



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 a 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 HCl.

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

#### DOSAGE AND ADMINISTRATION:

**Table 1** (Recommended Dosages) summarizes the recommended volumes and concentrations of lidocaine hydrochloride injection 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.

There have been adverse event reports of chondrolysis in patients receiving intra-articular infusions of local anesthetics following arthroscopic and other surgical procedures. Lidocaine is not approved for this use (see **WARNINGS** and **DOSAGE AND ADMINISTRATION**).

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 depend 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 elderly and debilitated patients and patients with cardiac and/or liver disease.

The onset of anesthesia, the duration of anesthesia and the degree of muscular relaxation are proportional to the volume and concentration (i.e. total dose) of local anesthetic used. Thus, an increase in volume and concentration of lidocaine hydrochloride injection will decrease the onset of anesthesia, prolong the duration of anesthesia, provide a greater degree of muscular relaxation and increase the segmental spread of anesthesia. However, increasing the volume and concentration of lidocaine hydrochloride injection may result in a more profound fall in blood pressure when used in epidural anesthesia. Although the incidence of side effects with lidocaine is quite low, caution should be exercised when employing large volumes and concentrations, since the incidence of side effects is directly proportional to the total dose of local anesthetic agent injected.

#### MAXIMUM RECOMMENDED DOSAGES:

**NOTE: The products accompanying this insert do not contain epinephrine.**

#### Adults

For normal healthy adults, the individual maximum recommended dose of lidocaine hydrochloride without epinephrine should not exceed 4.5 mg/kg (2 mg/lb) of body weight and in general it is recommended that the maximum total dose does not exceed 300 mg.

The maximum recommended dose per 90 minute period of lidocaine hydrochloride for paracervical block in obstetrical and non-obstetrical patients is 200 mg total. One half of the total dose is usually administered to

each side. Inject slowly, five minutes between sides (see also discussion of paracervical block in **PRECAUTIONS**).

**TABLE 1**  
**RECOMMENDED DOSAGES OF LIDOCAINE HYDROCHLORIDE INJECTION (WITHOUT EPINEPHRINE)**  
**FOR VARIOUS ANESTHETIC PROCEDURES IN NORMAL HEALTHY ADULTS**

PROCEDURE	LIDOCAINE HYDROCHLORIDE INJECTION (WITHOUT EPINEPHRINE) CONCENTRATION (%)	VOLUME (mL)	TOTAL DOSE (mg)
<b>INFILTRATION</b>			
PERCUTANEOUS	0.5 or 1	1 to 60	5 to 300
<b>PERIPHERAL NERVE BLOCKS, E.G.</b>			
BRACHIAL	1.5	15 to 20	225 to 300
DENTAL	2	1 to 5	20 to 100
INTERCOSTAL	1	3	30
PARAVERTEBRAL	1	3 to 5	30 to 50
PUDENDAL (EACH SIDE)	1	10	100
<b>PARACERVICAL</b>			
OBSTETRICAL ANALGESIA (EACH SIDE)	1	10	100
<b>SYMPATHETIC NERVE BLOCKS, E.G.</b>			
CERVICAL (STELLATE GANGLION)	1	5	50
LUMBAR	1	5 to 10	50 to 100

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 EXCEEDED.

#### 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 over three years of age who have a normal lean body mass and normal body development, the maximum dose is determined by the child's age and weight. For example, in a child of five years weighing 50 lbs., the dose of lidocaine hydrochloride should not exceed 75 to 100 mg (1.5 to 2 mg/lb).

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.

#### Sterilization, Storage and Technical Procedures

Disinfecting agents containing heavy metals, which cause release of respective ions (mercury, zinc, copper, etc.) should not be used for skin or mucous membrane disinfection as they have been related to incidents of swelling and edema. 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 not of USP grade, contain denaturants which are injurious to rubber and therefore are not to be used.

Parenteral drug products should be visually inspected for particulate matter and discoloration prior to administration, whenever the solution and container permit. The injection is not to be used if its color is pinkish or darker than slightly yellow or if it contains a precipitate.

#### HOW SUPPLIED:

Lidocaine Hydrochloride Injection is preserved with 0.1% methylparaben and is available in the following concentrations:

Product Code	Unit of Sale	Strength	Each
920102	NDC 63323-201-02 Unit of 25	1% 20 mg per 2 mL (10 mg per mL)	NDC 63323-201-01 2 mL Vial
20110	NDC 63323-201-10 Unit of 25	1% 100 mg per 10 mL (10 mg per mL)	NDC 63323-201-03 10 mL Multiple Dose Vial
20202	NDC 63323-202-02 Unit of 25	2% 40 mg per 2 mL (20 mg per mL)	NDC 63323-202-01 2 mL Vial

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Protect from light.



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