MEDICATED DNA COLLECTION KIT- lidocaine hydrochloride, glycerin solution
TrueFit RX LLC

Medicated DNA Collection Kit

A Topical Anesthetic for the Mucous Membranes of the Mouth and Pharynx.

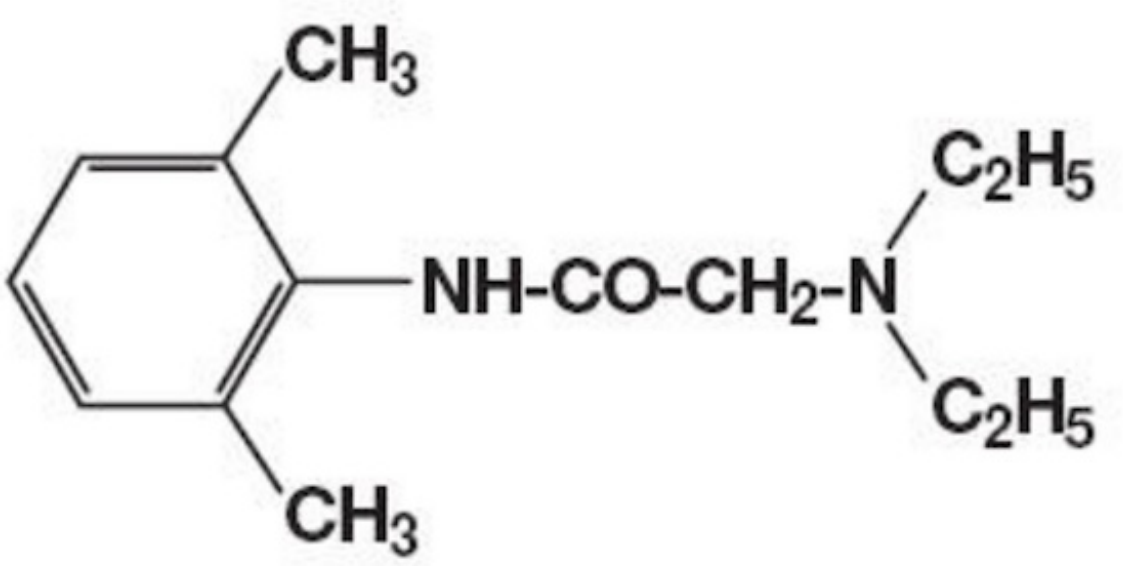
For Oral Use Only.

Rx Only

Lidocaine Ointment 2% contains a local anesthetic agent and is administered topically.

See INDICATIONS AND USAGE for specific uses.

Lidocaine Ointment 2% contains lidocaine, which is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, and has the following structural formula: $C_{14}H_{22}N_{2O}$
Molecular Weight 234.34



Composition of Lidocaine Ointment 2%: acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, (lidocaine) 2% in a water miscible ointment vehicle containing polyethylene glycols and peppermint oil.

Mechanism of action
Conduction of impulses, thereby effecting local anesthetic action.

Onset of anesthesia
Lidocaine Ointment 2% effects local, topical anesthesia. The onset of action is 3-5 minutes. It is ineffective when applied to intact skin.

Hemodynamics

Excessive blood levels may cause changes in cardiac output, total peripheral resistance, and mean arterial pressure. These changes may be attributable to a direct depressant effect of the local anesthetic agent on various components of the cardiovascular system.

Pharmacokinetics and metabolism

Lidocaine may be absorbed following topical administration to mucous membranes, its rate and extent of absorption depending upon the specific site of application, duration of exposure, concentration, and total dosage. In general, the rate of absorption of local anesthetic agents following topical application occurs most rapidly after intratracheal administration. Lidocaine is also well-absorbed from the

gastrointestinal tract, but little intact drug appears in the circulation because of biotransformation in the liver.

Lidocaine is metabolized rapidly by the liver, and metabolites and unchanged drug are excreted by the kidneys. Biotransformation includes oxidative N-dealkylation, ring hydroxylation, cleavage of the amide linkage, and conjugation. N-dealkylation, a major pathway of biotransformation, yields the metabolites monoethylglycinexylidide and glycinexylidide. The pharmacological/toxicological actions of these metabolites are similar to, but less potent than, those of lidocaine. Approximately 90% of lidocaine administered is excreted in the form of various metabolites, and less than 10% is excreted unchanged. The primary metabolite in urine is a conjugate of 4 hydroxy-2,6-dimethylaniline.

The plasma binding of lidocaine is dependent on drug concentration, and the fraction bound decreases with increasing concentration. At concentrations of 1 to 4 mcg of free base per mL, 60 to 80 percent of lidocaine is protein bound. Binding is also dependent on the plasma concentration of the alpha-l-acid glycoprotein.

Lidocaine crosses the blood-brain and placental barriers, presumably by passive diffusion.

Studies of lidocaine metabolism following intravenous bolus injections have shown that the elimination halflife of this agent is typically1.5 to 2.0 hours. Because of the rapid rate at which lidocaine is metabolized, any condition that affects liver function may alter lidocaine kinetics. The half-life may be prolonged two-fold or more in patients with liver dysfunction. Renal dysfunction does not affect lidocaine kinetics but may increase the accumulation of metabolites.

Factors such as acidosis and the use of CNS stimulants and depressants affect the CNS levels of lidocaine required to produce overt systemic effects. Objective adverse manifestations become increasingly apparent with increasing venous plasma levels above 6 mcg free base per mL. In the rhesus monkey arterial blood levels of 18-21 mcg/mL have been shown to be threshold for convulsive activity.

Lidocaine Ointment 2% is indicated for production of anesthesia of accessible mucous membranes of the oropharynx.

Lidocaine is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type or to other components of Lidocaine Ointment 2%.

EXCESSIVE DOSAGE, OR SHORT INTERVALS BETWEEN DOSES, CAN RESULT IN HIGH PLASMA LEVELS AND SERIOUS ADVERSE EFFECTS, PATIENTS SHOULD BE INSTRUCTED TO STRICTLY ADHERE TO THE RECOMMENDED DOSAGE AND ADMINISTRATION GUIDELINES AS SET FORTH IN THIS PACKAGE INSERT.

THE MANAGEMENT OF SERIOUS ADVERSE REACTIONS MAY REQUIRE THE USE OF RESUSCITATIVE EQUIPMENT, OXYGEN, AND OTHER RESUSCITATIVE DRUGS.

Lidocaine Ointment 2% should be used with extreme caution in the presence of sepsis or severely traumatized mucosa in the area of application, since under such conditions there is the potential for rapid systemic absorption.

General

The safety and effectiveness of lidocaine depend on proper dosage, correct technique, adequate precautions, and readiness for emergencies. (See WARNINGS and ADVERSE REACTIONS). The lowest dosage that results in effective anesthesia should be used to avoid high plasma levels and serious adverse effects. Repeated doses of lidocaine may cause significant increases in blood levels with each repeated dose because of slow accumulation of the drug and/or its metabolites. Tolerance to elevated blood levels varies with the status of the patient. Debilitated, elderly patients, acutely ill patients, and children should be given reduced doses commensurate with their age and physical condition. Lidocaine should also be used with caution in patients with severe shock or heart block.

Lidocaine Ointment 2% should be used with caution in patients with known drug sensitivities. Patients allergic to paraaminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown

cross sensitivity to lidocaine. Many drugs used during the conduct of anesthesia are considered potential triggering agents for familial malignant hyperthermia. Since it is not known whether amide-type local anesthetics may trigger this reaction and since the need for supplemental general anesthesia cannot be predicted in advance, it is suggested that a standard protocol for the management of malignant hyperthermia should be available. Early unexplained signs of tachycardia, tachypnea, labile blood pressure and metabolic acidosis may precede temperature elevation. Successful outcome is dependent on early diagnosis, prompt discontinuance of the suspect triggering agent(s) and institution of treatment, including oxygen therapy, indicated supportive measures and dantrolene (consult dantrolene sodium intravenous package insert before using).

Information for Patients

When topical anesthetics are used in the mouth, the patient should be aware that the production of topical anesthesia may impair swallowing and thus enhance the danger of aspiration. For this reason, food should not be ingested for 60 minutes following the use of local anesthetic preparations in the mouth or throat area. This is particularly important in children because of their frequency of eating.

Numbness of the tongue or buccal mucosa may enhance the danger of unintentional biting trauma. Food and chewing gum should not be taken while the mouth or throat area is anesthetized.

Carcinogenesis, mutagenesis, impairment of fertility
Studies of lidocaine in animals to evaluate the carcinogenic and mutagenic potential or the effect on fertility have not been conducted.

Use in Pregnancy

Teratogenic Effects

Pregnancy Category B

Reproduction studies have been performed in rats at doses up to 6.6 times the human dose and have revealed no evidence of harm to the fetus caused by lidocaine. There are, however, no adequate and well-controlled studies in pregnant women. Animal reproduction studies are not always predictive of human response. General consideration should be given to this fact before administering lidocaine to women of childbearing potential, especially during early pregnancy when maximum organogenesis takes place.

Labor and Delivery

Lidocaine is not contraindicated in labor and delivery. Should Lidocaine Ointment 2% be used concomitantly with other products containing lidocaine, the total dose contributed by all formulations must be kept in mind.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when lidocaine is administered to a nursing woman.

Pediatric use

Dosage in children should be reduced, commensurate with age, body weight and physical condition. Caution must be taken to avoid overdosage when applying Lidocaine Ointment 2% to large areas of injured or abraded skin, since the systemic absorption of lidocaine may be increased under such conditions. See DOSAGE AND ADMINISTRATION.

To report SUSPECTED ADVERSE REACTIONS, contact Hi-Tech Pharmacal Co., Inc. at 1-800-262-9010 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Adverse experiences following the administration of lidocaine are similar in nature to those observed with other amide local anesthetic agents. These adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage or rapid absorption, or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Serious adverse

experiences are generally systemic in nature. The following types are those most commonly reported:

Central nervous system

CNS manifestations are excitatory and/or depressant and may be characterized by lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. The excitatory manifestations may be very brief or may not occur at all, in which case the first manifestation of toxicity may be drowsiness merging into unconsciousness and respiratory arrest. Drowsiness following the administration of lidocaine is usually an early sign of a high blood level of the drug and may occur as a consequence of rapid absorption.

Cardiovascular system

Cardiovascular manifestations are usually depressant and are characterized by bradycardia, hypotension, and cardiovascular collapse, which may lead to cardiac arrest.

Allergic

Allergic reactions are characterized by cutaneous lesions, urticaria, edema or anaphylactoid reactions. Allergic reactions may occur as a result of sensitivity either to the local anesthetic agent or to other components in the formulation. Allergic reactions as a result of sensitivity to lidocaine are extremely rare and, if they occur, should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

Acute emergencies from local anesthetics are generally related to high plasma levels encountered during therapeutic use of local anesthetics. (see ADVERSE REACTIONS, WARNINGS, and PRECAUTIONS).

Management of local anesthetic emergencies

The first consideration is prevention, best accomplished by careful and constant monitoring of cardiovascular and respiratory vital signs and the patient's state of consciousness after each local anesthetic administration. At the first sign of change, oxygen should be administered.

The first step in the management of convulsions consists of immediate attention to the maintenance of a patent airway and assisted or controlled ventilation with oxygen and a delivery system capable of permitting immediate positive airway pressure by mask. Immediately after the institution of these ventilatory measures, the adequacy of the circulation should be evaluated, keeping in mind that drugs used to treat convulsions sometimes depress the circulation when administered intravenously. Should convulsions persist despite adequate respiratory support, and if the status of the circulation permits, small increments of an ultra-short acting barbiturate (such as thiopental or thiamylal) or a benzodiazepine (such as diazepam) may be administered intravenously. The clinician should be familiar, prior to use of local anesthetics, with these anticonvulsant drugs. Supportive treatment of circulatory depression may require administration of intravenous fluids and, when appropriate, a vasopressor as directed by the clinical situation (e.g., ephedrine).

If not treated immediately, both convulsions and cardiovascular depression can result in hypoxia, acidosis, bradycardia, arrhythmias and cardiac arrest. If cardiac arrest should occur, standard cardiopulmonary resuscitative measures should be instituted.

Dialysis is of negligible value in the treatment of acute overdosage with lidocaine.

The oral LD_{50} of lidocaine HCl in non-fasted female rats is 459 (346-773) mg/kg (as the salt) and 214 (159-324) mg/kg (as the salt) in fasted female rats.

When Lidocaine Ointment 2% is used concomitantly with other products containing lidocaine, the total dose contributed by all formulations must be kept in mind.

Adult:
The maximum recommended single dose of Lidocaine Hydrochloride Oral Topical Solution, USP

(Viscous) 2% for healthy adults should be such that the dose of lidocaine HCI does not exceed 4.5 mg/kg or 2 mg/lb body weight and does not in any case exceed a total of 300 mg.

For symptomatic treatment of irritated or inflamed mucous membranes of the mouth and pharynx, the usual adult dose is one 15 mL tablespoonful undiluted. For use in the mouth, the solution should be swished around in the mouth and spit out. For use in the pharynx, the undiluted solution should be gargled and may be swallowed. This dose should not be administered at intervals of less than three hours, and not more than eight doses should be given in a 24-hour period. The dosage should be adjusted commensurate with the patient's age, weight and physical condition. (See PRECAUTIONS).

Pediatric:
Care must be taken to ensure correct dosage in all pediatric patients as there have been cases of overdose due to inappropriate dosing.

It is difficult to recommend a maximum dose of any drug for children since this varies as a function of age and weight. For children over 3 years of age who have a normal lean body mass and normal body development, the maximum dose is determined by the child's weight or age. For example: in a child of 5 years weighing 50 lbs., the dose of lidocaine hydrochloride should not exceed 75-100 mg (3.7 to 5 mL of Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%).

For infants and in children under 3 years of age, the solution should be accurately measured and no more than 1.2 mL be applied to the immediate area with a cotton-tipped applicator. Wait at least 3 hours before giving the next dose; a maximum of four doses may be given in a 12-hour period. Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%) should only be used if the underlying condition requires treatment with a volume of product that is less than or equal to 1.2 mL.

Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2% is a clear, viscous liquid with a very slight orange flavor available in 100 mL polyethylene squeeze bottles and in 15 mL unit dose in trays of ten cups.

The solution should be stored at controlled room temperature 15° - 30°C (59° - 86°F).

SHAKE WELL BEFORE USE.

Manufactured by:

Hi-Tech Pharmacal Co., Inc.

Amityville, NY 11701

Made in U.S.A.

Rev. 775:07 03/15

Principal Display Panel - Carton Only
NDC 69938-202-22 Rx Only

Medicated DNA Collection Kit

Kit Contains:
- Lidocaine 2% (Hi Tech Pharmacal) NDC 50383-0775-15
- Lemon Glyceryn swabsticks
- Plastic applicator
- Pair of Sterile Exam Gloves
- Face Mask
- Sterile Drape

CONTENTS

- **(1) High Tech Pharmacal Lidocaine Hydrochloride Oral Topical Solution, USP Viscous 2% RX Only**
- **(1) Pack of Dukal Corporation oral lemon glycerin 4" swab sticks (pack of 3 swabs)**
- **(3) Puritan buccal swabs**
- **(1) Pair of Sterile Triflex Latex Powdered Surgical Glove***
- **(1) Blue isolation mask**
- **(1) Dynarex Sterile Towel Drape 18" X 26"**
- **(1) DNA collection requisition form**
- **(1) Laboratory return label**

*Sterile as long as the package is unopened or undamaged

INSTRUCTIONS FOR USE

Medicated DNA Collection Kit

STEP 1
Have the patient rinse their mouth with water for 30 seconds and follow with a clear mouthwash if available.

STEP 2
The collector should remove the swab from the collection tube and hand it to the patient. Be sure to only handle the swab by the stick or the blue portion of the handle.

STEP 3
Have the patient put the swab into their mouth ensuring the flat side is pressing against the cheek. Apply firm pressure throughout the process. Scrape continually on both sides of the swab for 30 "seconds" each side.

Remember: you are collecting cells not saliva, so brush vigorously

STEP 4
Repeat the same procedure for the additional swabs #2 and #3.

STEP 5
The collector should insert the swab back into the collection tube.

STEP 6
If the patient is experiencing any discomfort, swelling or bleeding, determine if the patient would like to use the Lidocaine solution and or glycerin swabs to assist with pain and inflammation.

STEP 7
Process the label, then package and record the swab sample per directions of the reference lab where the swabs are being sent.

LIDOCAINE HYDROCHLORIDE ORAL TOPICAL SOLUTION USP (VISCOUS) 2%
A TOPICAL ANESTHETIC FOR THE MUCOUS MEMBRANES OF THE MOUTH AND PHARYNX

WARNING: FOR ORAL USE ONLY

WARNING: LIFE THREATENING AND FATAL EVENTS IN INFANTS AND YOUNG CHILDREN

Postmarketing causes of seizures, cardiopulmonary arrest and death in patients under 3 years of age have been reported with use of Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2 % when it was not administered in strict adherence to the dosing recommendations. In the setting of teething pain, Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2% should not be used. For other conditions, the use of the product in patients less than 3 years of age should be limited to those situations where safer alternatives are not available or have been tried but failed. To decrease the risk of serious adverse events with use of, Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2% instruct caregivers to strictly adhere to prescribed dose and frequency of administration and store prescription safely out of reach of children.

PRECAUTIONS:

- First consideration is prevention best accomplished by careful and constant monitoring of cardiovascular and respiratory vital signs and patients state of consciousness during procedure.
- For patients under three (3) years of age, special care must be given to accurately measure the prescribed dose and not administering the product more often than described.
- To ensure accuracy, we recommend you use a measuring device to carefully measure the correct volume.
- The product should only be used for prescribed indication.
- To reduce the risk of accidental ingestion, the product container should be tightly closed and the product should be kept well out of reach of all children immediately after use.
- If patient shows signs of systemic toxicity (e.g., lethargy, shallow breathing, seizure activity) emergency medical attention should be sought immediately and no additional product should be administered.
- Unused product should be discarded in a manner that prevents possible exposure to children and pets.
- All patients should be aware that when topical anesthetics are used by mouth or throat, the production of topical anesthesia may impair swallowing and thus enhance the danger of aspiration. For this reason food should not be ingested for 60 minutes following use of local anesthetic preparation in mouth or throat. This is particularly important for children because of frequency of eating. Numbness of the tongue or buccal mucosa may increase the danger of biting trauma. For this reason food and/or chewing gum should not be used while mouth or throat is
- The lowest dosage that results in effective anesthesia should be used to minimize adverse reactions.
- Repeated doses of Lidocaine may cause significant increases in blood levels with each repeated dose.
- Debilitated, elderly or acutely ill patients and children should be given reduced dosages commensurate with age, weight and physical condition. Lidocaine should be used with caution in patients in severe shock or heart block.
- Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2% should be used with caution in persons with known drug sensitivities. Patients allergic to para-aminobenzoic acid derivatives (procaine, tetracaine, benzocaine etc.) have shown cross sensitivity to Lidocaine.

DOSAGE AND ADMINISTRATION:

Adult:
The maximum recommended single dosage of Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2% for healthy adults should be such that the dose does not exceed 4.5mg/kg or 2 mg/lb body weight and does not exceed a total of 300mg.

Pediatric:
Do not administer to children under three (3) years of age. It is difficult to recommend dosage for children since it varies as a function of age and weight. For example in a child of 5 years and 50 lbs, the dose of lidocaine should not exceed 75-100 mg (3.7 to 5 ml of Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

used while mouth or throat is anesthetized.

Storage best at room temperature

Medicated DNA COLLECTION KIT

TrueFit Rx

Medicated DNA

COLLECTION KIT

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MEDICATED DNA COLLECTION KIT

lidocaine hydrochloride, glycerin solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69938-151(NDC:50383-775)
Route of Administration	ORAL, TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE ANHYDROUS (UNII: EC2CNF7XFP) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
WATER (UNII: 059QF0KO0R)	
ORANGE (UNII: 5EVU04N5QU)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69938-151-11	1 in 1 CARTON	12/04/2015	
1		15 mL in 1 CUP; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040014	12/04/2015	

Labeler - TrueFit RX LLC (079868455)

Registrant - TrueFit RX LLC (079868455)

Establishment

Name	Address	ID/FEI	Business Operations
TrueFit RX		079868455	repack(69938-151)

Revised: 12/2015 TrueFit RX LLC