LIDO-K- lidocaine hydrochloride lotion
SOLUTECH PHARMACEUTICALS 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.

Lido-K
(Lidocaine Hydrochloride 3% Lotion)

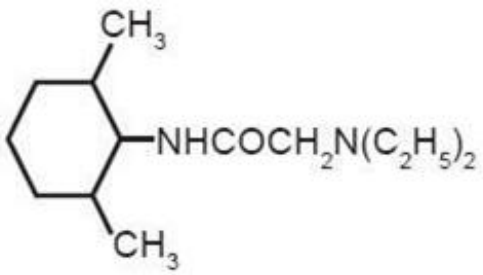
Topical Anesthetic

For external use only.
Not for ophthalmic use.

Rx only

DESCRIPTION

Contains Lidocaine Hydrochloride. Lidocaine is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl), and has the following structure:



$C_{14}H_{22}N_2O$

Each mL of **Lido-K Lotion** contains **ACTIVE:** Lidocaine HCl 30 mg in a lotion base of **INACTIVES**: Mineral Oil, Petrolatum, Cetyl Alcohol, Stearic Acid, Methylparaben, Propylparaben, Lexemul, Water, Sodium Hydroxide (50%), Aluminum Sulfate, and Calcium Acetate

CLINICAL PHARMACOLOGY

MECHANISM OF ACTION

Lidocaine stabilizes the neuronal membrane by inhibiting the ionic fluxes required for initiation and conduction of impulses, thereby effecting local anesthetic action.

PHARMACOKINETICS

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 1-4 g 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-1-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 half-life of this agent is typically 1.5 to 2 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 g free base per mL. In the rhesus monkey, arterial blood levels of 18-21 g/ml have been shown to be threshold for convulsive activity.

INDICATIONS

Topical anesthetic for use on intact skin for pain and local analgesic.

CONTRAINDICATIONS

Traumatized mucosa, secondary bacterial infection of the area of proposed application and known hypersensitivity to any of the components. Lido-K is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type or to any other component of the product.

WARNINGS

For external use only. Not for ophthalmic use. Avoid contact with eyes, lips or mucous membranes. Do not use on areas of broken skin. If irritation or sensitivity occurs or infection appears, discontinue use. If swallowed, get medical help or contact a Poison Control Center right away.

Application of lidocaine to larger areas or for longer times than those recommended could result in sufficient absorption of lidocaine resulting in serious adverse effects.

Patients treated with class III anti-arrhythmic drugs (e.g., amiodarone, bretylium, sotalol, dofetilide) should be under close surveillance and ECG monitoring considered, because cardiac effects may be additive.

Lidocaine 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.

PRECAUTIONS

If irritation or sensitivity occurs or infection appears, discontinue treatment and institute appropriate therapy. **Lido-K** should be used with caution in ill, elderly, debilitated patients and children who may be more sensitive to the systemic effects of lidocaine.

CARCINOGENESIS, MUTAGENESIS AND IMPAIRMENT OF FERTILITY

Studies of Lidocaine in animals to evaluate the carcinogenic and mutagenic potential of 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.

Lidocaine does pass very quickly through the placenta so doctors and experts suggest only using the anesthetic for established medical needs only as directed by your physician.

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 this drug is administered to a nursing mother. Your doctor and you will decide if the benefits outweigh the risk of using lidocaine.

PEDIATRIC USE

Dosage in pediatric patients would be reduced commensurate with age, body weight and physical condition.

If your child becomes very dizzy, excessively sleepy, or develops duskiness of the face or lips after applying lidocaine lotion, remove the lotion and contact your physician at once.

ADVERSE REACTIONS

During or immediately after treatment, the skin at the site of treatment may develop erythema or edema or maybe the locus of abnormal sensation.

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.

DOSAGE AND ADMINISTRATION

Apply a thin film to the affected area two or three times daily or as directed by a physician.

Caution should be exercised, particularly when employing large amounts, since the incidence of adverse effects is directly proportional to the total dose of local anesthetic agent administered.

HOW SUPPLIED

Lido-K Lotion is supplied in the following size:

Size	NDC#
6oz (177 mL) Bottle	70350-2618-6

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.

STORAGE

Store at 25°C (77°F); excursions permitted to 15° - 30°C (59° - 86°F). Protect from freezing [See USP Controlled Room Temperature].

Manufactured for:
Solutech Pharmaceuticals LLC
Peoria, AZ 85345

Rx only

PRINCIPAL DISPLAY PANEL - 177 mL Bottle Label

NDC 70350-2618-6

TOPICAL ANESTHETIC

LIDO-K

LIDOCAINE HCL 3% LOTION

Smooth
Easily Spreadable

Rx Only

Solutech
PHARMACEUTICALS

Net WT. 6OZ (177 mL)

NDC 70350-2618-6

TOPICAL ANESTHETIC

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ACTIVE INGREDIENT: Lidocaine Hydrochloride 3%

INACTIVE INGREDIENTS: Mineral Oil, Petrolatum, Cetyl Alcohol, Stearic Acid, Methylparaben, Propylparaben, Lexemul, Water, Sodium Hydroxide (50%), Aluminum Sulfate, Calcium Acetate.

STORAGE: Store at 25°C (77°F): excursions permitted to 15°- 30°C (59°- 86°F). Protect from Freezing [See USP Controlled Room Temperature]. Keep tightly closed.

USUAL DOSAGE: Apply LIDOCAINE HCI 3% LOTION two or three times daily or as directed by a physician.
See insert for complete product information.

CAUTION: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE. If pregnant or breastfeeding, ask your doctor before use. If irritation or sensitivity occurs or infection appears, discontinue use. Avoid contact with eyes, lips or mucous membranes. Do not use on areas of broken skin. If swallowed, get medical help or contact a Poison Control Center immediately.

Keep this and all other medications out of reach of children.

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MANUFACTURED FOR:
Solutech PHARMACEUTICALS
PEORIA, AZ 85342

LIDO-K
lidocaine hydrochloride lotion

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70350-2618
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	30 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	

CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERYL DILAURATE (UNII: MFL3ZIE8SK)	
WATER (UNII: 059QF0KO0R)	
ALUMINUM SULFATE (UNII: 34S289N54E)	
CALCIUM ACETATE (UNII: Y882YXF34X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70350-2618-6	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/15/2016	

Labeler - SOLUTECH PHARMACEUTICALS LLC (080040396)

Revised: 2/2018 SOLUTECH PHARMACEUTICALS LLC