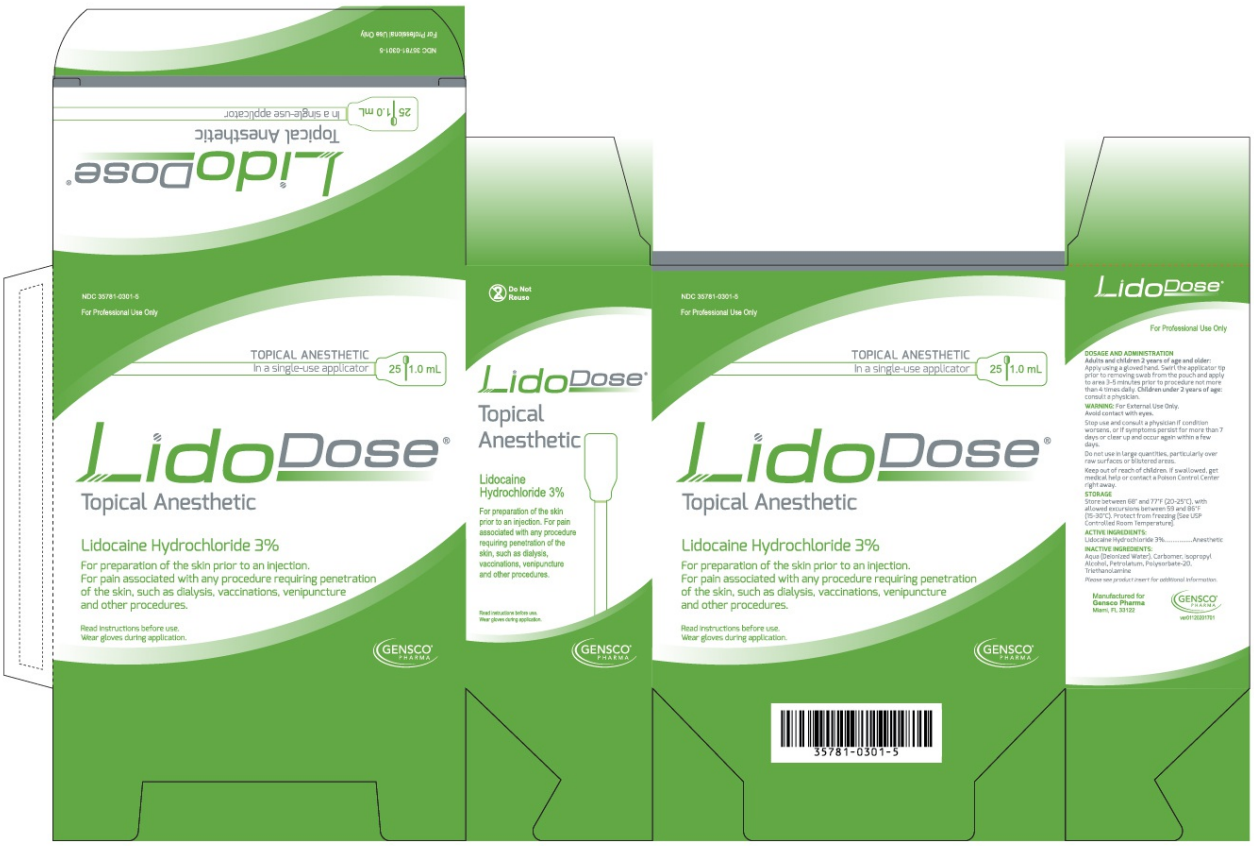

LidoDose®

Topical Anesthetic

For Professional Use Only

NDC 35781-0301-5: 25 x 1 single-dose swabs (1.0 mL each)

DOSAGE AND ADMINISTRATION

Adults and children 2 years of age and older: Apply using a gloved hand. Swirl the applicator tip prior to removing swab from the pouch and apply to area 3-5 minutes prior to procedure not more than 4 times daily.

Children under 2 years of age: Consult a physician.

WARNING: For External Use Only. Avoid contact with eyes.

METHEMOGLOBINEMIA WARNING: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:
• pale, gray, or blue colored skin (cyanosis) • headache • rapid heart rate • shortness of breath • dizziness or lightheadedness • fatigue or lack of energy

Allergy alert: Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics.

Stop use and consult a physician if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

STORAGE

Store between 68° and 77°F (20-25°C), with allowed excursions between 59° and 86°F (15-30°C). Protect from freezing [See USP Controlled Room Temperature].

ACTIVE INGREDIENTS:

Lidocaine Hydrochloride 3%.............................Anesthetic

INACTIVE INGREDIENTS:

Aqua (Deionized Water), Carbomer, Isopropyl Alcohol, Petrolatum, Polysorbate-20, Triethanolamine

LidoDose®

Drug Facts

Active ingredient — **Purpose**

Lidocaine Hydrochloride 3%.............................Topical anesthetic

Uses Temporary relief of minor pain.

Warnings **For external use only. Avoid contact with eyes.**

Methemoglobinemia Warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:
• pale, gray, or blue colored skin (cyanosis) • headache • rapid heart rate • shortness of breath • dizziness or lightheadedness • fatigue or lack of energy

Allergy Alert: Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics.

When using this product

- do not use in large quantities, particularly over raw surfaces or blistered areas

Stop use and ask doctor

- if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions Apply using a gloved hand. Swirl the applicator tip prior to removing swab from the pouch.

Adults and children over 2 years of age	Apply to area 3-5 minutes prior to procedure not more than 4 times daily
Children under 2	Consult a physician

Other information

- package not child resistant
- avoid storing product in direct sunlight
- protect product from excessive moisture
- store between 68° and 77°F (20-25°C)

Inactive ingredients Aqua (Deionized Water), Carbomer, Isopropyl Alcohol, Petrolatum, Polysorbate-20, Triethanolamine

Questions or Comments? 1-855-743-6726

Manufactured for
Gensco Pharma
Miami, FL 33172
855-743-6726

www.genscopharma.com

GENSCO® PHARMA

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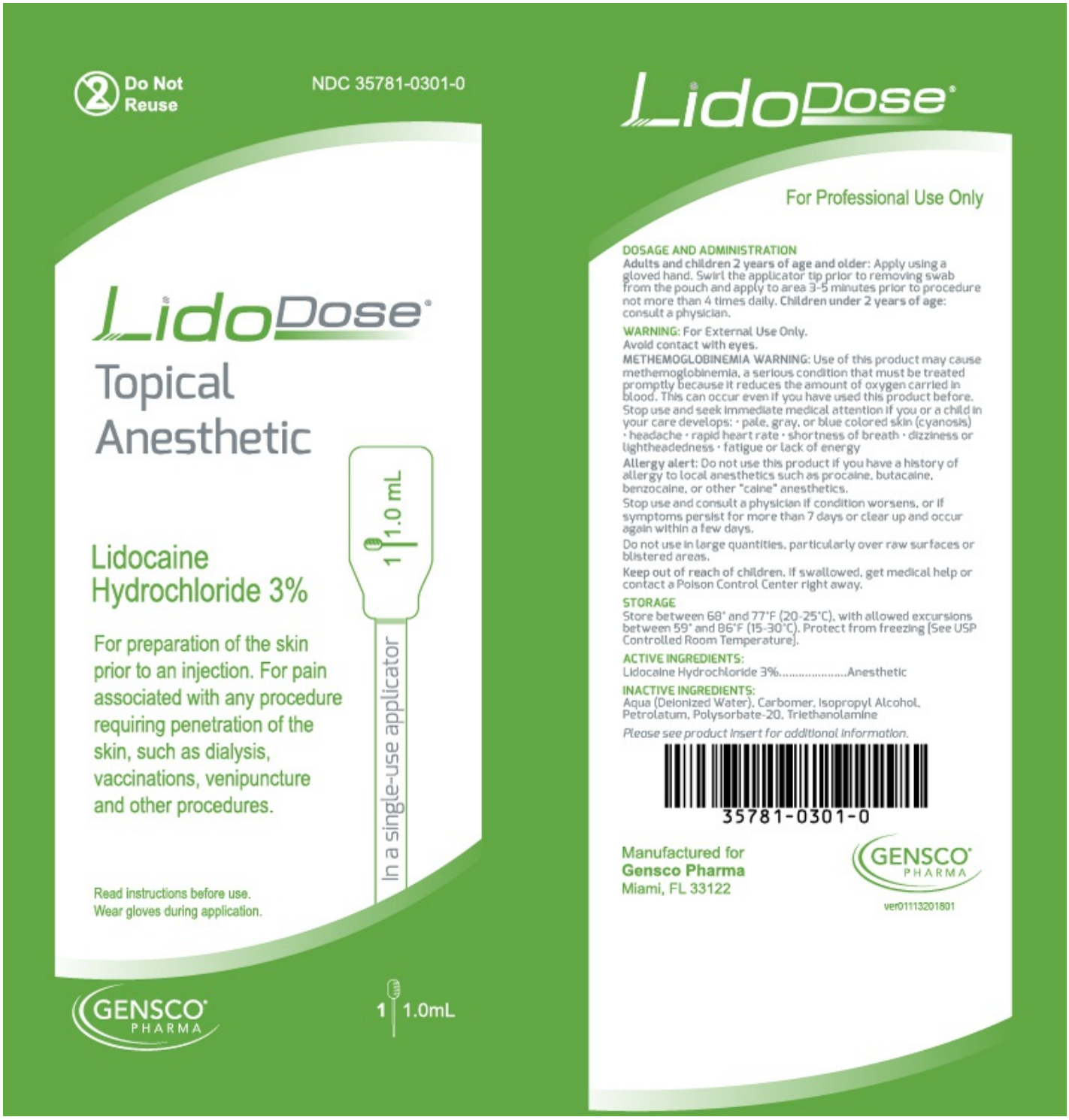

LIDODOSE

lidocaine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:35781-0301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	3 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TRIETHANANOLAMINE PHENYLBENZIMIDAZOLE SULFONATE (UNII: TQA10H23WC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35781-0301-5	25 in 1 BOX	01/01/2018	
1	NDC:35781-0301-0	1 mL in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:35781-0301-1	100 in 1 BOX	01/01/2018	
2	NDC:35781-0301-0	1 mL in 1 POUCH; 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	01/01/2018	

Labeler - Gensco Laboratories, LLC (831042325)

Revised: 10/2022 Gensco Laboratories, LLC