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

Concurrent use of these agents should generally be avoided. In situations where corticosteroid therapy is necessary, careful patient monitoring is essential.

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

Drug Laboratory Test Interactions: The intramuscular injection of lidocaine or other local anesthetic agents should not be given to patients who are taking monoamine oxidase inhibitors.

Cardiomyopathy, Myocardial Failure, or Impairment of Fertility: Studies of lidocaine or other local anesthetics in animals have not shown evidence of a teratogenic potential or the effect on fertility have not been conducted.

Phenothiazines have a teratogenic effect, therefore, use of this drug during pregnancy is contraindicated. It is not known whether the use of this drug during pregnancy has a teratogenic effect or results in fetal harm. There is no evidence that this drug is excreted in human milk or breast milk.

Labor and Delivery: Local anesthetics rapidly cross the placenta and enter the fetal circulation. While the fetal dose is likely to be very low, it is not known whether this drug can cause fetal harm when used for local anesthesia during labor and delivery. It is not known whether this drug has a teratogenic potential or the effect on fertility have not been conducted.

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made slowly and with frequent aspiration. Allow a 5-minute interval between sides.

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.

ADVERSE REACTIONS
Systemic: Adverse experiences following the administration of lidocaine are similar in nature to those observed with other amide local anesthetic agents. These reactions may manifest as general toxic responses, and may result from high plasma levels caused by excessive dosage, rapid absorption or inadvertent intravascular injection, or may result from a hypersensitivity to the local anesthetic substance or any of its components. Adverse reactions can be minimized or eliminated by: (a) selection of the agent and dosage appropriate to the patient and the surgical procedure; (b) using the smallest effective dose; (c) avoiding intravascular injection of the agent; (d) delaying injections until sensitivity to the test dose has been determined; (e) employing appropriate diluents when necessary; (f) use of epinephrine, unless contraindicated; and (g) being prepared to treat local anesthetic toxicity should it occur. The use of the ephedrine and epinephrine should not be synonymous.

In the practice of caudal or lumbar epidural block, occasional unintentional intravascular injection of the local anesthetic agent may occur. Subsequent adverse effects may depend partially on the amount of drug administered subcutaneously. These may include spinal block of variable magnitude, ephedrine hypotension secondary to spinal blood loss, block of bladder and bowel control, and loss of perineal sensation and sexual function. Persistent motor, sensory and/or autonomic (sphincter) deficits of some local sensory anesthesia may result. 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.

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

OVERDOSAGE
Acute emergencies from local anesthetics are generally related to high plasma levels and are manifested during treatment by the use of local anesthetics or to unintentional subcutaneous injection of local anesthetic solution (see ADVERSE REACTIONS, WARNINGS and PRECAUTIONS).

Management of Local Anesthetic Emergencies: The initial consideration is prevention, best accomplished by careful 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 under ventilation or apnea due to unintentional subcutaneous injection of drug solution, consists of immediate attention to the maintenance of a patent airway and assisted or controlled ventilation with oxygen and a 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 thiamyl) or a benzodiazepine (such as diazepam) may be administered intravenously. The clinician should be familiar with the use of anesthesics, 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 subcutaneous 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 maintaining a patent airway or if prolonged ventilatory support (assisted or controlled) is indicated. Dialysis is of negligible value in the treatment of acute overdose with lidocaine.

The oral LD₅₀ of lidocaine HCI in non-fasted female rats is 405 (C46-173) mg/kg (as the salt) and 214 (159-324) mg/kg (as the salt) in fasted females.

DOSAGE AND ADMINISTRATION
Table 1 (Recommended Dosages) summarizes the recommended volumes

<table>
<thead>
<tr>
<th>Drug Concentration</th>
<th>Size</th>
<th>Lidocaine Hydrochloride and Ephedrine Injection, USP</th>
<th>Three-Dose Kit (3 single-dose ampuls)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-dose</td>
<td>30 ml</td>
<td>1%</td>
<td>1 ampul</td>
</tr>
<tr>
<td>Multiple-dose</td>
<td>50 ml</td>
<td>0.5%</td>
<td>1 ampul</td>
</tr>
<tr>
<td>Single-dose</td>
<td>20 ml</td>
<td>1%</td>
<td>1 ampul</td>
</tr>
<tr>
<td>Multiple-dose</td>
<td>50 ml</td>
<td>0.5%</td>
<td>1 ampul</td>
</tr>
<tr>
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<td>Multiple-dose</td>
<td>50 ml</td>
<td>0.5%</td>
<td>1 ampul</td>
</tr>
</tbody>
</table>

Table 1

Tramadol Hydrochloride and Ephedrine Injection, USP is supplied in single-dose and multidose containers as shown below:

<table>
<thead>
<tr>
<th>List No.</th>
<th>Container Size</th>
<th>Lidocaine Hydrochloride and Ephedrine Injection, USP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1313</td>
<td>20 ml</td>
<td>1%</td>
</tr>
<tr>
<td>1319</td>
<td>20 ml</td>
<td>1%</td>
</tr>
<tr>
<td>1320</td>
<td>20 ml</td>
<td>1%</td>
</tr>
<tr>
<td>1321</td>
<td>20 ml</td>
<td>1%</td>
</tr>
</tbody>
</table>

Concentration by number of ampuls to be administered (2 to 3 mL dermals):

The ABOVE SUGGESTED CONCENTRATIONS AND VOLUMES ARE ADOPTED AS A GUIDE. DO NOT USE PROVIDED THE TOTAL MAXIMUM RECOMMENDED DOSE IS NOT EXCEEDED.