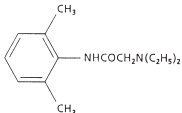


R_x Only

LIDAMANTLE[®] Cream

(Lidocaine HCl 3%) In an AcidMantle vehicle

DESCRIPTION: Contains lidocaine HCl 3% in a compatible AcidMantle vehicle adjusted to the pH range for normal skin. Lidocaine is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl), and has the following structure:



C₁₄H₂₂N₂O

Mol. wt. 234.34

Each gram of **LIDAMANTLE[®] Cream** contains Lidocaine HCl 30 mg, Aluminum Sulfate, Calcium Acetate, Cetyl Alcohol, Glycerin, Light Mineral Oil, Methylparaben, Petrolatum, Polysorbate 60, Propylparaben, Purified Water, Sodium Hydroxide, Sorbitan Stearate, Stearic Acid, and Stearyl Alcohol.

Each mL of **LIDAMANTLE[®] Lotion** contains Lidocaine HCl 30 mg, Aluminum Sulfate, Calcium Acetate, Cetyl Alcohol, Glycerin, Light Mineral Oil, Methylparaben, Petrolatum, Polysorbate 60, Propylparaben, Purified Water, Sodium Hydroxide, Sorbitan Stearate, Stearic Acid, and Stearyl Alcohol.

CLINICAL PHARMACOLOGY:

MECHANISM OF ACTION: **LIDAMANTLE[®] Cream** and **LIDAMANTLE[®] Lotion** release lidocaine which stabilizes the neuronal membrane by inhibiting the ionic fluxes required for initiation and conduction of impulses, thereby effecting local anesthetic action. AcidMantle 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,

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LIDAMANTLE[®] Lotion

(Lidocaine HCl 3%) In an AcidMantle vehicle

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: 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 treatment and institute appropriate therapy. **LIDAMANTLE**[®] 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.

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:

LIDAMANTLE[®] Cream

1 oz. (28.35 g) tube NDC 10337-700-52

3 oz. (85 g) tube NDC 10337-700-19

LIDAMANTLE[®] Lotion

177 mL bottle NDC 10337-705-10

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

Store at controlled room temperature 15°-30° C (59°-86° F). Protect from freezing.

Mfd. for:



DOAK DERMATOLOGICS

A SUBSIDIARY OF BRADLEY PHARMACEUTICALS, INC.

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