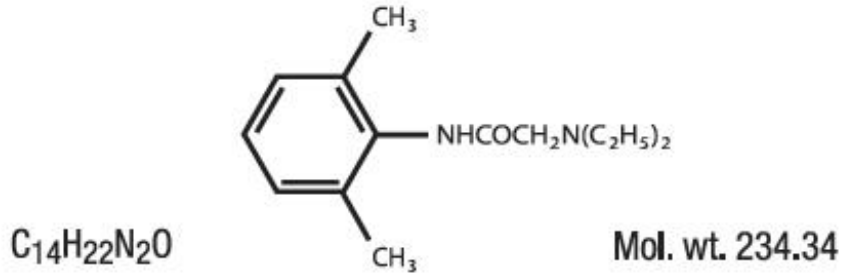
LIDOGEL- lidocaine hcl gel
Advanced Rx Pharmacy of Tennessee, LLC

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.

Lidogel

DESCRIPTION

Contains Lidocaine HCl 2.8% in a mild acidic vehicle. Lidocaine is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl), and has the following structure:



INGREDIENTS: Each gram of **Lidogel™ 2.8% Gel**contains Lidocaine HCl USP 28 mg. Inactive Ingredients include: Aloe Barbadensis (Aloe Vera) Leaf Juice, Citric Acid, Hydroxyethylcellulose, Methylparaben, PEG-4, Propylene Glycol, Propylparaben, Purified Water.

CLINICAL PHARMACOLOGY:

MECHANISM OF ACTION:

Lidogel™ 2.8% Gelreleases Lidocaine from a mild acidic vehicle to stabilize the neuronal membrane by inhibiting the ionic fluxes
required for initiation and conduction of impulses, thereby affecting local anesthetic action. A mild acidic vehicle lowers pH to increase protection against alkaline irritants and to provide a favorable environment for healing.

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 drugs 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 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:

For temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritation.

CONTRAINDICATIONS:

Tuberculous or fungal lesions of skin vaccinia, varicella, and acute herpes simplex and in persons who have shown hypersensitivity to any of its components. Lidocaine is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type.

WARNINGS:

For external use only.Not for ophthalmic use.

Keep out of reach of children.

PRECAUTIONS:

If irritation of sensitivity occurs or infection appears, discontinue use and institute appropriate therapy. **Lidogel™ 2.8%**Gel 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 potential of the effect on

fertility have not been conducted.

USE IN PREGNANCY

Teratogenic Effects; Pregnancy Category B. Reproduction studies have been performed for Lidocaine 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.

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.

PEDIATRIC USE:

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

ADVERSE REACTIONS:

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

DOSAGE AND ADMINISTRATION:

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

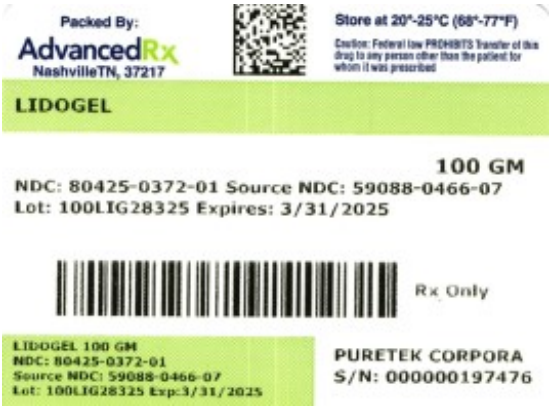
HOW SUPPLIED:

Lidogel 2.8% Gel 3.5 oz. (100 g) tube - NDC 80425-0372-01

KEEP THIS AND ALL MEDICATIONS OUT OF REACH OF CHILDREN.

STORAGE AND HANDLING:

Store at 20°-25°C (68°-77° F) [see USP Controlled Room Temperature]. Protect from freezing.



LIDOGEL

lidocaine hcl gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:80425-0372(NDC:59088-466)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	28 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYETHYLENE GLYCOL 200 (UNII: R95B8J264J)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0372-1	100 g in 1 TUBE; Type 0: Not a Combination Product	01/18/2023	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
unapproved drug other		01/18/2023	

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0372)