NEW
LidoWorx®
Gel (4% Lidocaine)
Rapid Acting Topical Anesthetic in a Unique Delivery System

- Rapid-acting - clinically proven to attain optimum results in 25 to 35 minutes
- Safe and effective
- No Occlusion Necessary
- Most Cost Effective
- Time Saver for Patient & Staff
- Unit of Use Tube
- For Professional Use Only

LidoWorx® incorporates our Small Molecule Solubilization System® (SMSS®), a proprietary topical drug delivery system which allows lidocaine to exhibit a rapid onset of topical anesthetic action by increasing the solubility of the active ingredient and decreasing the amount of time it will take for the product to act without occlusion.

SPECIAL INTRODUCTORY PRICE
ITEM # 555-0025 / Promotion code JR
Regular Price per Officepak* = $99.00
PLATINUM PRICE = $79.00**

*Each Officepak contains 6 X 12 Gm unit of use tubes per box
**Offer expires 9/30/10

Contact your HENRY SCHEIN® Representative for more information or to place an order.
CALL: 1-800-P-SCHEIN (1-800-772-4346) 8 AM-9 PM (ET)
FAX: 1-800-329-9109 24 HOURS | www.henryschein.com/medical
LidoWorx® is an alcoholic, non-toxic, transdermal gel containing 4% lidocaine with skin permeation enhancers, indicated as a topical analgesic for use on normal intact skin for rapid local analgesia.

COMPOSITION

Each gram of LidoWorx® contains lidocaine (40 mg) in a gel composed of hexane/ethylalcohol, hydroxyethylcellulose, isopropanol alcohol, sodium alcohol, propylene glycol USP, and vanilla fragrance.

The chemical designation of lidocaine is acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl); melting point 66-69°C; molecular weight 234.34. It has the chemical designation of lidocaine is acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl); melting point 66-69°C; molecular weight 234.34. It has the

MECHANISM OF ACTION

LidoWorx® when applied to intact skin provides deep analgesia by the release of lidocaine from the gel into the epidermal and dermis. LidoWorx® is a local anesthetic agent of the amide type. Local anesthetics irreversibly block the initiation and conduction of nerve impulses by interfering with the flux of sodium ions through the neuronal membrane. The onset, depth and duration of dermal analgesia provided by LidoWorx® depend primarily on the site of application and duration of application. Significant anesthetic effect is attained without occlusion in approximately 25-30 minutes. However, optimum effects were observed between 35-40 minutes. The effect persists for approximately 30 minutes after removal. Areas such as the upper lip may become numb after 10 to 15 minutes of application. Dermal application of LidoWorx® may cause local blanching followed by local redness or erythema. These effects are mild and transitory.

PHARMACOKINETICS

LidoWorx® is formulated to ensure local penetration of lidocaine into the skin. A side effect of this desired local effect may be the systemic absorption of lidocaine. The amount of lidocaine systemically absorbed is directly related to both the duration of application and to the area over which it is applied. By inference from published clinical studies, the application of lidocaine to broken or inflamed skin, or to 2,000 cm² or more of skin in an adult, (600 cm² in children 10-20 kg body weight, 100 cm² in children up to 10 kg) could result in plasma levels that could, in susceptible individuals, produce a systemic pharmacologic response. Patients receiving lidocaine by prolonged infusion for suppression of ventricular dysrhythmias present objective systemic toxic effects at plasma concentrations of 6-10 μg/mL. When lidocaine is administered intravenously, it distributes to highly perfused organs such as brain, liver, kidney, and heart. LidoWorx® binds to plasma proteins (approx. 70%). It can cross the placental and blood-brain barriers, presumably by passive diffusion. It is not known whether lidocaine is metabolized in the skin. When administered intravenously it is metabolized by the fatty liver. Major metabolites are monoethylglycylxylidide (MEX) and glycolxylidide (GX). The biological half-life of lidocaine is 1.5 hrs., its plasma clearance averages 1 L/min and is dependent on liver blood flow. Both MEXand GX have pharmacologic effects, both as antiarrythmics and in terms of toxicity.

A LidoWorx® study was specifically designed to determine the systemic concentrations of lidocaine at various time points and to substantiate the hypothesis that theoretical toxic systemic concentrations do not exist. This study, entitled, “Safety and Efficacy of a Rapid Acting Topical 4% Lidocaine in a Unique Drug Delivery System,” was performed at the Geomtice Medicine and Research Institute, University of Miami Miller School of Medicine. Fourteen (14) subjects completed the LidoWorx® (4%) gel study. Gel was applied without occlusion post injection to Botox® to the crows feet wrinkles.

Each subject had LidoWorx® applied in 5 of 6 separate zones demarcated in the lateral perioral regions bilaterally. Blood samples were taken from each subject at times 0 (no LidoWorx), 20, 30, 45, and 45 minutes. At 45 minutes the remaining LidoWorx was wiped off each subject and a final blood sample taken approximately 15 minutes later (60 minutes after initial application) for a total of 7 blood samples per subject. The average lidocaine plasma concentrations obtained are shown in the following figure.

Individual lidocaine plasma levels from LidoWorx® were between 0 and 15 ng/mL (0 and 0.015 μg/mL) with a maximum average of 4 ng/mL (0.004 μg/mL). These levels are far below the reported toxicities for lidocaine that may be observed at 6.0 mcg/mL, but more commonly occur only levels exceed 10.0 mcg/mL. These data clearly show that when used in accordance with the recommended dosage instructions, LidoWorx® does not produce lidocaine plasma levels that may be considered toxic and confirms that LidoWorx® can be used effectively and safely as a topical anesthetic in the dermatologist’s office when applied to small areas without occlusion.

INDICATION AND USAGE

LidoWorx® is indicated for the rapid temporary relief of pain and itching. It is a topical analgesic for penetrating local pain relief on normal intact skin.

LidoWorx® is not recommended for use on mucous membranes because of much greater absorption than though intact skin. LidoWorx® is not recommended for use in the ear, except that it may be used on the external part of the ear.

CONTRAINDICATION

LidoWorx® is contraindicated in patients with sensitivity to the amide type local anesthetics or to any other component of the product.

WARNING

For external use only. Not for opthalmic use. Flammable: Keep away from open fire or flame.

Caution - Do not use in the eyes. If不慎, consult a doctor. Keep this and all other topicals out of the reach of children.  In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

PRECAUTIONS

General

Repeated doses of LidoWorx® may increase blood levels of lidocaine. Avoid contact with the eye since it may cause severe irritation and/or protective reflexes. If eye contact occurs, immediately wash out the eye with water or saline. Patients with severe hepatic disease are at a greater risk of developing toxic plasma concentrations of lidocaine.

Information for Patients

When LidoWorx® is used after the patient should be aware that the production of dermal anaesthesia may be accompanied by the block of all sensations in the treated skin. For this reason, the patient should avoid inadvertent trauma to the treated area by scratching, shaving or exposure to extreme heat or cold temperatures until complete sensation has returned.

Drug Interactions

LidoWorx® should be used with caution in patients receiving Class I antidysrhythmics (such as tocainide and tetrabenazine) since the toxic effects are additive and potentially synergistic.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

In animals and rodents, carcinogenicity has been shown to be carcinogenic in laboratory animals. A two-year oral toxicity study of 2.6-10⁻⁶, a metabolite of lidocaine, has shown that in both male and female rats daily doses of 100 mg/kg (60 times SAD) resulted in adrenals and carcass of the nasal cavity. With daily dose of 2.6-10⁻³ mg/kg (60 times SAD), the increase in incidence of nasal carcinomas and adenomas in each sex of the rat were not statistically greater than the control group. In the low dose (90 mg/kg, 6 times SAD) and control groups, no nasal tumors were observed.

Mutagenesis

The mutagenic potential of lidocaine HOCl has been noted in the Ames Salmonella –mammalian microsome test and by analysis of structural chromosomal aberrations in human lymphocytes in vitro, and by the mouse micronucleus test in vivo. There was no indication in these three tests of any mutagenic effect. The mutagenicity of 2,6-xylene, a metabolite of lidocaine has been studied in different tests with mixed results. The compound was found to be weakly mutagenic in the Ames test only under metabolizable activation conditions. In addition, 2,6-xylene was observed to be mutagenic at the thymidine kinase locus, with or without activation, and induced chromosome aberrations in isolated chromosomes in the stock precipitated out of solution (1.2 mg/mL). No evidence of genotoxicity was found in the in vitro assays measuring unscheduled DNA synthesis in rat hepatocytes, chromosome damage in polychromatic erythrocytes or preferential killing of DNA repair-deficient bacteria in liver, lung kidney, testes and blood extracts from mice. However, covariant binding studies of DNA from liver and ethane tubuluses in rats indicate that 2,6-xylene may be genotoxic under certain conditions in vivo.

Use in Pregnancy

Teratogenic Effects: Pregnancy Category B

Reproduction studies with lidocaine have been performed in rats and have revealed no evidence of harm to the fetus (30 mg/kg subcutaneously, 32 times SAD). There are no adequate and well-controlled studies on pregnant women. Therefore LidoWorx® should be used in pregnancy only under a doctor’s supervision.

Labor and Delivery

Lidocaine is not contraindicated in labor and delivery. Should LidoWorx® be used concomitantly with other products containing lidocaine, total doses contributed by all formulations must be considered.

Nursing Mothers

Lidocaine is excreted in human milk; therefore, caution should be exercised when LidoWorx® is administered to a nursing mother since the milk/plasma ratio of lidocaine is 0.4.

Pediatric Use

Consult a doctor. Observe the child during application to avoid accidental ingestion. Not for oral or opthalmic use.

ADVERSE REACTIONS

Localized Reactions

Drug reactions may result in localized reactions. Prolonged exposure to the eyes may result in irritation, stinging, burning, sensitivity, discharge, drying, or blurry vision. The signs and symptoms may be associated with lidocaine concentrations greater than 0.3 mg/mL.

Allergic Reactions

Allergic and anaphylactic reactions associated with lidocaine can occur. They are characterized by urticaria, angioedema, bronchospasm, and shock.

Systemic (Dose Related) Reactions

Systemic adverse reactions following appropriate use of LidoWorx® are unlikely. Systemic adverse effects of lidocaine are similar in nature to those observed with other amide type local anesthetics including CNS excitation and/or depression (light-headedness; nervousness; apprehension; euphoria; confusion; dizziness; drowsiness, tremors, blurred or double vision; vomiting; sensations of heat, cold or numbness; switch in mood; convulsions; unconsciousness; respiratory depression and arrest). Cardiac manifestations may include bradycardia, hypotension and cardiovascular collapse leading to arrest.

DIRECTIONS FOR USE

Adults and children 2 years and older: Apply externally to the affected area not more than 4 times daily. Children under 2 years of age, consult a doctor.

Apply a moderately thick layer to the affected area (approximately 1/8 inch thick). Allow time for numbness to develop, approximately 15 minutes. Significant anesthetic effect is attained without occlusion in approximately 25–30 minutes. However, optimum effects were observed between 35–40 minutes. Wipe-off excess gel.

LidoWorx® should not be applied to large areas of the body. LidoWorx® should not be used with occlusion.

HOW SUPPLIED

LidoWorx® 4% is supplied in single unit-of-use 0.4 oz (12 g) tubes. Keep out of reach of children. This package is not child resistant. Discard after initial use.

Please note that the tubes are filled by weight, not volume. Air bubbles may be present in the gel. Store at controlled room temperature, 15–30°C.