Uro-Jet® Prefilled Syringe for:
- Catheterization
- Urethral Dilation
- Cystoscopy

**URO-JET®**
Lidocaine HCl Jelly, USP, 2%
Prefilled Disposable Syringe

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

<table>
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<th>PRODUCT</th>
<th>UNIT SIZE</th>
<th>UNITS / BOX</th>
<th>NDC#</th>
<th>AMERISOURCE BERGEN</th>
<th>CARDINAL</th>
<th>MCKESSON</th>
<th>MORRIS &amp; DICKSON</th>
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<td>10106047</td>
<td>4596789</td>
<td>1619006</td>
<td>613778</td>
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*AC (Anatomically Constricted)*

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

INTERNATIONAL MEDICATION SYSTEMS, LTD
1886 Santa Anita Ave., South El Monte, CA 91733
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Please see reverse for important safety information, including boxed warning, and indications and usage.
Lidocaine Hydrochloride Jelly USP, 2% is a sterile aqueous gel containing lidocaine hydrochloride which is chemically designated as acetamide (2-diethylamino)-N-2,6-dimethylphenyl-, monohydrochloride and has the following structural formula:

**Composition of Lidocaine Hydrochloride Jelly USP, 2%:** Each mL contains 20 mg of lidocaine hydrochloride, and sodium hydroxide or hydrochloric acid to adjust the pH to 5.5 (range 5.0 to 6.5). The gel also contains the following inactive ingredients: propylene glycol, polyethylene glycol, carboxymethylcellulose sodium, and sorbic acid (0.01% w/v). Each mL contains 20 mg of lidocaine hydrochloride, and sodium hydroxide or hydrochloric acid to adjust the pH to 5.5 (range 5.0 to 6.5). The gel also contains the following inactive ingredients: propylene glycol, polyethylene glycol, carboxymethylcellulose sodium, and sorbic acid (0.01% w/v).

**Mechanism of action:** Lidocaine stabilizes the neuronal membrane by inhibiting the influx of ions required for the initiation and propagation of nerve impulses, thereby effecting local anesthetic action.

**Onset of action:** The onset of action is 3 to 5 minutes. It is ineffective when applied to intact skin.

**Hemodynamic:** Excessive blood levels may cause changes in cardiac output, total peripheral resistance, and mean arterial pressure. These changes may be explainable by a direct depressant effect of the local anesthetic agent on various components of the cardiovascular system.

**Pharmacokinetics and metabolism:** Lidocaine may be absorbed following topical administration to mucous membranes, but the amount absorbed is not known. After parenteral administration, approximately 60% of an oral dose is absorbed. Absorption is affected by factors such as application of pressure, area of application and duration of exposure. In general, the rate of absorption of local anesthetic agents following topical absorption is slower than their rate following systemic absorption. Following intravenous administration from the gastroenteral tract, but little drug can appear 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. Bioavailability of intravenous Lidocaine is 100%. Lidocaine is metabolized in the liver, and metabolites are excreted by the kidney. Bioavailability of intravenous Lidocaine is 100%.

Lidocaine crosses the blood-brain and placental barriers, presumably by passive diffusion. The plasma binding of lidocaine is dependent on drug concentration, and the fraction bound decreases with increasing concentration. At concentrations of 1 to 4 mg of free base per mL, 60 to 80% of lidocaine is protein bound. Binding is also dependent on the plasma concentration of alpha-1 acid glycoprotein. The fraction bound decreases in increasing concentrations due to saturation of the binding sites. The volume of distribution of lidocaine is 1.2 to 1.6 L/kg (range 0.9 to 2.2 L/kg).

**Toxicity:** Acute systemic toxicity follows the administration of lidocaine by any route of administration. In clinical studies, the incidence of toxicity was less when lidocaine was administered by the pteryal and intravenous routes and was lower when the drug was administered by the topical route. The toxicity of lidocaine is also dependent on the plasma concentration of the alpha-1 acid glycoprotein. The half-life may be prolonged two-fold or more in patients with liver dysfunction. Renal impairment delays lidocaine elimination and the halflife may be prolonged to as long as 4 hours when plasma levels of lidocaine are more than 50 mg/mL.

**Plasma levels:** Plasma levels of lidocaine have been shown to be directly proportional to the dosage administered. Plasma levels above 6 μg per mL are generally associated with toxicity. In the rhesus monkey arterial blood levels of 18-21 μg / mL have been shown to produce overt systemic effects. Objective adverse manifestations become increasingly apparent with increasing venous plasma levels.

**Indications and Usage:** 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).

**Usability:** Lidocaine Hydrochloride Jelly USP, 2% should be used with caution in patients with known drug sensitivities. Patients should be warned of the possibility of an allergic reaction and advised to discontinue use of the product immediately if irritation occurs.

**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 and Precautions:** Use in Pregnancy:

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