smooth sailing
FOR YOUR URETHRAL PROCEDURES

Prefilled. Preassembled. Preferred by 80%¹ of polled U.S. urologists and urology nurses.

- GLYDO syringe is the nonbreakable, cost-saving² 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 is available in 11 mL (NDC 25021-673-77) and 6 mL (NDC 25021-673-76) syringes in sterile individual packs.

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.

Please see a brief summary of prescribing information for GLYDO (lidocaine HCl jelly, USP, 2%) on reverse.
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 stick on the inner surface leaving a residue which tends to a) occlude. (See also ADVERSE REACTIONS and DOSAGE AND ADMINISTRATION.)

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. Repetitive doses may result in 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 the patient's ability to swallow 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.

Number 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 induction of any of these tests in in vivo 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/m²) 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 a dose of 5 mg/kg, s.c. (60 mg/m² on a body surface area basis) in the rat model. In the rabbit model, there was no evidence of harm to the fetus at the dose of 5 mg/kg, s.c. (60 mg/m² on a body surface area basis). Treatment of rabbits with 25 mg/kg (300 mg/m²) 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 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 significant decrease in fetal weight (7%) and an increase in minor skeletal anomalies (skull and sternebral defect, reduced ossification of the phalanges).

The oral LD₅₀ of lidocaine HCl in fasted female rats was 159 to 324 mg/kg (as the salt) in fasted female rats. The oral LD₅₀ of lidocaine HCl in fasted female rats was 159 to 324 mg/kg (as the salt) in fasted female rats. The oral LD₅₀ of lidocaine HCl in fasted female rats was 159 to 324 mg/kg (as the salt) in fasted female rats.

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