glydo®

(lidocaine HCl jelly USP, 2%)

Innovative Technology Designated Product
vizient Awarded Supplier

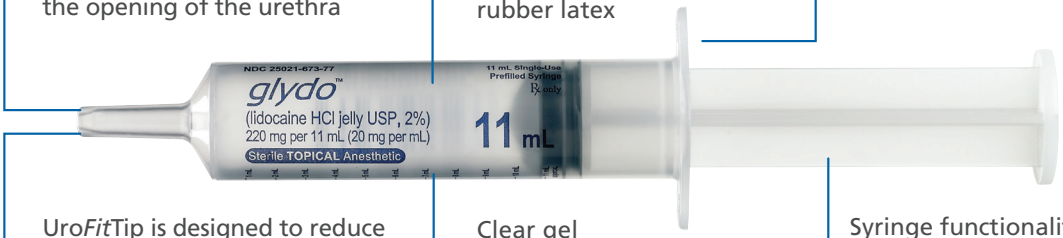
Prefilled. Preassembled. *Preferred*.[1]

- GLYDO syringe is the nonbreakable, cost-saving[2] alternative to competitive glass vial-based syringes that can inadvertently break.
- GLYDO syringe is prefilled, preassembled and ready to use, providing efficiency and convenience from use through disposal.
- GLYDO syringes in sterile individual packs are available in:
  - **11 mL** **(NDC 25021-673-77)**
  - **6 mL** **(NDC 25021-673-76)**

UroFitTip™ is anatomically designed for easy insertion into the opening of the urethra

Preservative-free, PVC-free and not made with natural rubber latex

Enhanced finger flanges for ease of use



UroFitTip is designed to reduce distention of the meatus

Clear gel transparency provides lubrication and unobstructed views

Syringe functionality allows for slow and steady instillation for prevention and control of pain in urethral procedures

Visit www.glydo.com for more product details and ordering information or to request your complimentary samples of GLYDO.

[1] A description of GLYDO was preferred by 159/193 clinicians in a June 2014 survey.
[2] Data on file, Sagent Pharmaceuticals, Inc., 2015.

Please see a brief summary of prescribing information for GLYDO (lidocaine HCl jelly, USP, 2%) on reverse.

SAGENT® Urology

GLYDO® (lidocaine HCl jelly USP, 2%)

Brief Summary of Prescribing Information

INDICATIONS AND USAGE

GLYDO (lidocaine HCl jelly USP, 2%) is indicated for prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal).

CONTRAINDICATIONS

Lidocaine is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type or to other components of GLYDO.

WARNINGS

EXCESSIVE DOSAGE, OR SHORT INTERVALS BETWEEN DOSES, CAN RESULT IN HIGH PLASMA LEVELS AND SERIOUS ADVERSE EFFECTS. PATIENTS SHOULD BE INSTRUCTED TO STRICTLY ADHERE TO THE RECOMMENDED DOSAGE AND ADMINISTRATION GUIDELINES AS SET FORTH IN THIS PACKAGE INSERT. THE MANAGEMENT OF SERIOUS ADVERSE REACTIONS MAY REQUIRE THE USE OF RESUSCITATIVE EQUIPMENT, OXYGEN, AND OTHER RESUSCITATIVE DRUGS.

GLYDO should be used with extreme caution in the presence of sepsis or severely traumatized mucosa in the area of application, since under such conditions there is the potential for rapid systemic absorption.

When used for endotracheal tube lubrication care should be taken to avoid introducing the product into the lumen of the tube. Do not use the jelly to lubricate the endotracheal stylettes. If allowed into the inner lumen, the jelly may dry on the inner surface leaving a residue which tends to clump with flexion, narrowing the lumen. There have been rare reports in which this residue has caused the lumen to occlude. (See also **ADVERSE REACTIONS** and **DOSAGE AND ADMINISTRATION**.)

Methemoglobinemia cases have been reported in association with the use of local anesthetics. 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 clinical manifestations.

Signs of methemoglobinemia manifesting as cyanotic skin discoloration and/or abnormal blood coloration may occur immediately or may be delayed. Immediate treatment is required to avert more serious adverse central nervous system and cardiovascular adverse effects including seizures, coma, arrhythmias and death. Discontinue GLYDO. Patients with severe signs and symptoms may respond to oxygen therapy and hydration. A more severe presentation may require methylene blue, exchange transfusion or hyperbaric oxygen.

PRECAUTIONS

General

The safety and effectiveness of lidocaine depend on proper dosage, correct technique, adequate precautions, and readiness for emergencies. (See **WARNINGS** and **ADVERSE REACTIONS**.) The lowest dosage that results in effective anesthesia should be used to avoid high plasma levels and serious adverse effects. Repeated doses of lidocaine may cause significant increases in blood levels with each repeated dose because of slow accumulation of the drug or its metabolites. Tolerance to elevated blood levels varies with the status of the patient. Debilitated, elderly patients, acutely ill patients, and children should be given reduced doses commensurate with their age and physical status. Lidocaine should also be used with caution in patients with severe shock or heart block.

GLYDO should be used with caution in patients with known drug sensitivities. Patients allergic to para-aminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown cross sensitivity to lidocaine.

Many drugs used during the conduct of anesthesia are considered potential triggering agents for familial malignant hyperthermia. Since it is not known whether amide-type local anesthetics may trigger this reaction and since the need for supplemental general anesthesia cannot be predicted in advance, it is suggested that a standard protocol for management should be available. Early unexplained signs of tachycardia, tachypnea, labile blood pressure, and metabolic acidosis may precede temperature elevation. Successful outcome is dependent on early diagnosis, prompt discontinuance of the suspect triggering agent(s) and institution of treatment, including oxygen therapy, indicated supportive measures and dantrolene (consult dantrolene sodium intravenous package insert before using).

Information for Patients

When topical anesthetics are used in the mouth, the patient should be aware that the production of topical anesthesia may impair swallowing and thus enhance the danger of aspiration. For this reason, food should not be ingested for 60 minutes following use of local anesthetic preparations in the mouth or throat area. This is particularly important in children because of their frequency of eating.

Numbness of the tongue or buccal mucosa may enhance the danger of unintentional biting trauma. Food and chewing gum should not be taken while the mouth or throat area is anesthetized.

Carcinogenesis - Long-term studies in animals have not been performed to evaluate the carcinogenic potential of lidocaine.

Mutagenesis - The mutagenic potential of lidocaine has been tested in the Ames Salmonella reverse mutation assay, an *in vitro* chromosome aberrations assay in human lymphocytes and in an *in vivo* mouse micronucleus assay. There was no indication of any mutagenic effect in these studies.

Impairment of Fertility - The effect of lidocaine on fertility was examined in the rat model. Administration of 30 mg/kg, s.c. (180 mg/m^2) to the mating pair did not produce alterations in fertility or general reproductive performance of rats. There are no studies that examine the effect of lidocaine on sperm parameters. There was no evidence of altered fertility.

Use in Pregnancy

Teratogenic Effects: Pregnancy Category B

Reproduction studies for lidocaine have been performed in both rats and rabbits. There was no evidence of harm to the fetus at subcutaneous doses of up to 50 mg/kg lidocaine (300 mg/m^2 on a body surface area basis) in the rat model. In the rabbit model, there was no evidence of harm to the fetus at a dose of 5 mg/kg, s.c. (60 mg/m^2 on a body surface area basis). Treatment of rabbits with 25 mg/kg (300 mg/m^2) produced evidence of maternal toxicity and evidence of delayed fetal development, including a non-significant decrease in fetal weight (7%) and an increase in minor skeletal anomalies (skull and sternebral defect, reduced ossification of the phalanges). The effect of lidocaine on post-natal development was examined in rats by treating pregnant female rats daily subcutaneously at doses of 2, 10, and 50 mg/kg (12, 60, and 300 mg/m^2) from day 15 of pregnancy and up to 20 days postpartum. No signs of adverse effects were seen either in dams or in the pups up to and including the dose of 10 mg/kg (60 mg/m^2); however, the number of surviving pups was reduced at 50 mg/kg (300 mg/m^2), both at birth and the duration of lactation period, the effect most likely being secondary to maternal toxicity. No other effects on litter size, litter weight, abnormalities in the pups and physical developments of the pups were seen in this study.

A second study examined the effects of lidocaine on post-natal development in the rat that included assessment of the pups from weaning to sexual maturity. Rats were treated for 8 months with 10 or 30 mg/kg, s.c. lidocaine (60 mg/m^2 and 180 mg/m^2 on a body surface area basis, respectively). This time period encompassed 3 mating periods. There was no evidence of altered post-natal development in any offspring; however, both doses of lidocaine significantly reduced the average number of pups per litter surviving until weaning of offspring from the first 2 mating periods.

There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery

Lidocaine is not contraindicated in labor and delivery. Should GLYDO be used concomitantly with other products containing lidocaine, the total dose contributed by all formulations must be kept in mind.

Nursing Mothers

Lidocaine is secreted 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

Although, the safety and effectiveness of GLYDO in pediatric patients have not been established, a study of 19 premature neonates (gestational age <33 weeks) found no correlation between the plasma concentration of lidocaine or monoethylglycinexylidide and infant body weight when moderate amounts of lidocaine (i.e. 0.3 mL/kg of lidocaine gel 20 mg/mL) were used for lubricating both intranasal and endotracheal tubes. No neonate had plasma levels of lidocaine above 750 mcg/L. Dosages in children should be reduced, commensurate with age, body weight, and physical condition. (See **DOSAGE AND ADMINISTRATION**.)

ADVERSE REACTIONS

Adverse experiences following the administration of lidocaine are similar in nature to those observed with other amide local anesthetic agents. These adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage or rapid absorption, or may result from a hypersensitivity, idiosyncrasy, or diminished tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature. The following types are those most commonly reported:

There have been rare reports of endotracheal tube occlusion associated with the presence of dried jelly residue in the inner lumen of the tube. (See also **WARNINGS** and **DOSAGE AND ADMINISTRATION**.)

Central Nervous System

CNS manifestations are excitatory and/or depressant and may be characterized by lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression, and arrest. The excitatory manifestations may be very brief or may not occur at all, in which case the first manifestation of toxicity may be drowsiness merging into unconsciousness and respiratory arrest.

Drowsiness following the administration of lidocaine is usually an early sign of a high blood level of the drug and may occur as a consequence of rapid absorption.

Cardiovascular System

Cardiovascular manifestations are usually depressant and are characterized by bradycardia, hypotension, and cardiovascular collapse, which may lead to cardiac arrest.

Allergic

Allergic reactions are characterized by cutaneous lesions, urticaria, edema, or anaphylactoid reactions. Allergic reactions may occur as a result of sensitivity either to the local anesthetic agent or to other components in the formulation. Allergic reactions as a result of sensitivity to lidocaine are extremely rare and, if they occur, should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

To report SUSPECTED ADVERSE REACTIONS, contact Sagent Pharmaceuticals, Inc. at 1-866-625-1618 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

Acute emergencies from local anesthetics are generally related to high plasma levels encountered during therapeutic use of local anesthetics. (See **ADVERSE REACTIONS, WARNINGS**, and **PRECAUTIONS**.)

Management of Local Anesthetic Emergencies

The first consideration is prevention, best accomplished by careful and constant monitoring of cardiovascular and respiratory vital signs and the patient's state of consciousness after each local anesthetic administration. At the first sign of change, oxygen should be administered.

The first step in the management of convulsions consists of immediate attention to the maintenance of a patent airway and assisted or controlled ventilation with oxygen and a delivery system capable of permitting immediate positive airway pressure by mask. Immediately after the institution of these ventilatory measures, the adequacy of the circulation should be evaluated, keeping in mind that drugs used to treat convulsions sometimes depress the circulation when administered intravenously. Should convulsions persist despite adequate respiratory support, and if the status of the circulation permits, small increments of an ultra-short acting barbiturate (such as thiopental or thiamylal) or a benzodiazepine (such as diazepam) may be administered intravenously. The clinician should be familiar, prior to use of local anesthetics, with these anticonvulsant drugs. Supportive treatment of circulatory depression may require administration of intravenous fluids and, when appropriate, a vasopressor as directed by the clinical situation (e.g., ephedrine).

If not treated immediately, both convulsions and cardiovascular depression can result in hypoxia, acidosis, bradycardia, arrhythmias, and cardiac arrest. If cardiac arrest should occur, standard cardiopulmonary resuscitative measures should be instituted.

Dialysis is of negligible value in the treatment of acute overdosage with lidocaine.

The oral LD_{50} of lidocaine HCl in non-fasted female rats is 459 (346 to 773) mg/kg (as the salt) and 214 (159 to 324) mg/kg (as the salt) in fasted female rats.

Mfd. for SAGENT Pharmaceuticals®
Schaumburg, IL 60195 (USA)
Mfd. by Klosterfrau Berlin GmbH
Made in Germany

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You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full prescribing information for GLYDO (lidocaine HCl jelly USP, 2%).

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