Your Partner in Parenteral Products

URO-JET® DELIVERY SYSTEM

Lidocaine HCl Jelly, USP 2%
Prefilled Disposable Syringe

Rx Only
- Catheterization
- Urethral Dilation
- Cystoscopy
- Retrograde Stone Manipulation

The most complete line of prefilled syringe: 5 mL, 10 mL, 20 mL
- Ranges of sizes provides greater dosing flexibility and cost savings by delivering exact amount required; reduces product waste
- Dual lubricant / anesthetic action
- Conical, rounded syringe tip conforms closely to urogenital tissue anatomy
- Sterile packaging eliminates need for presterilization of syringe or tip
- Contains no preservatives

<table>
<thead>
<tr>
<th>PRODUCT DESCRIPTION</th>
<th>DELIVERY SYSTEM</th>
<th>UNIT SIZE</th>
<th>UNITS/ BOX</th>
<th>NDC#</th>
<th>New NDC# as of April 2012</th>
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</thead>
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<tr>
<td>Lidocaine HCl Jelly, USP 2% Sterile Pak, 100 mg</td>
<td>Uro-Jet® AC*</td>
<td>5 mL</td>
<td>25</td>
<td>0548-3011-00</td>
<td>76329-3011-5</td>
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<tr>
<td>Lidocaine HCl Jelly, USP 2% Sterile Pak, 100 mg</td>
<td>Uro-Jet®</td>
<td>5 mL</td>
<td>25</td>
<td>0548-3012-00</td>
<td>76329-3012-5</td>
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<tr>
<td>Lidocaine HCl Jelly, USP 2% Sterile Pak, 200 mg</td>
<td>Uro-Jet®</td>
<td>10 mL</td>
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<td>Lidocaine HCl Jelly, USP 2% Sterile Pak, 400 mg</td>
<td>Uro-Jet®</td>
<td>20 mL</td>
<td>25</td>
<td>0548-3015-00</td>
<td>76329-3015-5</td>
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*AC (Anatomically Constricted)

TO PLACE AN ORDER, PLEASE CALL 1-800-423-4136

INTERNATIONAL MEDICATION SYSTEMS, Limited
1886 Santa Anita Ave., So. El Monte, CA 91733
An Amphastar Pharmaceuticals Company • www.ims-limited.com
**LIDOCAINE HYDROCHLORIDE JELLY, USP, 2%**

**DESCRIPTION**
Lidocaine Hydrochloride Jelly USP 2% is a sterile aqueous product that contains a local anesthetic agent and is administered topically. See INDICATIONS AND USAGE for specific uses.

**PHARMACODYNAMICS AND PHARMACOKINETICS**
Lidocaine is rapidly absorbed after topical administration. Absorption is complete in a few minutes after application. The rate of entry into the systemic circulation is influenced by the local blood supply and local plasma concentration. The plasma concentration transiently exceeds the therapeutic range. Under normal circumstances, the drug is rapidly metabolized and excreted. However, under altered states of health, the rate of metabolism may be reduced, and lidocaine may accumulate in the blood stream. The elimination half-life of lidocaine in blood is 1.5 to 2 hours. The plasma half-life in individuals with liver disease may be 10 hours or longer. Partial absorption may occur when the drug is administered by the intradermal route. In such cases, the plasma concentrations of lidocaine are lower than those observed after oral administration.

**REPRODUCTION STUDIES**
Studies of lidocaine metabolism following intravenous bolus injections have shown that the elimination half-life of this agent is 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 alter elimination.

**Pharmacology:** Lidocaine is a close chemical analog of procaine. Both agents produce qualitatively similar local anesthetic effects. It is essentially free from the cardiovascular toxicity ascribed to procaine. At the usual dosage levels, the incidence of allergic reactions is about the same for both agents. The cardiovascular reactions which occur are essentially limited to a rare incidence of cardiovascular depression, which may be manifested by hypotension, decreased cardiac output, bradycardia or tachycardia. Convulsions may occur at unusually high dosage levels or when lidocaine is used in the presence of CNS excitation. Lidocaine, like procaine, may produce phlebitis in the kidneys when used in very high concentration. Lidocaine has been shown to cause increased permeability of the blood-brain and blood-CSF barriers. Lidocaine may be observed following intrathecal or spinal administration, and the clinical significance of this finding is unknown.

**ADVERSE REACTIONS**
Adverse experiences following the administration of lidocaine are similar in nature to those observed with other local anesthetic agents.

**Labor and Delivery:** Lidocaine is not contraindicated in labor and delivery. Should Lidocaine Hydrochloride Jelly USP 2% be used concomitantly with other products containing lidocaine, the total dose contributed by all these products 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 Lidocaine Hydrochloride Jelly USP 2% 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 monoglycinexylylde and infant body weight when moderate amounts of lidocaine (i.e. 0.3 mg/kg of lidocaine gel 20%) were used for lubricating both endotracheal 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.)

**DOSE AND ADMINISTRATION**
Lidocaine Hydrochloride 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 Lidocaine Hydrochloride Jelly USP 2%.

**WARNINGS**
**EXCESSIVE DOSAGE OR INTERVERTEBRAL SPACES IN VARIOUS MAMMALIAN SPECIES, including man, may be achieved by the use of a local anesthetic agent on various components of the cardiovascular system.**

**INDICATIONS AND USAGE**
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