DESCRIPTION:
Xylocaine (lidocaine HCl) Injections are sterile, nonpyrogenic, aqueous solutions that contain a local anesthetic agent, lidocaine HCl, which is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)acetamide hydrochloride monohydrate, with the molecular weight 270.8. Xylocaine HCl (C₆H₁₃NO₂HCl•H₂O) has the following structural formula:

\[ \text{C₆H₁₃NO₂HCl•H₂O} \]

The pharmacological/toxicological actions of lidocaine HCl are those of a local anesthetic of the aminoalkylbenzene type. Potentiation of vagal tone, which are potentiated by lidocaine HCl. Potentiation of vagal reflexes may occur following administration of lidocaine HCl hydrochloride (see ADVERSE REACTIONS). In the case of severe overdose, discontinue the use of the drug.

PRECAUTIONS:
The safety and effectiveness of lidocaine HCl have been established for various regional anesthetic procedures. Xylocaine solutions contain epinephrine or norepinephrine, which should be used with caution in patients receiving monoamine oxidase inhibitors or tricyclic antidepressants may produce severe, prolonged hypertension. Use of large doses may produce cardiovascular collapse following use of some local anesthetics for paracervical block in early pregnancy (as anesthesia for elective abortion) suggest that systemic absorption under these conditions may be more rapid. The maximum dose of drug should not be increased in terms of weight and size by the patient, allowing a 5-minute interval between subsequent doses.

Nursing Mothers
It is not known whether this drug is excreted in human milk. Caution should be exercised when Xylocaine HCl is administered to a nursing woman.

Pediatric Use
Doses in children should be reduced commensurate with age, body weight and physiological factors. See DOSAGE AND ADMINISTRATION.

ADVERSE REACTIONS:
Adverse experiences following the administration of local anesthetic agents are usually caused by the systemic absorption of such agents and the resultant toxicity. When these agents are administered under the control of the dentist or the anesthesiologist in the proper dosage, toxic reactions are infrequent and usually of short duration. When signs of toxicity appear, they may be controlled by stopping the administration of the drug, by administering an antidote, and by instituting other supportive measures. The toxicity of a local anesthetic drug is dependent upon a combination of factors, including rate of absorption, rate of distribution, and rate of excretion.

In the case of severe overdose, discontinue the use of the drug. For the initiation and conduction of impulses thereby effecting local anesthetic action. Excessive blood levels may cause changes in cardiac output, total peripheral resistance, and mean arterial pressure. With central neural techniques such as lumbar and epidural anesthesia, the administration of local anesthetic solutions containing epinephrine or norepinephrine may be accompanied by systemic toxicity. Ineffective anesthesia should be accompanied by this fact before administering Xylocaine HCl to pregnant women. Careful consideration should be given to the dosage and use of local anesthetic solutions containing epinephrine or norepinephrine since they may be less able to compensate for functional changes associated with pregnancy and fetal distress. Careful consideration should be given to the dosage and use of local anesthetic solutions containing epinephrine or norepinephrine since they may be less able to compensate for functional changes associated with pregnancy and fetal distress.

Nurture the patient, allowing a 5-minute interval between subsequent doses. With intravenous regional anesthesia, the injection of Xylocaine HCl in multiple dose vials should be accomplished after each local anesthetic injection. It should be kept in mind at such times that restlessness, anxiety, tinnitus, dizziness, blurred or double vision, numbness, or drowsiness may be early warning signs of central nervous system toxicity. Measurements of blood pressure and pulse rate should be made before the injection of Xylocaine HCl in multiple dose vials. If the systolic blood pressure begins to fall, intravenous epinephrine or norepinephrine should be administered immediately. The recommended dose of Xylocaine HCl in multiple dose vials is 2 mL. When the systolic blood pressure begins to fall, intravenous epinephrine or norepinephrine should be administered immediately. The recommended dose of Xylocaine HCl in multiple dose vials is 2 mL. When the patient's condition so indicates, intravenous epinephrine or norepinephrine should be administered immediately. The recommended dose of Xylocaine HCl in multiple dose vials is 2 mL. When the patient's condition so indicates, intravenous epinephrine or norepinephrine should be administered immediately.

Lidocaine HCl should be used with caution in patients with severe cardiovascular disease, including those with cardiac arrhythmias, who are hypovolemic, or who have received large doses of Xylocaine HCl in multiple dose vials. Patients with cardiovascular disease, including those with cardiac arrhythmias, who are hypovolemic, or who have received large doses of Xylocaine HCl in multiple dose vials. Patients with cardiovascular disease, including those with cardiac arrhythmias, who are hypovolemic, or who have received large doses of Xylocaine HCl in multiple dose vials. Patients with cardiovascular disease, including those with cardiac arrhythmias, who are hypovolemic, or who have received large doses of Xylocaine HCl in multiple dose vials. Patients with cardiovascular disease, including those with cardiac arrhythmias, who are hypovolemic, or who have received large doses of Xylocaine HCl in multiple dose vials. Patients with cardiovascular disease, including those with cardiac arrhythmias, who are hypovolemic, or who have received large doses of Xylocaine HCl in multiple dose vials. Patients with cardiovascular disease, including those with cardiac arrhythmias, who are hypovolemic, or who have received large doses of Xylocaine HCl in multiple dose vials. Patients with cardiovascular disease, including those with cardiac arrhythmias, who are hypovolemic, or who have received large doses of Xylocaine HCl in multiple dose vials. Patients with cardiovascular disease, including those with cardiac arrhythmias, who are hypovolemic, or who have received large doses of Xylocaine HCl in multiple dose vials. Patients with cardiovascular disease, including those with cardiac arrhythmias, who are hypovolemic, or who have received large doses of Xylocaine HCl in multiple dose vials.
**Cardiovascular System**

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

**Allergic Reactions**

Allergic reactions are characterized by cutaneous lesions, urticaria, edema or anaphylactoid reaction. Allergic reactions appear to result from sensitivity either to local anesthetic agents or to the methylparaben used as a preservative in the multiple dose vials. Allergic reactions, including anaphylactic reactions, may occur as a result of sensitivity to Xylocaine, but are infrequent. If allergic reactions do occur, they should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

There have been no reports of cross-sensitivity between lidocaine and procaine or between lidocaine hydrochloride and quinidine.

**Neurologic**

The incidences of adverse reactions associated with lidocaine HCl and those associated with epinephrine are very similar. However, epinephrine may be related to the total dose of local anesthetic administered and also to the dose of epinephrine used, the route of administration and the physical condition of the patient. For example, the incidence of ventricular extrasystoles in 10,440 patients who received lidocaine HCl for spinal anesthesia or epidural anesthesia and in whom epinephrine reactions were reported to be about 3 percent for each 1:200,000 epinephrine in 2% lidocaine. If large volumes are required, only solutions containing epinephrine should be used as those cases where vasopressor drugs may be contraindicated.

There have been adverse event reports of chondritis in patients who have had long-term local articular infusions of local anesthetics following arthroscopic and other surgical procedures. The incidence of chondritis is very infrequent. Xylocaine is not approved for this use (see WARNINGS).

**DOSAGE AND ADMINISTRATION**

These recommended doses serve only as a guide to the amount of anesthetic required for most routine procedures. Volumes and concentrations of solutions to be used depend on a number of factors such as age, weight, and physical condition of the patient, presence of systemic disease, extent and depth of surgical procedure, depth and degree of muscular relaxation required, and the physical condition of the patient. If the degree of muscular relaxation, sensory and/or autonomic block is incomplete, epidural anaesthesia may be attempted. Backache and headache have also been noted following use of these anesthetic procedures.

There have been reported cases of permanent injury to intracranial muscles requiring surgical repair following retrobulbar administration of Xylocaine.

**Hematologic**

Methemoglobinemia

**OVERDOSAGE**

Acute emergencies from local anesthetics are generally related to high plasma levels encountered during prolonged or repeated use of local anesthetics or to unintended subarachnoid injection of Xylocaine Injection. The symptoms of overdosage are variable and may include paresthesias, weakness, headache, dizziness, blurred vision, tinnitus, nausea, vomiting, dyspnea, and hypotension. When administered intravenously. Should con-

1.5% with epinephrine 30 mL, 50 mL, 100 mL 1.0% with epinephrine 10 mL, 20 mL, 30 mL
2% without epinephrine 10 mL Plastic Ampule 2% with epinephrine 10 mL Plastic Ampule, 20 mL, 30 mL, 60 mL

Although these solutions are intended specifically for epidural anesthesia, they may also be used for infusion and peripheral nerve blockade. When epinephrine is used, the solution is provided as single dose units, these doses contain epinephrine as the preservative agent.

In epidural anesthesia, the dosage varies with the number of dermatomes to be anesthetized (generally 2 to 3 mL of the indicated concentration per dermatome).

**Caution and Lumbal Epidural Block**

As a precaution against the adverse experience sometimes followed by unintended intrathecal injection of the subarachnoid space, tests should be made to ensure that the total volume of Xylocaine has been injected into the epidural space. If epidural anesthesia has been initiated, the volume injected should be calculated and the total volume of Xylocaine HCl should be reduced accordingly.

This is to prevent an epidural block with a subsequent high spinal block. Should the epidural block be followed by a high spinal block, the patient should be observed for a very brief period in order to detect any adverse reactions which might result. If, in the event of an epidural block of varying magnitude (including total spinal block), hypotension secondary to spinal block, loss of cerebrospinal fluid (such as 10 mL a day), backache, and headache have also been noted following use of these anesthetic procedures.

**MAXIMUM RECOMMENDED DOSES**

Maximum recommended doses are not to exceed 2 mg/kg of body weight. The maximum recommended dosage should not be administered to children under 3 years of age. The maximum recommended dosage should not be exceeded, even when the child's individual weight is less than 30 lb.

**Maximal dosage**

- For Lovrenz and ethyl alcohol (70%) is recommended. Many commercially available brands of rubbing alcohol, as well as solutions of ethyl alcohol are injurious to rubber and therefore are not to be used. For dilution, either isopropyl alcohol (91%) or ethyl alcohol (70%) is recommended. Many commercially available brands of rubbing alcohol, as well as solutions of ethyl alcohol are injurious to rubber and therefore are not to be used.

**Sterilization, Storage and Technical Considerations**

Disinfecting agents containing heavy metals, which cause release of respective ions (mercury, silver, copper) into the local anesthetic solution, should be avoided. When chemical disinfection of multi-dose vials is desired, either isopropyl alcohol (91%) or ethyl alcohol (70%) is recommended. Many commercially available brands of rubbing alcohol, as well as solutions of ethyl alcohol are injurious to rubber and therefore are not to be used.

**Dosage forms**

The above suggested concentrations are given solely as a guide. Other volumes and concentrations may be used provided the total maximum dose is not exceeded.

**STORAGE**

Stabilization of Xylocaine (lidocaine hydrochloride) with 0.9% sodium chloride injection in order to obtain the required final concentration.

**HOW SUPPLIED**

Table 1: Recommended Dosages

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cnc (%)</th>
<th>Vol (mL)</th>
<th>Total Dose (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intravenous</td>
<td>0.5</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>Intravenous</td>
<td>1.0</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>Peripheral Nerve Block, e. g.</td>
<td>1.5</td>
<td>20</td>
<td>150</td>
</tr>
<tr>
<td>Spinal anesthesia</td>
<td>1</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Epidural*</td>
<td>1</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Thoracic</td>
<td>2</td>
<td>20</td>
<td>100</td>
</tr>
<tr>
<td>Lumbar</td>
<td>2</td>
<td>10</td>
<td>100</td>
</tr>
<tr>
<td>Analgesia</td>
<td>2</td>
<td>20</td>
<td>100</td>
</tr>
<tr>
<td>Cervical</td>
<td>0.5</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>Central Neural Blocks</td>
<td>1</td>
<td>20</td>
<td>100</td>
</tr>
<tr>
<td>Epidural</td>
<td>1</td>
<td>50</td>
<td>500</td>
</tr>
<tr>
<td>Thoracic</td>
<td>2</td>
<td>100</td>
<td>200</td>
</tr>
<tr>
<td>Lumbar</td>
<td>2</td>
<td>100</td>
<td>200</td>
</tr>
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<td>Analgesia</td>
<td>2</td>
<td>100</td>
<td>200</td>
</tr>
<tr>
<td>Cervical</td>
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<td>20</td>
<td>100</td>
</tr>
<tr>
<td>Surgical anesthesia</td>
<td>1.5</td>
<td>25</td>
<td>250</td>
</tr>
</tbody>
</table>

*Dose determined by number of dermatomes to be anesthetized (2 to 3 mL/dermatome).