ZIONODIL EXTERNAL- lidocaine hydrochloride lotion
Bodyshphere, 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.

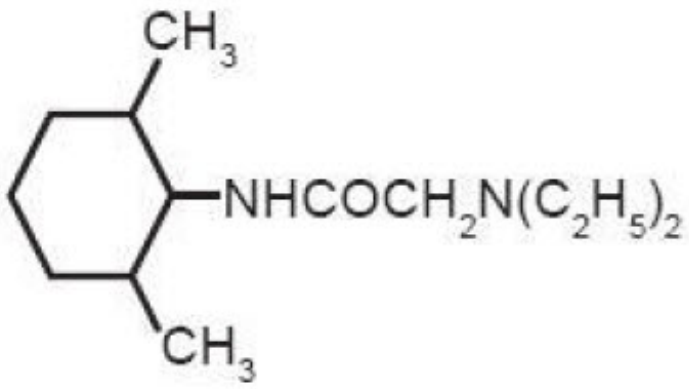
Zionodil™
Lidocaine HCl 3% Lotion

Topical Anesthetic

Rx only

DESCRIPTION

Contains lidocaine HCl 3%. 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**

Each gram of **Lidocaine HCl 3% Lotion** contains **ACTIVE:** Lidocaine HCl 30 mg in a lotion base of **INACTIVES**: aluminum sulfate, calcium acetate, cetyl alcohol, edetate disodium, glycerine, methylparaben, mineral oil, petrolatum, polysorbate 60, propylparaben, purified water, sodium hydroxide, sorbitan stearate, stearic acid and stearyl alcohol.

CLINICAL PHARMACOLOGY

MECHANISM OF ACTION

Lidocaine HCl 3% Lotion releases lidocaine which stabilizes the neuronal membrane by inhibiting the ionic fluxes required for initiation and conduction of impulses, thereby effecting local anesthetic action.

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 1-4 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 & PRECAUTIONS

For external use only. Not for ophthalmic use.

If irritation or sensitivity occurs or infection appears, discontinue treatment and institute appropriate therapy. Lidocaine HCl 3% Lotion 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.

METHEMOGLOBINEMIA

Cases of methemoglobinemia have been reported in association with local anesthetic use. Although all patients are at risk for methemoglobinemia, patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, infants under 6 months of age, and concurrent exposure to oxidizing agents or their metabolites are more

susceptible to developing clinical manifestations of the condition. If local anesthetics must be used in these patients, close monitoring for symptoms and signs of methemoglobinemia is recommended. Signs and symptoms of methemoglobinemia may occur immediately or may be delayed some hours after exposure and are characterized by a cyanotic skin discoloration and abnormal coloration of the blood. Methemoglobin levels may continue to rise; therefore, immediate treatment is required to avert more serious central nervous system and cardiovascular adverse effects, including seizures, coma, arrhythmias, and death. Discontinue Lidocaine 3% Lotion and any other oxidizing agents. Depending on the severity of the symptoms, patients may respond to supportive care, i.e., oxygen therapy, hydration. More severe symptoms may require treatment with methylene blue, exchange transfusion, or hyperbaric oxygen.

Class	**Examples**
Nitrates/Nitrites	nitroglycerin, nitroprusside, nitric oxide, nitrous oxide
Local anesthetics	benzocaine, lidocaine, bupivacaine, mepivacaine, tetracaine, prilocaine, procaine, articaine, ropivacaine
Antineoplastic agents	cyclophosphamide, flutamide, rasburicase, ifosfamide,hydroxvurea
Antibiotics	dapsone, sulfonamides, nitrofurantoin, para-aminosalicylic acid
Antimalarials	chloroquine, primaquine
Anticonvulsants	phenvtoin, sodium valoroate, phenobarbital
Other drugs	acetaminophen, metoclopramide, sulfa drugs (i.e., sulfasalazine), quinine

DRUG INTERACTIONS

Patients that are administered local anesthetics may be at increased risk of developing methemoglobinemia when concurrently exposed to the following oxidizing agents:

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 maybe the locus of abnormal sensation.

DOSAGE AND ADMINISTRATION

Apply a thin film to the affected area 1 -3 times daily or as directed by a physician.

HOW SUPPLIED

Lidocaine HCl 3% Lotion is supplied in the following size:

SIZE	NDC#
6oz. (177 mL) Bottle	73247-391-06

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

STORAGE

Store at 25°C (77°F); excursions permitted to 15° - 30°C (59° - 86°F). Protect from freezing [See USP Controlled Room Temperature].

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Mfg. for & Distributed by: Bodysphere, LLC, Las Vegas, NV 89120

For Customer Service or Adverse Reactions: 1-866-660-2626

PRINCIPAL DISPLAY PANEL - 177 ml Bottle Label

NDC 73247-0391-06
Rx Only

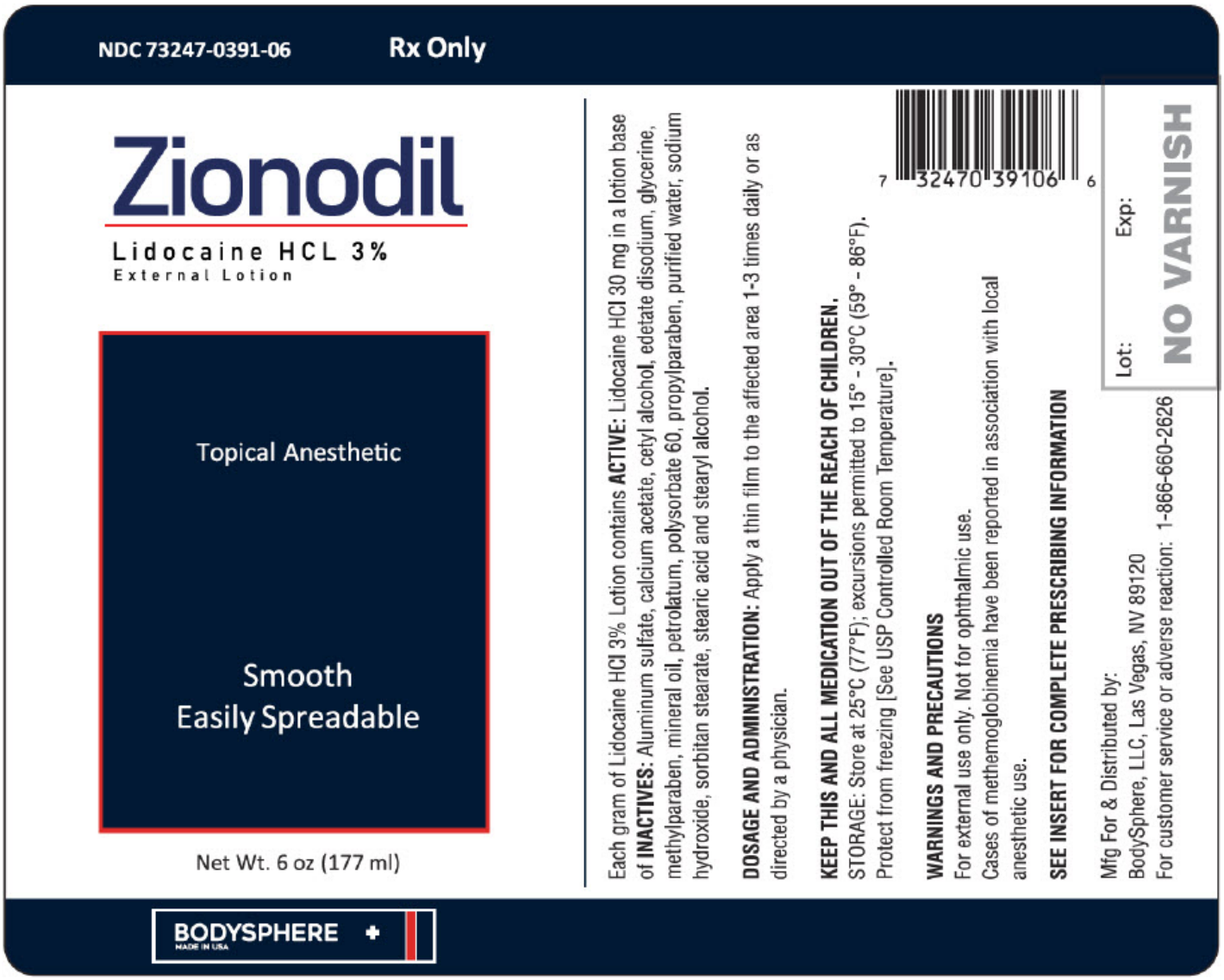
Zionodil
Lidocaine HCL 3%
External Lotion

Topical Anesthetic

Smooth
Easily Spreadable

Net Wt. 6 oz (177 ml)

BODYSPHERE +
MADE IN USA



ZIONODIL EXTERNAL

lidocaine hydrochloride lotion

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73247-391
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 177 mL

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73247-391-06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/20/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		11/20/2019	

Labeler - Bodyshphere, LLC (117131105)

Revised: 11/2019 Bodyshphere, LLC