

XYLENE

Jelly

Composition

Each gram contains Lidocaine hydrochloride 2%.

Action

Xylene 2% provides prompt and profound anaesthesia of mucous membranes and lubrication that reduces friction. Its water-miscible base, characterised by high viscosity and low surface tension, brings the anaesthetic into intimate and prolonged contact with the tissue, giving effective anaesthesia of long duration (approx. 20-30 min). Anaesthesia usually occurs rapidly (within 5 min, depending upon the area of application).

Lidocaine like other local anaesthetics causes a reversible blockade of impulse propagation along nerve fibres by preventing the inward movement of sodium ions through the nerve membrane. Local anaesthetics of the amide type are thought to act within the sodium channels of the nerve membrane.

Local anaesthetic drugs may also have similar effects on excitable membranes in the brain and myocardium. If excessive amounts of drug reach the systemic circulation rapidly, symptoms and signs of toxicity will appear, emanating from the central nervous and cardiovascular systems.

Central nervous system toxicity usually precedes the cardiovascular effects as it occurs at lower plasma concentrations. Direct effects of local anaesthetics on the heart include slow conduction, negative inotropism and possibly cardiac arrest.

Pharmacokinetics

Lidocaine is readily absorbed from mucous membranes and through damaged skin. Lidocaine undergoes first-pass metabolism in the liver and about 90% is dealkylated to form monoethylglycinexylidide and glycinexylidide. Further metabolism occurs and the metabolites are excreted in the urine with less than 10% as unchanged lidocaine.

Indications

Xylene 2% jelly are indicated as a surface anesthetic and lubricant for:

- The male and female urethra during cystoscopy, catheterisation, exploration by sound and other endourethral procedures.
- Nasal and pharyngeal cavities in endoscopic procedures such as gastroscopy and bronchoscopy.
- During proctoscopy and rectoscopy.
- Tracheal intubation.
- To relieve pain after circumcision in children.

Contraindications

Patients with a known history of hypersensitivity to local anaesthetics of the amide type.

Warnings

Excessive doses of Lidocaine products or short intervals between doses can result in high plasma levels and serious adverse effects. Patients should be instructed to adhere strictly to the recommended dosage (the management of serious adverse reactions may require the use of resuscitative equipment, oxygen and other resuscitative drugs.)

Absorption from wound surfaces and mucous membranes is relatively high and especially high in the bronchial tree. The absorption of Lidocaine jelly from the nasopharynx is variable but usually lower than with other Lidocaine products. Following instillation in urethra and bladder, adsorption is low. Lidocaine jelly should be used with caution in patients with traumatised mucosa and/or sepsis in the region of the proposed application.

The Oropharyngeal use of topical anaesthetic agents may interfere with swallowing and thus enhance the danger of aspiration. Numbness of the tongue or buccal mucosa may increase the danger of biting trauma.

When used for endotracheal tube lubrication, care should be taken to avoid introduction of the jelly into the lumen of the tube. The jelly may dry on the inner surface leaving a residue that tends to clump with flexion, narrowing the lumen. There have been rare reports in which this residue has caused the lumen to occlude.

Patients treated with anti-arrhythmic drugs class III (eg. amiodarone) should be kept under close surveillance and ECG monitoring considered, since cardiac effects may be additive.

If the dose or administration is likely to result in high blood levels, some patients require special attention to prevent potentially dangerous side effects:

- Patients with partial or complete heart block.
- The elderly and patients in poor general health.
- Patients with advanced liver disease or severe renal dysfunction.

Pregnancy

Category B

Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Therefore, caution should be exercised when Lidocaine is administered to nursing mothers.

Paediatric Use

Dosage in children should be reduced in accordance with age, body weight and physical conditions.

Adverse Reactions

The potential for systemic adverse reactions with Xylene gel is very low.

Local reactions

An increased incidence of postoperative "sore throat" has been reported following endotracheal tube lubrication with Lidocaine jelly .

Allergic reactions

Allergic reactions (in most severe instances anaphylactic shock) to local anaesthetics of the amide type are rare (<1/1000).

Acute systemic toxicity

Lignocaine may have acute toxic effects if high systemic levels occur due to fast absorption or overdosage.

Precautions

The safety and effectiveness of Lidocaine depends on proper dosage, correct technique, adequate precautions and readiness for emergencies. Therefore, the smallest amount of the gel that results in effective anaesthesia should be used in order to avoid high plasma levels and serious adverse effects. Reduced amounts should be applied to debilitated, elderly and acutely ill patients and children, commensurate with their age and physical status. It should be used with caution in patients with epilepsy, reduced hepatic or renal function, or impaired cardiac conduction.

Topical Lidocaine should be used with caution in patients with severely traumatized mucosa and/or sepsis in the region of the proposed application, and in persons with known drug sensitivities.

Patients with allergic sensitivity to para-aminobenzoic acid derivatives (e.g. procaine, tetracaine, benzocaine and others) have not shown cross-sensitivity to Lidocaine.

Dosage and Administration

Surface Anaesthesia of the Adult Male Urethra

For adequate analgesia in males, 20-30 ml of gel is required. The gel is instilled slowly into the urethra until almost half the tube (10-15 ml) is emptied. A penile clamp is then applied for several minutes at the corona, and an additional 10-15 ml of the gel is instilled.

When anaesthesia is especially important (e.g. during sounding or cystoscopy), a larger quantity of gel, for example 30-40 ml, may be instilled in 3-4 portions and allowed to work for 10-12 minutes before insertion of the instrument.

Prior to catheterization, a small volume of gel (5-10 ml) is usually adequate for lubrication.

Surface Anaesthesia of the Adult Female Urethra

Instil 5-10 ml in small portions to fill the whole urethra. If desired, some gel may be deposited on a cotton swab and introduced into the urethra. In order to obtain adequate anaesthesia, wait several minutes prior to performing urological procedures.

Lubrication for Endotracheal Intubation

Apply approximately 5 ml to the external surface of the endotracheal tube just prior to intubation. Care should be taken to avoid introducing the gel into the lumen of the endotracheal tube.

Presentation

Tube of 30 grams