LIDOPIN- lidocaine hydrochloride cream
Adler-Stern 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.

LIDOPIN - Lidocaine Hydrocholoride Cream
Lidocaine 3.25% Cream

Rx Only

DESCRIPTION:

Lidocaine 3.25% Cream is a topical anesthetic indicated for the relief of pruritus, pruritic eczemas, abrasions, minor burns, insect bites, pain, soreness, and discomfort due to pruritus ani, pruritus vulvae, hemorrhoids, anal fissures, and similar conditions of the skin and mucous membranes.

ACTIVE INGREDIENTS: Each gram of Lidocaine 3.25% Cream contains lidocaine hydrochloride 3.25% (32.5 mg).

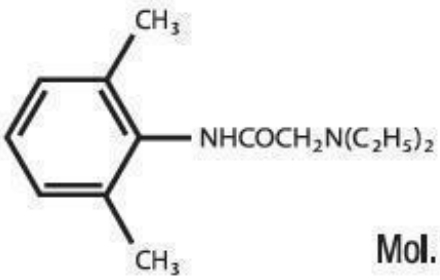
INACTIVE INGREDIENTS: aluminum sulfate, calcium acetate, cetyl alcohol, glycerine, glyceryl monostearate SE, methyl paraben, mineral oil, propyl paraben, purified water, sodium hydroxide, sorbitan stearate, stearic acid, stearyl alcohol, and white petrolatum.

CLINICAL PHARMACOLOGY:

MECHANISM OF ACTION:

Lidocaine 3.25% Cream releases 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.

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



$C_{14}H_{22}N_2O$ Mol. wt. 234.34

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 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:

Anesthetic for relief of pruritus, pruritic eczemas, abrasions, minor burns, insect bites, pain, soreness and discomfort due to pruritus ani, pruritus vulvae, hemorrhoids, anal fissures, and similar conditions of the skin and mucous membranes.

CONTRAINDICATIONS:

Traumatized mucosa, secondary bacterial infection of the area of proposed application and known hypersensitivity to any of the 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. Lidocaine 3% Cream 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:

Lidocaine is excreted in human milk. The clinical significance of this observation is unknown. Caution should be exercised when lidocaine is administered to a nursing woman.

PEDIATRIC USE:

Dosage in pediatric patients should 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.

CALL YOUR DOCTOR ABOUT SIDE EFFECTS.

Call your doctor about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

DOSAGE AND ADMINISTRATION:

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

HOW SUPPLIED:

Lidocaine 3.25% Cream is supplied as a white cream in:
3 oz. (85 g) tubes, NDC 69054-231-03.

1 oz. (28 g) tubes, NDC 69054-231-01.

STORAGE AND HANDLING:

KEEP THIS AND ALL MEDICATIONS OUT OF REACH OF CHILDREN.

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product. This product may be administered only under a physician's supervision. There are no implied or explicit claims on the therapeutic equivalence.

Store at 25ºC (77ºF); excursions permitted to 15º-30ºC (59º-86º F). See USP Controlled Room Temperature. Protect from freezing.

Manufactured for:

Adler-Stern Pharmaceuticals, LLC

Tampa, FL 33629

Rev 10/14

Rx Only

Adler-Stern Pharmaceuticals,LLC

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Rx Only NDC-69054-231-03 Net Wt. 3 oz. (85 g)

Lidocaine 3.25% Cream
Topical Anesthetic

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

ADLER STERN PHARMACEUTICALS LLC

LIDOPIN

lidocaine hydrochloride cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69054-231
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE ANHYDROUS (UNII: EC2CNF7XFP) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	32.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALUMINUM SULFATE (UNII: 34S289N54E)	
CALCIUM ACETATE (UNII: Y882YXF34X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69054-231-03	1 in 1 CARTON		
1		85 g in 1 TUBE		
2	NDC:69054-231-01	1 in 1 CARTON		
2		28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/11/2014	

Labeler - Adler-Stern Pharmaceuticals, LLC (079403232)

Revised: 11/2014 Adler-Stern Pharmaceuticals, LLC