LIDOCAINE HYDROCHLORIDE- lidocaine hydrochloride cream
Proficient Rx LP

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.

LIDOCAINE HCL - lidocaine hcl cream

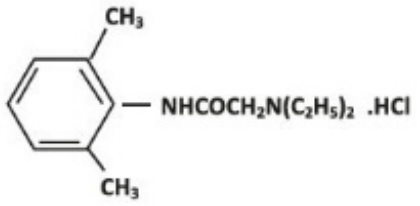
Westminster Pharmaceuticals, LLC.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA.

Prescribing Information

DESCRIPTION

Contains lidocaine HCl 3% in a mild acidic vehicle. Lidocaine is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl).



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

INGREDIENTS: Each gram of **Westminster Pharmaceuticals Lidocaine HCl 3% Cream** contains Lidocaine HCl USP 3%, Inactive ingredients include: Aluminum Sulfate, Calcium Acetate, Cetyl Alcohol, Methylparaben, Mineral Oil, Petrolatum, Polysorbate 80, Propylene Glycol, Propylparaben, Purified Water, Sodium Hydroxide, Sorbitan Monostearate, Stearic Acid, Stearyl Alcohol.

CLINICAL PHARMACOLOGY

MECHANISM OF ACTION

Westminster Pharmaceuticals Lidocaine HCl 3% 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.

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

Indications

For the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, minor skin irritation, and discomfort due to pruritus ani, pruritus vulvae, hemorrhoids, anal fissures, and similar conditions of the skin and mucous membranes.

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 or sensitivity occurs or infection appears, discontinue use and institute appropriate therapy. Westminster Pharmaceuticals Lidocaine HCl 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 potential of the effect on fertility have not been conducted.

USE IN PREGNANCY

Teratogenic Effects

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

Westminster Pharmaceuticals Lidocaine HCl 3% Cream

1 oz (28.35g) tube - NDC- 71205-973-01
3 oz (85 g) tube – NDC- 71205-973-03

STORAGE AND HANDLING

Store at controlled room temperature 15° - 30°C (59° - 86°F). Avoid excessive heat and cold, Protect from sunlight and freezing.

Manufactured for:
Westminster Pharmaceuticals, LLC
Tampa, FL 33618

Relabeled by:
Proficient Rx LP
Thousand Oaks, CA 91320

Rev. 07/19

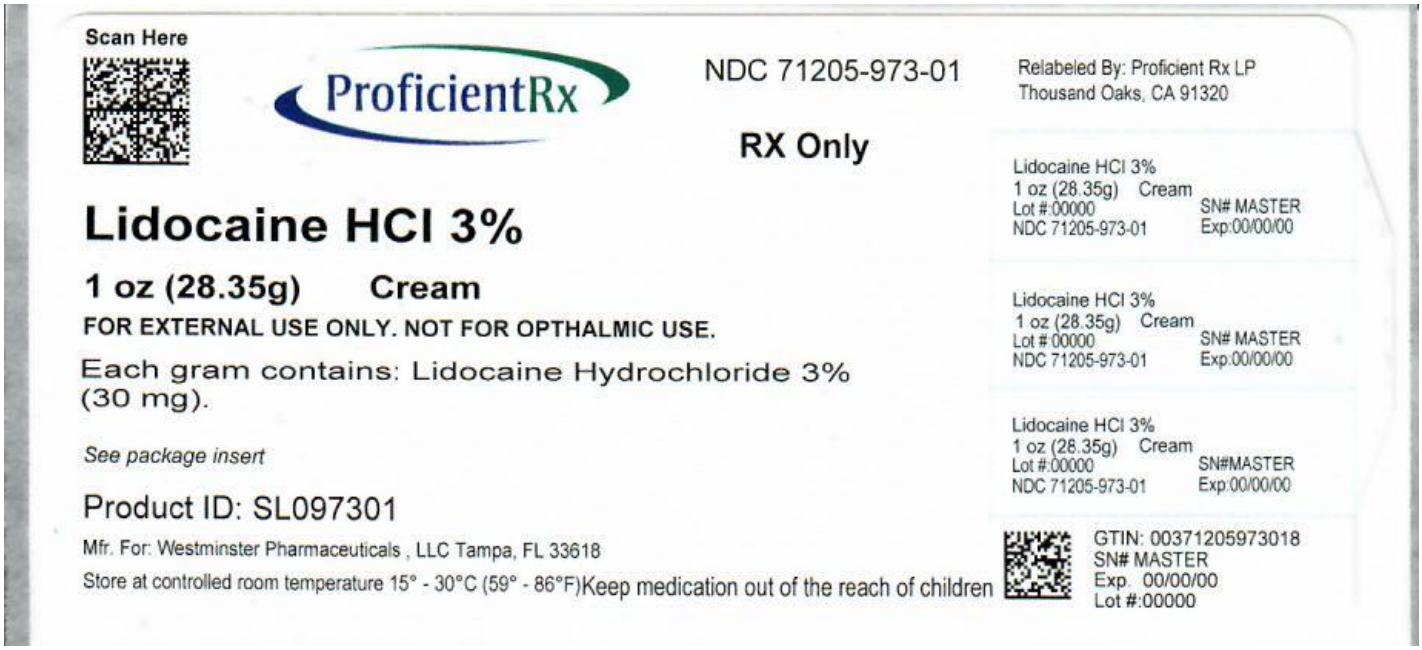
PRINCIPAL DISPLAY PANEL - 85 g Tube Carton

NDC 71205-973-01
Rx Only

Lidocaine HCl 3% Cream
Topical Anesthetic

FOR EXTERNAL USE ONLY.
NOT FOR OPTHALMIC USE.

Net Wt 3 oz (28.35g)



LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71205-973(NDC:69367-202)
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 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALUMINUM SULFATE (UNII: 34S289N54E)	
CALCIUM ACETATE (UNII: Y882YXF34X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71205-973-01	1 in 1 CARTON	05/11/2020	
1		28.35 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:71205-973-03	1 in 1 CARTON	05/11/2020	
2		85 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		08/19/2019	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(71205-973) , RELABEL(71205-973)

Revised: 5/2020 Proficient Rx LP