Lidocaine Hydrochloride

**Ingredients:** Lidocaine Hydrochloride

**Indications:** Arrhythmia, ventricular; Anesthesia, topical; Anesthesia, local; Anesthesia, regional; Anesthesia, infiltration; Anesthesia, spinal

**Off-label Indications:** Not clinically relevant: Status Epilepticus.

**Pregnancy Category B**

**FDA Approved 1948-11-01**

**DRUG CLASS:** Anesthetics, local; Anesthetics, topical; Antiarrhythmics, class IB; Dermatologics

**Brand Names:**
- Anestacaine (US)
- Dequaspray (England, Ireland)
- Dynexan (France)
- L-Caine (US)
- Lidoject 1 (US)
- Lidoject 2 (US)
- Truxacaine (US)
- Xylocaine Dental Cartridges (US)
- Xylocaine HCl (US)
- Xylocaine HCl For Spinal (US)
- Xylocaine-MPF (US)

*(International brand names outside U.S. in italics)*

**DESCRIPTION:**

Lidocaine HCl is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride and has the molecular weight 270.8. The molecular formula for lidocaine HCl is C_{14}H_{22}N_{2}O·HCl.

For the solutions containing epinephrine, it is chemically designated as (-)-3,4-Dihydroxy-α-[((methylamino)methyl] benzyl alcohol and has the molecular weight 183.21. Its molecular formula is C_{9}H_{13}NO_{3}.

**Lidocaine HCl Sterile Solution and Lidocaine HCl with Epinephrine**

See INDICATIONS AND USAGE for specific uses.

Lidocaine HCl injections are sterile, nonpyrogenic, aqueous solutions that contain a local anesthetic agent with or without epinephrine and are administered parenterally by injection.

**Dosage forms listed as Xylocaine-MPF indicate solutions that are Methyl Paraben Free (MPF).**

**Xylocaine MPF**

A sterile, nonpyrogenic, isotonic solution containing sodium chloride. Xylocaine MPF in multiple-dose vials: Each milliliter also contains 1 mg methylparaben as antiseptic preservative. The pH of these solutions is adjusted to approximately 6.5 (5.0-7.0) with sodium hydroxide and/or hydrochloric acid.

The chemical name for epinephrine is (-)-3,4-dihydroxy-α-{(methylamino) methyl} benzyl alcohol. It has the molecular weight 183.21. The molecular formula for epinephrine is C_{9}H_{13}NO_{3}.

**Xylocaine MPF With Epinephrine**

A sterile, nonpyrogenic, isotonic solution containing sodium chloride. Each milliliter contains lidocaine HCl and epinephrine, with 0.5 mg sodium metabisulfite as an antioxidant and 0.2 mg citric acid as a stabilizer. Xylocaine with epinephrine in multiple dose vials: Each milliliter also contains 1 mg methylparaben as antiseptic preservative. The pH of these solutions is adjusted to approximately 4.5 (3.3-5.5) with sodium hydroxide and/or hydrochloric acid. Filled under nitrogen.

**Lidocaine HCl for Ventricular Arrhythmias**

Lidocaine HCl injection is a sterile aqueous solution of lidocaine, an antiarrhythmic agent, prepared with hydrochloric acid. It is intended for intravenous administration by either direct injection or continuous infusion. The composition of available solutions is shown in TABLE 1.
TABLE 1 Composition of Available Solutions

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Lidocaine HCl (mg/ml)</th>
<th>Sodium Chloride (mg/ml) to Adjust Tonicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>For Direct IV Injection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1%</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>2%</td>
<td>20</td>
<td>6</td>
</tr>
<tr>
<td>20% For Dilution Only</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For Preparation of Intravenous Infusions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 g</td>
<td>200</td>
<td>None</td>
</tr>
<tr>
<td>2 g</td>
<td>200</td>
<td>None</td>
</tr>
</tbody>
</table>

* pH of all solutions adjusted to 5.0-7.0 with sodium hydroxide and/or hydrochloric acid.

The medication and fluid pathway of these disposable syringes are sterile and nonpyrogenic in the original, unopened package with component caps in place. These dosage forms do not contain preservatives; once the unit is assembled and used, any remaining portion of the solution must be discarded with the entire unit.

**Lidocaine HCl With Dextrose**

Xylocaine-MPF 5% with glucose 7.5% is a sterile hyperbaric solution that contains a local anesthetic agent and is administered into the spinal subarachnoid space by injection. For specific uses see INDICATIONS AND USAGE, *Lidocaine HCl With Dextrose*.

Xylocaine-MPF 5% with glucose 7.5% contains *lidocaine* HCl, which is chemically designated as acetamide, 2-[(diethylamino)-N-(2,6-dimethylphenyl)-], monohydrochloride, and dextrose (D-Glucose, anhydrous).

Xylocaine-MPF 5% with glucose 7.5% may be autoclaved at 15 lb pressure at 121°C (250°F) for 15 minutes. Since this preparation contains glucose, caramelization may occur under prolonged heating and, in some instances, prolonged storage. Therefore, this preparation should not be autoclaved more than once, according to the above instructions, and should not be permitted to remain in the autoclave any longer than necessary. The solution should not be used if it is discolored or a precipitate is present.

Each ml of Xylocaine-MPF 5% with glucose 7.5% contains *lidocaine* HCl, 50 mg; dextrose (D-Glucose, anhydrous), 75 mg; sodium hydroxide and/or hydrochloric acid to adjust pH to 5.5-7.0.

Specific gravity: 1.032-1.037.

**Lidocaine HCl Topical Solution**

*Lidocaine* HCl topical solution is a sterile, aqueous solution containing a local anesthetic agent and is administered topically.

**Composition of Lidocaine HCl 4% Topical Solution**: Each milliliter of aqueous solution contains *lidocaine* HCl, 40 mg, and sodium hydroxide and/or hydrochloric acid to adjust pH to 5.0-7.0. No preservative is added since all or part of the contents of the syringe unit is administered as a single dose and the unit should not be reused.

**Lidocaine HCl Jelly**

*Lidocaine* HCl jelly, 2% is a sterile aqueous product that contains a local anesthetic agent and is administered topically. For specific uses see INDICATIONS AND USAGE, *Lidocaine* HCl Jelly.

Each milliliter contains 20 mg of *lidocaine* HCl, and sodium carboxymethylcellulose as a viscosity-increasing agent. Sodium hydroxide may have been added to adjust pH to 6-7. Carboxymethylcellulose sodium adjusts the resulting mixture to a suitable consistency, to enhance contact with mucosa and provide lubrication for instrumentation. This product contains no preservative and any unused portion should be discarded after initial use.

**CLINICAL PHARMACOLOGY:**

**Mechanism of Action**

*Lidocaine* stabilizes the neuronal membrane by inhibiting the ionic fluxes required for the initiation and conduction of impulses thereby effecting local anesthetic action.
Mechanism of Action and Electrophysiology of Lidocaine HCl for Ventricular Arrhythmia

Studies of the effects of therapeutic concentrations of lidocaine on the electrophysiological properties of mammalian Purkinje fibers have shown that lidocaine attenuates phase 4 diastolic depolarization, decreases automaticity, and causes a decrease or no change in excitability and membrane responsiveness. Action potential duration and effective refractory period of Purkinje fibers are decreased, while the ratio of effective refractory period to action potential duration is increased. Action potential duration and effective refractory period of ventricular muscle are also decreased. Effective refractory period of the AV node may increase, decrease, or remain unchanged, and atrial effective refractory period is unchanged. Lidocaine raises the ventricular fibrillation threshold. No significant interactions between lidocaine and autonomic nervous system have been described and, consequently, lidocaine has little or no effect on autonomic tone.

Onset of Action Lidocaine HCl Topical Solution

The onset of action is rapid.

Lidocaine HCl Jelly

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

Clinical electrophysiological studies with lidocaine have demonstrated no change in sinus node recovery time or sinoatrial conduction time. AV nodal conduction time is unchanged or shortened, and His-Purkinje conduction time is unchanged.

Onset and Duration of Anesthesia of Lidocaine HCl With Dextrose

The onset of action is rapid. The duration of perineal anesthesia provided by 1 ml (50 mg) lidocaine HCl with dextrose averages 100 minutes, with analgesia continuing for an additional 40 minutes. The duration of surgical anesthesia provided by 1.5-2 ml (75-100 mg) of this agent is approximately 2 hours.

Hemodynamics

Excessive blood levels may cause changes in cardiac output, total peripheral resistance, and mean arterial pressure. With central neural blockade these changes may be attributable to block of autonomic fibers, a direct depressant effect of the local anesthetic agent on various components of the cardiovascular system, and/or the beta-adrenergic receptor stimulating action of epinephrine when present. The net effect is normally a modest hypotension when the recommended dosages are not exceeded.

Additional Information for Lidocaine HCl for Ventricular Arrhythmia

At therapeutic doses, lidocaine has minimal hemodynamic effects in normal subjects and in patients with heart disease. Lidocaine has been shown to cause no, or minimal, decrease in ventricular contractility, cardiac output, arterial pressure or heart rate.

Pharmacokinetics and Metabolism

Information derived from other formulations, concentrations and usages reveals that lidocaine is completely absorbed following parenteral administration, its rate of absorption depending, for example, upon such factors as the site of administration and the presence or absence of a vasoconstrictor agent. Lidocaine may be absorbed following topical administration to mucous membranes, its rate and extent of absorption depending upon concentration and total dose administered, the specific site of application and duration of exposure. In general, the rate of absorption of local anesthetic agents following topical application occurs most rapidly after intratracheal administration. Lidocaine is also well absorbed from the gastrointestinal tract, but little intact drug appears in the circulation because of biotransformation by the liver. Except for intravascular administration, the highest blood levels are obtained following intercostal nerve block and the lowest after subcutaneous administration.

Lidocaine is metabolized rapidly by the liver, and metabolites and unchanged drug are excreted by the kidneys. Biotransformation includes oxidative N-dealkylation, ring hydroxylation, cleavage of the amide linkage, and conjugation. N-dealkylation, a major pathway of biotransformation, yields the metabolites monoethylglycineexylidide and glycineexylidide. The pharmacological/toxicological actions of these metabolites are similar to, but less potent than, those of lidocaine. Approximately 90% of lidocaine administered is excreted in the form of various
metabolites, and less than 10% is excreted unchanged. The primary metabolite in urine is a conjugate of 4-
hydroxy-2,6-dimethylaniline.

Studies have shown that peak blood levels of lidocaine may occur as early as 5 and as late as 30 minutes after
endotracheal administration of a lidocaine HCl solution.

Therapeutic effects of lidocaine are generally associated with plasma levels at 6-25 μmol/L (1.5-6.0 μg free base
per ml). The blood to plasma distribution ratio is approximately 0.84. Objective adverse manifestations become
increasingly apparent with increasing plasma levels above 6 μg free base per ml.

The plasma binding of lidocaine is dependent on drug concentration, and the fraction bound decreases with
increasing concentration. At concentrations of 1-4 μg of free base per ml 60-80% of lidocaine is protein bound.
Binding is also dependent on the plasma concentration of the alpha-1-acid glycoprotein.

Lidocaine crosses the blood-brain and placental barriers, presumably by passive diffusion.

The elimination half-life of lidocaine following an intravenous bolus injection is typically 1.5-2.0 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 2-fold or more in patients with liver dysfunction. Renal dysfunction does not
affect lidocaine kinetics but may increase the accumulation of metabolites.

Factors such as acidosis and the use of CNS stimulants and depressants affect the CNS levels of lidocaine
required to produce overt systemic effects. Objective adverse manifestations become increasingly apparent with
increasing venous plasma levels above 6 μg free base per ml. In the rhesus monkey arterial blood levels of 18-21
μg/ml have been shown to be threshold for convulsive activity.

INDICATIONS AND USAGE:

Lidocaine HCl and Lidocaine HCl With Epinephrine Injections

Lidocaine HCl injections are indicated for production of local or regional anesthesia by infiltration techniques such
as percutaneous injection and intravenous regional anesthesia by peripheral nerve block techniques such as
brachial plexus and intercostal and by central neural techniques such as lumbar and caudal epidural blocks, when
the accepted procedures for these techniques as described in standard textbooks are observed.

Lidocaine HCl Sterile Solution

Lidocaine HCl sterile solution is indicated for the production of topical anesthesia of the mucous membranes of the
respiratory tract or the genito-urinary tract. It may be injected trans-tracheally to anesthetize the larynx and trachea,
and it may be administered by retrobulbar injection to provide anesthesia for ophthalmic surgery.

Lidocaine HCl for Ventricular Arrhythmias

Lidocaine HCl injection administered intravenously is specifically indicated in the acute management of ventricular
arrhythmias such as those occurring in relation to acute myocardial infarction, or during cardiac manipulation, such
as cardiac surgery.

Lidocaine HCl With Dextrose

Lidocaine HCl with dextrose is indicated for the production of spinal anesthesia when the accepted procedures for
this technique as described in standard textbooks are observed.

Lidocaine HCl Topical Solution

Lidocaine HCl topical solution is indicated for the production of topical anesthesia of the mucous membranes of
the respiratory tract.

Lidocaine HCl Jelly
Lidocaine HCl jelly 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 any of the forms of this drug.

**Lidocaine HCl for Ventricular Arrhythmia**

Lidocaine HCl for ventricular arrhythmia should not be used in patients with Stoke-Adams syndrome, Wolff-Parkinson-White syndrome, or with severe degrees of sinoatrial, atrioventricular, or intraventricular block in the absence of an artificial pacemaker.

**Lidocaine HCl With Dextrose**

The following conditions preclude the use of spinal anesthesia:

1. Severe hemorrhage, shock or heart block.
2. Local infection at the site of proposed puncture.
4. Known sensitivity to the local anesthetic agent.

**WARNINGS:**

**LIDOCAINE** HCl SHOULD BE EMPLOYED ONLY BY CLINICIANS WHO ARE WELL VERSED IN DIAGNOSIS AND MANAGEMENT OF DOSE-RELATED TOXICITY AND OTHER ACUTE EMERGENCIES THAT MIGHT ARISE AND THEN ONLY AFTER ENSURING THE IMMEDIATE AVAILABILITY OF OXYGEN, OTHER RESUSCITATIVE DRUGS, CARDIOPULMONARY EQUIPMENT AND THE PERSONNEL NEEDED FOR PROPER MANAGEMENT OF TOXIC REACTIONS AND RELATED EMERGENCIES. (See also ADVERSE REACTIONS and PRECAUTIONS.) DELAY IN PROPER MANAGEMENT OF DOSE-RELATED TOXICITY, UNDERVENTILATION FROM ANY CAUSE AND/OR ALTERED SENSITIVITY MAY LEAD TO THE DEVELOPMENT OF ACIDOSIS, CARDIAC ARREST AND, POSSIBLY, DEATH.

To avoid intravascular injection, aspiration should be performed before the local anesthetic solution is injected. The needle must be repositioned until no return of blood can be elicited by aspiration. Note, however, that the absence of blood in the syringe does not guarantee that intravascular injection has been avoided.

Local anesthetic solutions containing antimicrobial preservatives, (e.g., methylparaben) should not be used for epidural or spinal anesthesia because the safety of these agents has not been established with regard to intrathecal injection, either intentional or accidental.

**Additional Information for Lidocaine HCl With Epinephrine**

Solutions contain sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

**Additional Information for Lidocaine HCl With Dextrose**

Spinal anesthetics should not be injected during uterine contractions since spinal fluid current may carry the drug farther cephalad than desired.

**Additional Information for Lidocaine HCl Sterile Solution, Topical Solution, and Jelly**
**Lidocaine** HCl sterile solution and topical solution should be used with extreme caution if there is sepsis or severely traumatized mucosa in the area of application, since under such conditions there is the potential for rapid systemic absorption.

**Additional Information for Lidocaine HCl Jelly**

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.

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 dry on the inner surface leaving a residue which tends to clump with flexion, narrowing the lumen. There have been rare reports in which this residue has caused the lumen to occlude. See also ADVERSE REACTIONS and DOSAGE AND ADMINISTRATION.

**Additional Information for Lidocaine HCl for Ventricular Arrhythmias**

IN ORDER TO MANAGE POSSIBLE ADVERSE REACTIONS, RESUSCITATIVE EQUIPMENT, OXYGEN AND OTHER RESUSCITATIVE DRUGS SHOULD BE IMMEDIATELY AVAILABLE WHEN LIDOCAINE HCl INJECTION IS USED.

Systemic toxicity may result in manifestations of central nervous system depression (sedation) or irritability (twitching), which may progress to frank convulsions accompanied by respiratory depression and or arrest. Early recognition of premonitory signs, assurance of adequate oxygenation, and, where necessary, establishment of artificial airway with ventilatory support are essential to management of this problem. Should convulsions persist despite ventilatory therapy with oxygen, small increments of anticonvulsant drugs may be used intravenously. Examples of such agents include benzodiazepines (e.g., diazepam), ultra short-acting barbiturates (e.g., thiopental or thiamylal), or a short-acting barbiturate (e.g., pentobarbital or secobarbital). If a patient is under anesthesia, a short-acting muscle relaxant (e.g., succinylcholine) may be used. Longer-acting drugs should be used only when recurrent convulsions are evidenced.

Should circulatory depression occur, vasopressors may be used.

Constant electrocardiographic monitoring is essential to the proper administration of lidocaine HCl. Signs of excessive depression of cardiac electrical activity such as sinus node dysfunction, prolongation of the P-R interval and QRS complex or the appearance or aggravation of arrhythmias, should be followed by flow adjustment and, if necessary, prompt cessation of the intravenous infusion of this agent. Occasionally, acceleration of ventricular rate may occur when lidocaine HCl is administered to patients with atrial flutter or fibrillation.

**PRECAUTIONS:**

**General**

The safety and effectiveness of lidocaine depends on proper dosage, correct technique, adequate precautions, and readiness for emergencies.

Repeated doses of lidocaine may cause 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 physical condition 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.

Resuscitative equipment, oxygen, and other resuscitative drugs should be available for immediate use. (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.

Local anesthetic solutions containing a vasoconstrictor should be used cautiously and in carefully circumscribed quantities in areas of the body supplied by end arteries or having otherwise compromised blood supply. Patients
with peripheral vascular disease and those with hypertensive vascular disease may exhibit exaggerated vasoconstrictor response. Ischemic injury or necrosis may result. Preparations containing a vasoconstrictor should be used with caution in patients during or following the administration of potent general anesthetic agents, since cardiac arrhythmias may occur under such conditions.

Careful and constant monitoring of cardiovascular and respiratory (adequacy of ventilation) vital signs and the patient's state of consciousness should be accomplished after each local anesthetic injection. It should be kept in mind at such times that restlessness, anxiety, tinnitus, dizziness, blurred vision, tremors, depression or drowsiness may be early warning signs of central nervous system toxicity.

Since amide-type local anesthetics are metabolized by the liver, 
 **lidocaine** HCl should be used with caution in patients with hepatic disease. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at greater risk of developing toxic plasma concentrations. 
 **Lidocaine** HCl should also be used with caution in patients with impaired cardiovascular function since they may be less able to compensate for functional changes associated with the prolongation of AV conduction produced by these drugs.

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 the management of malignant hyperthermia 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).

Proper tourniquet technique, as described in publications and standard textbooks, is essential in the performance of intravenous regional anesthesia. Solutions containing epinephrine or other vasoconstrictors should not be used for this technique.

**Lidocaine** should be used with caution in persons with known drug sensitivities. Patients allergic to parabenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown cross sensitivity to 
 **lidocaine**.

Standard textbooks should be consulted for specific techniques and precautions for various regional anesthetic procedures.

### Additional Information for Lidocaine HCl With Epinephrine

Syringe aspirations should be performed before and during each supplemental injection when using indwelling catheter techniques.

During the administration of epidural anesthesia, it is recommend that a test dose be administered initially and that the patient be monitored for central nervous system toxicity and cardiovascular toxicity, as well as for signs of unintended intrathecal administration, before proceeding. When clinical conditions permit, consideration should be given to employing local anesthetic solutions that contain epinephrine for the test dose because circulatory changes compatible with epinephrine may also serve as a warning sign of unintended intravascular injection. An intravascular injection is still possible even if aspirations for blood are negative. Repeated doses of 
 **lidocaine** may cause 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 condition. 
 **Lidocaine** should also be used with caution in patients with severe shock or heart block.

Lumber and caudal epidural anesthesia should be used with extreme caution in persons with the following conditions: existing neurological disease, spinal deformities, septicemia, and severe hypertension.

### Additional Information for Lidocaine HCl With Dextrose

Neurologic deficits have been reported with the use of small bore needles and microcatheters for spinal anesthesia. It has been postulated, based on *in vitro* models, that these deficits were due to pooling and nonuniform distribution of concentrated local anesthetic within the subarachnoid space. Animal studies suggest mixing 5% 
 **lidocaine** HCl with an equal volume of CSF or preservative-free 0.9% saline solution may reduce the risk of nerve injury due to pooling of concentrated local anesthetic. (See DOSAGE AND ADMINISTRATION.)
The following conditions may preclude the use of spinal anesthesia, depending upon the physician’s ability to deal with the complications or complaints that may occur:

1. Pre-existing diseases of the central nervous system such as those attributable to poliomyelitis, pernicious anemia, paralysis from nerve injuries, and syphilis.

2. Disturbance in blood morphology and/or anticoagulant therapy. In these conditions, trauma to a blood vessel during needle puncture may result in uncontrollable hemorrhage into the epidural or subarachnoid space. Also profuse hemorrhage into the soft tissue may occur.

3. Extremes of age.

4. Chronic backache and preoperative headache.

5. Hypotension and hypertension.

6. Arthritis or spinal deformity.

7. Technical problems (persistent paresthesias, persistent bloody tap).

8. Psychotic or uncooperative patients.

CONSULT STANDARD TEXTBOOKS FOR SPECIFIC TECHNIQUES AND PRECAUTIONS FOR SPINAL ANESTHETIC PROCEDURES.

Careful and constant monitoring of cardiovascular and respiratory (adequacy of ventilation) vital signs and the patient’s state of consciousness should be accomplished after each local anesthetic injection. It should be kept in mind at such times that restlessness, anxiety, tinnitus, dizziness, blurred vision, tremors, depression or drowsiness may be early warning signs of central nervous system toxicity.

Since amide-type local anesthetics are metabolized by the liver, lidocaine should be used with caution in patients with hepatic disease. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at greater risk of developing toxic plasma concentrations. Lidocaine should also be used with caution in patients with impaired cardiovascular function since they may be less able to compensate for functional changes associated with the prolongation of AV conduction produced by these drugs.

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).

Lidocaine should be used with caution in persons with known drug sensitivities. Patients allergic to para-aminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown cross sensitivity to lidocaine.

Additional Information for Lidocaine HCl Injection for Ventricular Arrhythmia

Caution should be employed in the use of lidocaine HCl in patients with severe liver or kidney disease because accumulation of the drug or metabolites may occur.

Lidocaine HCl should be used with caution in the treatment of patients with hypovolemia, severe congestive heart failure, shock, and all forms of heart block. In patients with sinus bradycardia, or incomplete heart block, the administration of lidocaine HCl intravenously for the elimination of ventricular ectopic beats, without prior acceleration in heart rate (e.g., by atropine, isoproterenol or electric pacing), may promote more frequent and serious ventricular arrhythmias or complete heart block (see CONTRAINDICATIONS, Lidocaine HCl for Ventricular Arrhythmia).

Dosage should be reduced for children and for debilitated and/or elderly patients, commensurate with their age and physical status.
The safety of amide local anesthetic agents in patients with genetic predisposition to malignant hypothermia has not been fully assessed; therefore, lidocaine should be used with caution in such patients.

In hospital environments where drugs known to be triggering agents for malignant hypothermia (fulminant hypermetabolism) are administered, it is suggested that a standard protocol for management should be available.

It is not known whether lidocaine may trigger this reaction; however, large doses resulting in significant plasma concentrations, as may be achieved by intravenous infusion, pose potential risk to these individuals. Recognition of 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 triggering agent and institution of treatment including oxygen therapy, supportive measures and dantrolene (for details see dantrolene prescribing information/package insert).

**Use in Ophthalmic Surgery**

When local anesthetic solutions are employed for retrobulbar block, lack of corneal sensation should not be relied upon to determine whether or not the patient is ready for surgery since corneal sensation usually precedes clinically acceptable external ocular muscle akinesia.

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 suspected triggering agent(s) and institution of treatment, including oxygen therapy, indicated supportive measures, and dantrolene (consult dantrolene sodium intravenous package insert before using).

**Use in the Head and Neck Area**

Small doses of local anesthetics injected into the head and neck area, including retrobulbar, dental and stellate ganglion blocks, may produce adverse reactions similar to systemic toxicity seen with unintentional intravascular injections of larger doses. Confusion, convulsions, respiratory depression and/or respiratory arrest, and cardiovascular stimulation or depression have been reported. These reactions may be due to intra-arterial injection of the local anesthetic with retrograde flow to the cerebral circulation. Patients receiving these blocks should have their circulation and respiration monitored and be constantly observed. Resuscitative equipment and personnel for treating adverse reactions should be immediately available. Dosage recommendations should not be exceeded. (See DOSAGE AND ADMINISTRATION)

**Information for the Patient**

When appropriate, patients should be informed in advance that they may experience temporary loss of sensation and motor activity, usually in the lower half of the body, following proper administration of epidural anesthesia. The patient should be advised of the possible occurrence of the experiences listed under ADVERSE REACTIONS.

**Lidocaine HCI Sterile Solution, Topical, and Jelly**

When topical anesthetics are used in the mouth, the patient should be aware that the production of topical anesthesia may impair swallowing 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.

Numbness 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.

**Drug/Laboratory Test Interactions**

The intramuscular injection of lidocaine may result in an increase in creatine phosphokinase levels. Thus, the use of this enzyme determination, without isoenzyme separation, as a diagnostic test for the presence of acute myocardial infarction may be compromised by the intramuscular injection of lidocaine.
Carcinogenesis, Mutagenesis, and Impairment of Fertility

Studies of lidocaine in animals to evaluate the carcinogenic and mutagenic potential or the effect on fertility have not been conducted.

Pregnancy, Teratogenic Effects, Pregnancy Category B

Reproduction studies have been performed in rats at doses up to 6.6 times the human dose and have revealed no evidence of harm to the fetus caused by lidocaine. There are, however, no adequate and well-controlled studies in pregnant women. Animal reproduction studies are not always predictive of human response. General consideration should be given to this fact before administering lidocaine to women of childbearing potential, especially during early pregnancy when maximum organogenesis takes place.

Labor and Delivery

Lidocaine is not contraindicated in labor and delivery. Should lidocaine HCl be used concomitantly with other products containing lidocaine, the total dose contributed by all formulations must be kept in mind.

Local anesthetics rapidly cross the placenta and when used for epidural, paracervical, pudendal or caudal block anesthesia, can cause varying degrees of maternal, fetal and neonatal toxicity. See CLINICAL PHARMACOLOGY, Pharmacokinetics and Metabolism. The potential for toxicity depends upon the procedure performed, the type and amount of drug used, and the technique of drug administration. Adverse reactions in the parturient, fetus and neonate involve alterations of the central nervous system, peripheral vascular tone, and cardiac function.

Maternal hypotension has resulted from regional anesthesia. Local anesthetics produce vasodilation by blocking sympathetic nerves. Elevating the patient's legs and positioning her on her left side will help prevent decreases in blood pressure. The fetal heart rate also should be monitored continuously, and electronic fetal monitoring is highly advisable.

Epidural, spinal, paracervical, or pudendal anesthesia may alter the forces of parturition through changes in uterine contractility or maternal expulsive efforts. In one study, paracervical block anesthesia was associated with a decrease in the mean duration of first stage labor and facilitation of cervical dilation. However, spinal and epidural anesthesia have also been reported to prolong the second stage of labor by removing the parturient's reflex urge to bear down or by interfering with motor function. The use of obstetrical anesthesia may increase the need for forceps assistance.

The use of some local anesthetic drug products during labor and delivery may be followed by diminished muscle strength and tone for the first day or two of life. The long-term significance of these observations is unknown. Fetal bradycardia may occur in 20-30% of patients receiving paracervical nerve block anesthesia with the amide-type local anesthetics and may be associated with fetal acidosis. Fetal heart rate should always be monitored during paracervical anesthesia. The physician should weigh the possible advantages against risks when considering a paracervical block in prematurity, toxemia of pregnancy, and fetal distress. Careful adherence to recommended dosage is of the utmost importance in obstetrical paracervical block. Failure to achieve adequate analgesia with recommended doses should arouse suspicion of intravascular or fetal intracranial injection. Cases compatible with unintended fetal intracranial injection of local anesthetic solution have been reported following intended paracervical or pudendal block or both. Babies so affected present with unexplained neonatal depression at birth, which correlates with high local anesthetic serum levels, and often manifest seizures within 6 hours. Prompt use of supportive measures combined with forced urinary excretion of the local anesthetic has been used successfully to manage this complication.

Case reports of maternal convulsions and 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 circumstances may be rapid. The recommended maximum dose of each drug should not be exceeded. Injection should be made slowly and with frequent aspiration. Allow a 5-minute interval between sides.

The effects of lidocaine HCl on the mother and the fetus, when used in the management of cardiac arrhythmias during labor and delivery, are not known.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when lidocaine is administered to a nursing woman.
Pediatric Use

Dosages in pediatric patients should be reduced, commensurate with age, body weight and physical condition. (See DOSAGE AND ADMINISTRATION)

Additional Information for Lidocaine HCl With Dextrose

Safety and effectiveness in pediatric patients below the age of 16 years have not been established.

INTERACTIONS:

Lidocaine HCl Sterile Solution, Lidocaine HCl With Epinephrine and Lidocaine HCl With Dextrose

The administration of local anesthetic solutions containing epinephrine or norepinephrine to patients receiving monoamine oxidase inhibitors, tricyclic antidepressants, or phenothiazines may produce severe, prolonged hypotension or hypertension. Concurrent use of these agents should generally be avoided. In situations when concurrent therapy is necessary, careful patient monitoring is essential.

Concurrent administration of vasopressor drugs (for the treatment of hypotension related to obstetric blocks) and ergot-type oxytocic drugs may cause severe, persistent hypertension or cerebrovascular accidents.

Phenothiazines and butyrophenones may reduce or reverse the pressor effect of epinephrine.

Lidocaine HCl for Ventricular Arrhythmias

Lidocaine HCl injections should be used with caution in patients with digitalis toxicity accompanied by atrioventricular block. Concomitant use of beta-blocking agents or cimetidine may reduce hepatic blood flow and thereby reduce lidocaine clearance.

Lidocaine and tocainide are pharmacodynamically similar. The concomitant use of these two agents may cause an increased incidence of adverse reactions, including central nervous system adverse reactions such as seizure.

ADVERSE REACTIONS:

Systemic

Adverse experiences following the administration of lidocaine are similar in nature to those observed with other amide local anesthetic agents. These adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage, rapid absorption of inadvertent intravascular injection, or may result from a hypersensitivity, idiosyncrasy or diminished to tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature. The following types are those most commonly reported. The adverse experiences under Central Nervous System and Cardiovascular System are listed, in general, in a progression from mild to severe.

Additional Information for Lidocaine HCl Jelly

There have been rare reports of endotracheal tube occlusion associated with the presence of dried jelly residue in the inner lumen of the tube. (See also WARNINGS, Additional Information for Lidocaine HCl Jelly and DOSAGE AND ADMINISTRATION, Lidocaine HCl Jelly)

Central Nervous System

CNS manifestations are excitatory and/or depressant and may be characterized by lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. The excitatory manifestation may be very brief or may not occur at all, in which case the first manifestation of toxicity may be drowsiness merging into unconsciousness and respiratory arrest.

Drowsiness following the administration of lidocaine is usually an early sign of a high blood level of the drug and may occur as a consequence of rapid absorption.
**Cardiovascular System**

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

**Allergic**

Allergic reactions are characterized by cutaneous lesions, urticaria, edema or anaphylactoid reactions. Allergic reactions may occur as a result of sensitivity either to local anesthetic agents or to the methylparaben used as a preservative in the multiple-dose vials. Allergic reactions as a result of sensitivity to lidocaine are extremely rare and, if they occur, should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

**Neurologic**

The incidences of adverse reactions associated with the use of local anesthetics may be related to the total dose of local anesthetic administered and are also dependent upon the particular drug used, the route of administration and the physical status of the patient.

**Additional Information for Lidocaine HCl Sterile Solution**

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

**Additional Information for Lidocaine HCl With Epinephrine and Lidocaine HCl With Dextrose**

In a prospective review of 10,440 patients who received lidocaine for spinal anesthesia, the incidences of adverse reactions were reported to be about 3% each for positional headaches, hypotension, and backache; 2% for shivering; and <1% each for peripheral nerve symptoms, nausea, respiratory inadequacy, and double vision. Many of these observations may be related to local anesthetic techniques, with or without a contribution from the local anesthetic.

**Additional Information for Lidocaine HCl With Epinephrine**

In the practice of caudal or lumbar epidural block, occasional unintentional penetration of the subarachnoid space by the catheter may occur. Subsequent adverse effects may depend partially on the amount of drug administered subdurally. These may include spinal block or varying magnitude (including total spinal block), hypotension secondary to spinal block, loss of bladder and bowel control, and loss of perineal sensation and sexual function. Persistent motor, sensory and/or autonomic (sphincter control) deficit of some lower spinal segments with slow recovery (several months) or incomplete recovery have been reported in rare instances when caudal or lumbar epidural block has been attempted. Backache and headache have also been noted following use of these anesthetic procedures.

**Additional Information for Lidocaine HCl With Dextrose**

Neurologic effects following spinal anesthesia may include: loss of perineal sensation and sexual function; persistent anesthesia; paresthesia; weakness and paralysis of the lower extremities; and loss of sphincter control, all of which may have slow, incomplete, or no recovery; hypotension; high or total spinal block; urinary retention; headache; backache; septic meningitis; meningismus, arachnoiditis; slowing of labor; increased incidence of forceps delivery; shivering; cranial nerve palsies due to traction on nerves from loss of cerebrospinal fluid; and fecal and urinary incontinence.

**DRUG ABUSE:**

Although specific studies have not been conducted, lidocaine HCl has been used clinically without evidence of abuse of this drug or of psychological or physical dependence as a result of its use.

**OVERDOSAGE:**

Acute emergencies from local anesthetics are generally related to high plasma levels encountered during therapeutic use of local anesthetics or to unintended subarachnoid injection of local anesthetic solution (see ADVERSE REACTIONS, WARNINGS, and PRECAUTIONS).
Management of Local Anesthetic Emergencies

The first consideration is prevention, best accomplished by careful and constant monitoring of cardiovascular and respiratory vital signs and the patient's state of consciousness after each local anesthetic injection. At the first sign of change, oxygen should be administered.

The first step in the management of convulsions, as well as underventilation or apnea due to unintended subarachnoid injection of drug solution, consists of immediate attention to the maintenance of a patient airway and assisted or controlled ventilation with oxygen and delivery system capable of permitting immediate positive airway pressure by mask. Immediately after the institution of these ventilatory measures, the adequacy of the circulation should be evaluated, keeping in mind that drugs used to treat convulsions sometimes depress the circulation when administered intravenously. Should convulsions persist despite adequate respiratory support, and if the status of the circulation permits, small increments of an ultra-short acting barbiturate (such as thiopental or thiamylal) or a benzodiazepine (such as diazepam) may be administered intravenously. The clinician should be familiar, prior to the use of local anesthetics, with these anticonvulsant drugs. Supportive treatment of circulatory depression may require administration of intravenous fluids and, when appropriate, a vasopressor as directed by the clinical situation (e.g., ephedrine).

If not treated immediately, both convulsions and cardiovascular depression can result in hypoxia, acidosis, bradycardia, arrhythmias and cardiac arrest. Underventilation or apnea due to unintentional subarachnoid injection of local anesthetic solution may produce these same signs and also lead to cardiac arrest if ventilatory support is not instituted. If cardiac arrest should occur, standard cardiopulmonary resuscitative measures should be instituted.

Endotracheal intubation, employing drugs and techniques familiar to the clinician, may be indicated, after initial administration of oxygen by mask, if difficulty is encountered in the maintenance of patent airway or if prolonged ventilatory support (assisted or controlled) is indicated.

Dialysis is of negligible value in the treatment of acute overdosage with lidocaine.

**Lidocaine HCl With Epinephrine and Lidocaine HCl Jelly**

The oral LD<sub>50</sub> of lidocaine HCl in nonfasted female rats is 459 (346-773) mg/kg (as the salt) and 214 (159-324) mg/kg (as the salt) in fasted female rats.

**Lidocaine HCl Sterile Solution, Lidocaine HCl With Dextrose, and Lidocaine HCl Topical**

The intravenous LD<sub>50</sub> of lidocaine HCl in female mice is 26 (21-31) mg/kg and subcutaneous LD<sub>50</sub> is 264 (203-304) mg/kg.

**Lidocaine HCl for Ventricular Arrhythmias**

Overdosage of lidocaine HCl injection usually results in signs of central nervous system or cardiovascular toxicity. (See ADVERSE REACTIONS)

Should convulsions or signs of respiratory depression and arrest develop, the patency of the air way and adequacy of ventilation must be assured immediately. Should convulsions persist despite ventilatory therapy with oxygen, small increments of anticonvulsive agents may be given intravenously. Examples of such agents include a benzodiazepine (e.g., diazepam), an ultrashort-acting barbiturate (e.g., thiopental or thiamylal), or a short-acting barbiturate (e.g., pentobarbital or secobarbital). If the patient is under general anesthesia, a short-acting muscle relaxant (e.g., succinylcholine) may be administered.

Should circulatory depression occur, vasopressors may be used. Should cardiac arrest occur, standard CPR procedures should be instituted.

**DOSAGE AND ADMINISTRATION:**

When lidocaine HCl is used concomitantly with other products containing lidocaine, the total dose contributed by all formulations must be kept in mind.

The dosage varies and depends upon the area to be anesthetized, vasularity of the tissues, individual tolerance and the technique of anesthesia. The lowest dosage needed to provide effective anesthesia should be administered. Dosages should be reduced for children and for elderly and debilitated patients.
Although the incidence of adverse effects with lidocaine HCl is quite low, caution should be exercised, particularly when employing large volumes and concentrations of lidocaine HCl since the incidence of adverse effects is directly proportional to the total dose of local anesthetic agent administered. For specific techniques and procedures, refer to standard textbooks.

TABLE 2 summarizes the recommended volumes and concentrations of lidocaine HCl for various types of anesthetic procedures. The dosages suggested in this table are for normal healthy adults and refer to the use of epinephrine-free solutions. When larger volumes are required, only solutions containing epinephrine should be used except in those cases where vasopressor drugs may be contraindicated.

These recommended doses serve only as a guide to the amount of anesthetic required for most routine procedures. The actual volumes and concentrations to be used depends on a number of factors such as type and extent of surgical procedure, depth of anesthesia and degree of muscular relaxation required, duration of anesthesia required, and the physical condition of the patient. In all cases the lowest concentration and smallest dose that will produce the desired result should be given. Dosages should be reduced for children and for the elderly and debilitated patients and patients with cardiac and/or liver disease.

**TABLE 2 Recommended Dosages**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Conc.</th>
<th>Vol.</th>
<th>Total Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infiltration</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percutaneous</td>
<td>0.5 or 1%</td>
<td>1-60 ml</td>
<td>5-300 mg</td>
</tr>
<tr>
<td>Intravenous regional</td>
<td>0.5%</td>
<td>10-60 ml</td>
<td>50-300 mg</td>
</tr>
<tr>
<td><strong>Peripheral Nerve Blocks, e.g.,</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brachial</td>
<td>1.5%</td>
<td>15-20 ml</td>
<td>225-300 mg</td>
</tr>
<tr>
<td>Dental</td>
<td>2%</td>
<td>1-5 ml</td>
<td>20-100 mg</td>
</tr>
<tr>
<td>Intercostal</td>
<td>1%</td>
<td>3 ml</td>
<td>30 mg</td>
</tr>
<tr>
<td>Paravertebral</td>
<td>1%</td>
<td>3-5 ml</td>
<td>30-50 mg</td>
</tr>
<tr>
<td>Pudendal (each side)</td>
<td>1%</td>
<td>10 ml</td>
<td>100 mg</td>
</tr>
<tr>
<td><strong>Paracervical</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obstetrical analgesia (each side)</td>
<td>1%</td>
<td>10 ml</td>
<td>100 mg</td>
</tr>
<tr>
<td><strong>Sympathetic Nerve Blocks, e.g.,</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cervical (stellate ganglion)</td>
<td>1%</td>
<td>5 ml</td>
<td>50 mg</td>
</tr>
<tr>
<td>Lumbar</td>
<td>1%</td>
<td>5-10 ml</td>
<td>50-100 mg</td>
</tr>
<tr>
<td><strong>Central Neural Blocks</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epidural*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thoracic</td>
<td>1%</td>
<td>20-30 ml</td>
<td>200-300 mg</td>
</tr>
<tr>
<td>Lumbar</td>
<td>1%</td>
<td>25-30 ml</td>
<td>250-300 mg</td>
</tr>
<tr>
<td>Analgesia</td>
<td>1.5%</td>
<td>15-20 ml</td>
<td>225-300 mg</td>
</tr>
<tr>
<td>Anesthesia</td>
<td>2%</td>
<td>10-15 ml</td>
<td>200-300 mg</td>
</tr>
<tr>
<td><strong>Caudal</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obstetrical analgesia</td>
<td>1%</td>
<td>20-30 ml</td>
<td>200-300 mg</td>
</tr>
<tr>
<td>Surgical anesthesia</td>
<td>1.5%</td>
<td>15-20 ml</td>
<td>225-300 mg</td>
</tr>
</tbody>
</table>

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

THE ABOVE SUGGESTED CONCENTRATIONS AND VOLUMES SERVE ONLY AS A GUIDE. OTHER VOLUMES AND CONCENTRATIONS MAY BE USED PROVIDED THE TOTAL MAXIMUM RECOMMENDED DOSE IS NOT EXCEED.

For intravenous regional anesthesia, only the 50 ml single-dose vial containing lidocaine HCl 0.5% should be used.

**Additional Information for Lidocaine HCl and Lidocaine HCl With Epinephrine Epidural Anesthesia**

For epidural anesthesia, only the following dosage forms of lidocaine HCl are recommended:
1% without epinephrine; 1% with epinephrine 1:200,000.
1.5% without epinephrine; 1.5% with epinephrine 1:200,000.
2% without epinephrine; 2% with epinephrine 1:200,000.

Although these solutions are intended specifically for epidural anesthesia, they may also be used for infiltration and peripheral nerve block, provided they are employed as single-dose units. These solutions contain no bacteriostatic agent.

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

**Caudal and Lumbar Epidural Block**

As a precaution against the adverse experience sometimes observed following unintentional penetration of the subarachnoid space, a test dose such as 2-3 ml of 1.5% lidocaine should be administered at least 5 minutes prior to injecting the total volume required for a lumbar or caudal epidural block. The test dose should be repeated if the patient is moved in a manner that may have displaced the catheter. Epinephrine, if contained in the test dose, (10-15 μg have been suggested), may serve as a warning of unintentional intravascular injection. If injected into a blood vessel, this amount of epinephrine is likely to produce a transient “epinephrine response” within 45 seconds, consisting of an increase in heart rate and systolic blood pressure, circumoral pallor, palpitations and nervousness in the unsedated patient. The sedated patient may exhibit only a pulse rate increase of 20 or more beats per minute for 15 or more seconds. Patients on beta blockers may not manifest changes in heart rate, but blood pressure monitoring can detect an evanescent rise in systolic blood pressure. Adequate time should be allowed for onset of anesthetic after administration of each test dose. The rapid injection of a large volume of lidocaine HCl through the catheter should be avoided, and, when feasible, fractional doses should be administered.

In the event of the known injection of a large volume of local anesthetic solution into the subarachnoid space, after suitable resuscitation and if the catheter is in place, consider attempting the recovery of drug by draining a moderate amount of cerebrospinal fluid (such as 10 ml) through the epidural catheter.

**Maximum Recommended Dosages Adults**

For normal healthy adults, the individual maximum recommended dose of lidocaine HCl with epinephrine should not exceed 7 mg/kg (3.5 mg/lb) of body weight, and in general, it is recommended that the maximum total dose not exceed 500 mg. When used without epinephrine the maximum individual dose should be kept under 300 mg and in any case should not exceed 4.5 mg/kg (2 mg/lb) of body weight. For continuous epidural or caudal anesthesia, the maximum recommended dosage should not be administered at intervals of less than 90 minutes. When continuous lumbar or caudal epidural anesthesia is used for nonobstetrical procedures, more drug may be administered if required to produce adequate anesthesia.

The maximum recommended dose per 90 minute period of lidocaine HCl for paracervical block in obstetrical patients and nonobstetrical patients is 200 mg total. One-half of the total dose is usually administered to each side. Inject slowly, 5 minutes between sides (see also discussion of paracervical block in PRECAUTIONS, Labor and Delivery).

For intravenous regional anesthesia, the dose administered should not exceed 4 mg/kg in adults.

**Children**

It is difficult to recommend a maximum dose for any drug of children, since this varies as a function of age and weight. For children of less than 10 years of age who have a normal lean body mass and normal body development, the maximum dose may be determined by the application of one of the standard pediatric drug formulas (e.g., Clark’s rule). For example, in a child of 5 years weighing 50 lb, the dose of lidocaine HCl should not exceed 75-100 mg when calculated according to Clark’s rule. In any case, the maximum dose of lidocaine HCl with epinephrine should not exceed 7 mg/kg (3.2 mg/lb) of body weight. When used without epinephrine, the amount of lidocaine HCl is kept below 300 mg and in any case should not exceed 4.5 mg/kg (2 mg/lb) of body weight.

For example, in a child of 5 years weighing 50 lb the dose of lidocaine HCl should not exceed 75-100 mg (1.5-2 mg/lb). The use of even more dilute solutions (i.e., 0.25-0.5%) and total dosages not to exceed 3 mg/kg (1.4 mg/lb) are recommended for induction of intravenous regional anesthesia in children.
In order to guard against systemic toxicity, the lowest effective concentration and lowest effective dose should be used at all times. In some cases it will be necessary to dilute available concentrations with 0.9% sodium chloride injection in order to obtain the required final concentration.

Additional Information for Lidocaine HCl for Ventricular Arrhythmias Adults Single Direct Intravenous Injection (Bolus)

ONLY THE 50 mg OR 100 mg DOSAGE SIZES should be used for direct intravenous injection. The usual dose is 50-100 mg of lidocaine HCl (0.70-1.4 mg/kg; 0.32-0.63 mg/lb) administered intravenously under ECG monitoring. This dose may be administered at the rate of approximately 25-50 mg/min (0.35-0.70 mg/kg/min; 0.16-0.32 mg/lb/min). Sufficient time should be allowed to enable a slow circulation to carry the drug to the site of action. If the initial injection of 50-100 mg does not produce a desired response, a second dosage may be injected after 5 minutes. NO MORE THAN 200-300 MG OF LIDOCAINE HCl SHOULD BE ADMINISTERED DURING A 1 HOUR PERIOD.

Continuous Intravenous Infusion

Following bolus administration, intravenous infusions of lidocaine HCl may be initiated at the rate of 1-4 mg/min of lidocaine HCl (0.014-0.057 mg/kg/min; 0.006-0.026 mg/lb/min). The rate of intravenous infusions should be reassessed as soon as the patient’s basic cardiac rhythm appears to be stable or at the earliest signs of toxicity. It should rarely be necessary to continue intravenous infusions of lidocaine for prolonged periods.

Solutions for intravenous infusion may be prepared by the addition of 1 g (or 2 g) of lidocaine HCl to 1 L of 5% dextrose in water using aseptic technique. Approximately a 0.1% (or 0.2%) solution will result from this procedure; that is, each milliliter will contain approximately 1 (or 2) mg of lidocaine HCl. In those cases in which fluid restriction is medically appropriate, a more concentrated solution may be prepared.

Lidocaine HCl has been found to be chemically stable for 24 hours after dilution in 5% dextrose in water. However, as with all intravenous admixtures, dilution of the solution should be made just prior to its administration.

It is very important that after adding lidocaine HCl, or any other medication, to an IV container, the contents be thoroughly mixed before beginning the infusion.

When administered by continuous IV infusion, it is advisable to use a precision volume control IV set.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever the solution and container permit. Do not use if solution is discolored or cloudy.

Pediatric

Although controlled clinical studies to establish pediatric dosing schedules have not been conducted, the American Heart Association’s Standards and Guidelines recommends a bolus dose of 1 mg/kg followed by an infusion rate of 30 μg/kg/min.

Note Regarding Prolonged Infusions: There are data that indicate the half-life may be 3 hours or longer following infusions greater than 24 hours in duration.

Additional Information for Lidocaine HCl With Dextrose

Spinal anesthesia with lidocaine HCl with dextrose may be induced in the right or left lateral recumbent or the sitting position. Since this is a hyperbaric solution, the anesthetic will tend to move in the direction in which the table is tilted. After the desired level of anesthesia is obtained and the anesthetic has become fixed, usually in 5-10 minutes with lidocaine, the patient may be positioned according to the requirement of the surgeon or obstetrician.

In clinical trials, the safety of hyperbaric lidocaine for single injection spinal anesthesia was demonstrated using 22 or 25 gauge spinal needles. In these studies, free flow of CSF was visible before injection of lidocaine.

Neurologic deficits have been reported with the use of small bore needles and microcatheters for spinal anesthesia. It has been postulated, based on in vitro models, that these deficits were caused by pooling and nonuniform distribution of concentrated local anesthetic within the subarachnoid space. Animal studies suggest that mixing 5% lidocaine with an equal volume of CSF or preservative-free 0.9% saline solution may reduce the
risk of nerve injury due to pooling of concentrated local anesthetic (see PRECAUTIONS, Additional Information for Lidocaine HCl With Dextrose).

Intrathecal distribution of anesthetic may be facilitated by using a spinal needle of sufficient gauge to insure adequate withdrawal of CSF through the needle prior to and after anesthetic administration. If the technique is properly performed and the drug is properly placed in the subarachnoid space, a separate injection is seldom necessary.

An incomplete or patchy block not responsive to patient repositioning may indicate misplacement or inadequate distribution of drug. To avoid excessive drug pooling, additional doses of lidocaine HCl should not be administered with the same needle placement.

INJECTIONS SHOULD BE MADE SLOWLY. Consult standard textbooks for specific techniques for spinal anesthetic procedures.

**Recommended Dosages Normal Healthy Adults**

The following recommended dosages are for normal healthy adults and serve only as a guide to the amount of anesthetic required for most routine procedures. In all cases, the smallest dose that will produce the desired result should be given.

If the technique is properly performed, and the needle is properly placed in the subarachnoid space, it should not be necessary to administer more than one ampule (100 mg).

**Obstetrical Low Spinal or "Saddle Block" Anesthesia**

The dosage recommended for normal vaginal delivery is approximately 1 ml (50 mg). For Caesarean section and those deliveries requiring intrauterine manipulations, 1.5 (75 mg) is usually adequate.

**Surgical Anesthesia**

The dosage recommended for abdominal anesthesia is 1.5-2 ml (75-100 mg).

**Children**

The dosage recommendations in healthy adolescents, 16 years of age and older, is the same as for normal healthy adults. There is insufficient data in pediatric patients below the age of 16 years to make dosage recommendations (see PRECAUTIONS)

**NOTE:** Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever the solution and container permit. Solutions that are discolored and/or contain particulate matter should not be used.

**Additional Information for Lidocaine HCl Sterile Solution**

The dosages below are for normal, healthy adults.

**Retrobulbar Injection:** The suggested dose for a 70 kg person is 3-5 ml (120-200 mg of lidocaine HCl), \( i.e., 1.7-3 \) mg/kg or 0.9-1.5 mg/lb body weight. A portion of this is injected retrobulbarly and the rest may be used to block the facial nerve.

**Transtracheal Injection:** For local anesthesia by the transtracheal route 2-3 ml should be injected through a large enough needle so that the injection can be made rapidly. By injecting during inspiration some of the drug will be carried into the bronchi and the resulting cough will distribute the rest of the drug over the vocal cords and the epiglottis. Occasionally it may be necessary to spray the pharynx by oropharyngeal spray to achieve complete analgesia. For the combination of the injection and spray, it should rarely be necessary to utilize more than 5 ml (200 mg of lidocaine HCl), \( i.e., 3 \) mg/kg or 1.5 mg/lb body weight.

**Topical Application:** For laryngoscopy, bronchoscopy and endotracheal intubation, the pharynx may be sprayed with 1-5 ml (40-200 mg of lidocaine HCl) \( i.e., 0.6-3 \) mg/kg or 0.3-1.5 mg/lb body weight.

**Maximum Recommended Dosages**
**Normal Healthy Adults:** The maximum recommended dose of lidocaine HCl should be such that the dose of lidocaine HCl is kept below 300 mg and in any case should not exceed 4.5 mg/kg (2 mg/lb) body weight.

**Children:** It is difficult to recommend a maximum dose of any drug for children, since this varies as a function of age and weight. For children of less than 10 years of age who have a normal lean body mass and normal body development, the maximum dose may be determined by the application of one of the standard pediatric drug formulas (e.g., Clark's rule). For example, in a child of 5 years weighing 50 lb, the dose of lidocaine HCl should not exceed 75-100 mg when calculated according to Clark's rule. In any case, the maximum dose of lidocaine HCl with epinephrine should not exceed 7 mg/kg (3.2 mg/lb) of body weight. When used without epinephrine, the amount of lidocaine HCl is kept below 300 mg and in any case should not exceed 4.5 mg/kg (2.0 mg/lb) of body weight.

**NOTE:** Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever the solution and container permit. Solutions that are discolored and/or contain particulate matter should not be used.

**Additional Information for Lidocaine HCl Topical Solution**

**Topical Application:** For laryngoscopy, bronchoscopy, and endotracheal intubation, the pharynx may be sprayed with 1-5 ml (40-200 mg lidocaine HCl), (i.e., 0.6-3 mg/kg or 0.3-1.5 mg/lb body weight). For local anesthesia by the transtracheal route, it may be occasionally necessary to spray the pharynx by oropharyngeal spray to achieve complete analgesia.

**Maximum Recommended Dosages**

**Normal Healthy Adults:** The maximum recommended dose of lidocaine HCl should be such that the dose of lidocaine HCl is kept below 300 mg and in any case should not exceed 4.5 mg/kg (2 mg/lb) body weight.

**Children:** It is difficult to recommend a maximum dose of any drug for children, since this varies as a function of age and weight. For children of less than 10 years of age who have a normal lean body mass and normal body development, the maximum dose may be determined by the application of one of the standard pediatric drug formulas (e.g., Clark's rule). For example, in a child of 5 years weighing 50 lb, the dose of lidocaine HCl should not exceed 75-100 mg when calculated according to Clark's rule. The amount of lidocaine HCl topical solution administered should be such that the dose of lidocaine HCl is kept below 300 mg and in any case should not exceed 4.5 mg/kg (2.0 mg/lb) of body weight.

**Additional Information for Lidocaine HCl Jelly For Surface Anesthesia of the Male Adult Urethra**

The outer orifice is washed and disinfected. The plastic tip is introduced into the orifice, where it is firmly held in position. The jelly is instilled by an easy syringe-like action, until the patient has a feeling of tension or until about 15 ml (i.e., 300 mg of lidocaine HCl) is instilled. A penile clamp is then applied for several minutes at the corona and then additional jelly (about 15 ml) is instilled. To save time, the injection is performed against the resistance of the sphincter, possibly assisted by asking the patient to strain as for defecation or to press as in voiding. The jelly will then pass into the posterior urethra. Prior to sounding or cystoscopy, a penile clamp should be applied for 5-10 minutes to obtain adequate anesthesia. If the instrument is introduced immediately, a lubricant is unnecessary. Otherwise some jelly can be expressed from the vial and applied to the instrument tip. About 30 ml (i.e., 600 mg) may be required to fill and dilate the male urethra. When it is desired to anesthetize only the anterior male urethra, as prior to catheterization, considerably smaller volumes, such as the contents from a 5 ml (i.e., 100 mg) or 10 ml (i.e., 200 mg) size vial, are usually adequate for lubrication.

**For Surface Anesthesia of the Female Adult Urethra**

3-5 ml of the jelly is intilled slowly into the urethra by gently expressing the contents of the vial. If desired, some jelly may be deposited on a cotton swab and introduced into the urethra. In order to obtain adequate anesthesia, several minutes should be allowed prior to performing urological procedure.

**Lubrication for Endotracheal Intubation**

Apply a moderate amount of jelly to the external surface of the endotracheal tube shortly before use. Care should be taken to avoid introducing the product into the lumen of the tube. Do not use the jelly to lubricate endotracheal stylettes. See WARNINGS, Additional Information for Lidocaine HCl Jelly and ADVERSE REACTIONS, Additional Information for Lidocaine HCl Jelly concerning rare reports of inner lumen occlusion. It is also recommended that use of endotracheal tubes with dried jelly on the external surface be avoided for lack of lubricating effect.
Maximum Dosage

No more than 600 mg of lidocaine HCl should be given in any 12 hour period.

Children

It is difficult to recommend a maximum dose of any drug for children, since this varies as a function of age and weight. For children of less than 10 years of age who have a normal lean body mass and normal body development, the maximum dose may be determined by the application of one of the standard pediatric drug formulas (e.g., Clark’s rule). For example, in a child of 5 years weighing 50 lb, the dose of lidocaine HCl should not exceed 75-100 mg when calculated according to Clark’s rule. The amount of lidocaine HCl administered should not exceed 4.5 mg/kg (2.0 mg/lb) of body weight.

REFERENCES: