LIDOTRAL 3.88% ROLL ON- lidocaine hci gel
PureTek Corporation

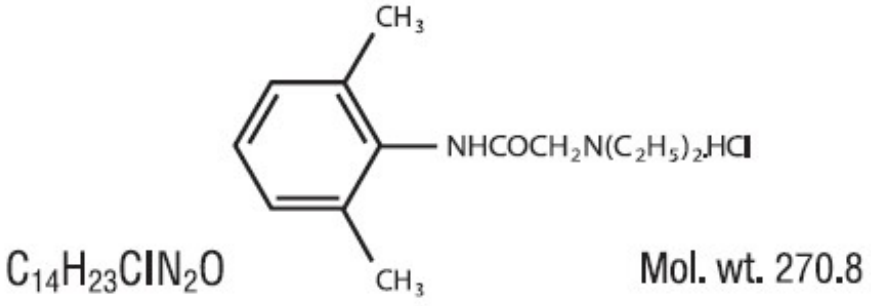
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Lidotral 3.88% Roll on Gel

DESCRIPTION

Lidotral® 3.88% Roll on Gel contains 38.8 mg of Lidocaine HCl per gram in a mild acidic vehicle with Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis (Aloe Vera) Leaf Juice, Aminomethyl Propanol, Aqua (Purified Water), C30-45 Alkyl Cetearyl Dimethicone Crosspolymer, Cetearyl Alcohol Ceteth-20 Phosphate, Cyclopentasiloxane Dicetyl Phosphate, Dimethicone, Disodium EDTA, Ethyl Alcohol Ethylhexylglycerin, Glyceryl Stearates, Phenoxyethanol, Steareth-21.

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



$C_{14}H_{23}ClN_2O$ Mol. wt. 270.8

CLINICAL PHARMACOLOGY

Mechanism of Action:Lidotral® 3.88% Roll on 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 effecting local anesthetic action. A mild acidic vehicle lowers pH to increase protection against alkaline irritations 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 of 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 conjungation. N-dealkylation, a major pathway of biotransformation, yields the metabolites monoethylglycinexylidide and glycinexlidide. 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 concentration 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 the 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.

PRECAUTIONS

If irritation or sensitivity occurs or infection appears, discontinue use and institute appropriate therapy. **Lidotral® 3.88% Roll on 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 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 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

Adults and children 4 years of age and older: apply a thin film to the affected area(s) two or three times daily or as directed by a licensed healthcare practitioner. See insert for complete product information.

HOW SUPPLIED

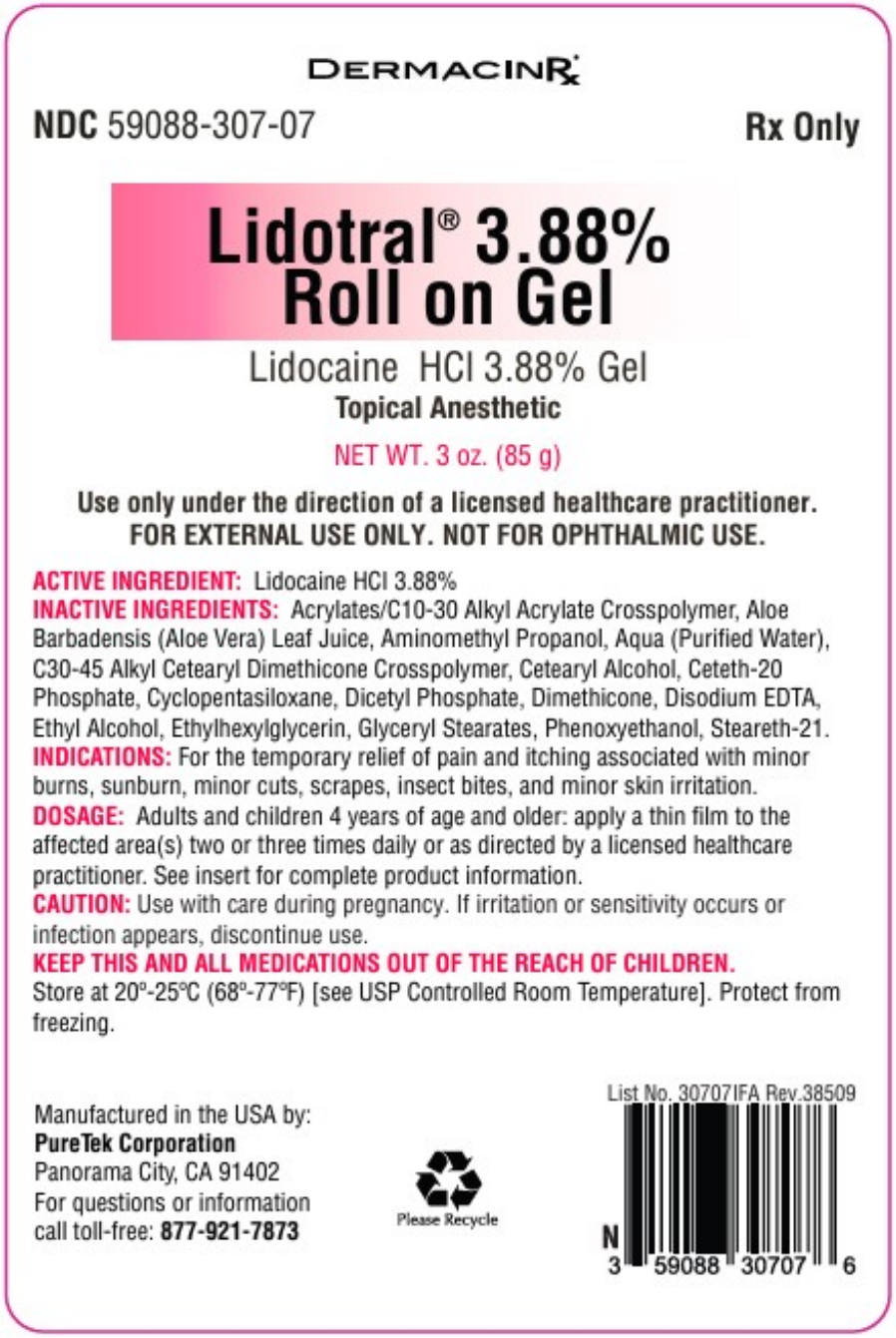
Lidotral® 3.88% Roll on Gel is supplied in a 3 oz. (85 g) roll on bottle (NDC 59088-307-07).

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

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

Manufactured in the USA by:
PureTek Corporation
Panorama City, CA 91402
For questions or information
call toll-free: **877-921-7873**

Lidotral® 3.88% Roll on Gel



LIDOTRAL 3.88% ROLL ON

lidocaine hci gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-307
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	38.8 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
WATER (UNII: 059QF0KO0R)	
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S) (UNII: 8Z5ZAL5H3V)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
C30-45 ALKYL CETEARYL DIMETHICONE CROSSPOLYMER (UNII: 4ZK9VP326R)	
ALCOHOL (UNII: 3K9958V90M)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
CETETH-20 PHOSPHATE (UNII: 921FTA1500)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
STEARETH-21 (UNII: 53J3F32P58)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-307-07	85 g in 1 BOTTLE; Type 0: Not a Combination Product	02/28/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/28/2024	

Labeler - PureTek Corporation (785961046)

Revised: 2/2024 PureTek Corporation