

LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE- lidocaine hydrochloride and epinephrine injection, solution
General Injectables & Vaccines

**Lidocaine Hydrochloride
and Epinephrine
Injection, USP**
For Infiltration and Nerve Block Ampul
Fliptop Vial
Multiple-dose Fliptop Vial
Protect from light. Rx only
EN-5828

Description

Lidocaine Hydrochloride and Epinephrine Injection, USP is a sterile, nonpyrogenic solution of lidocaine hydrochloride and epinephrine in water for injection for parenteral administration in various concentrations with characteristics as follows:

| Concentration | | Lidocaine HCl | Epinephrine | Sodium Chloride |
|----------------------|--------------------|-----------------------|--------------------|------------------------|
| Lidocaine HCl | Epinephrine | (anhyd.) mg/mL | mcg/mL | mg/mL |
| 0.5% | 1:200,000 | 5 | 5 | 8 |
| 1% | 1:200,000 | 10 | 5 | 7 |
| 1.5% | 1:200,000 | 15 | 5 | 6.5 |
| 2% | 1:200,000 | 20 | 5 | 6 |
| 1% | 1:100,000 | 10 | 10 | 7 |
| 2% | 1:100,000 | 20 | 10 | 6 |

Sodium metabisulfite 0.5 mg/mL and citric acid, anhydrous 0.2 mg/mL added as stabilizers. The headspace of Lists 1209, 3177, 3178, 3181, 3182 and 3183 are nitrogen gassed. May contain sodium hydroxide and/or hydrochloric acid to adjust pH; pH is 4.5 (3.3 to 5.5). See **HOW SUPPLIED** section for various sizes and strengths.

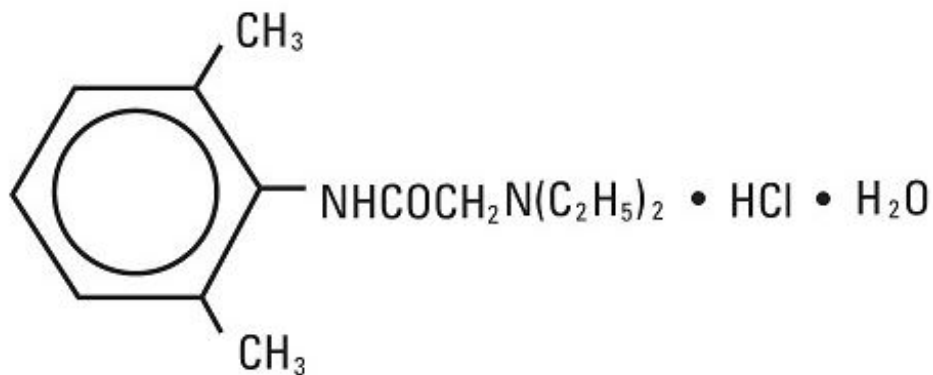
Multiple-dose vials contain methylparaben 1 mg/mL added as preservative.

Single-dose ampuls and vials contain no bacteriostat or antimicrobial agent.

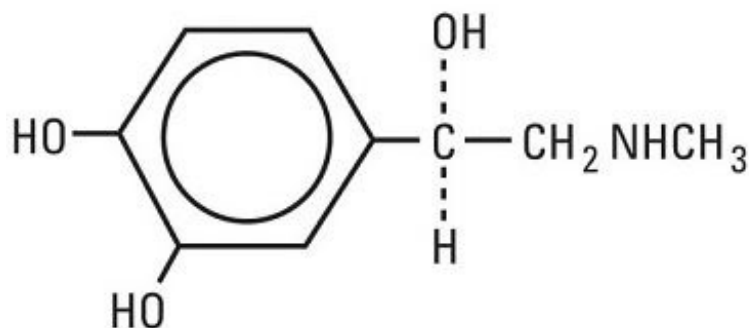
Discard unused portion.

Lidocaine is a local anesthetic of the amide type.

Lidocaine Hydrochloride, USP is chemically designated 2-(diethyl-amino)-2',6'-acetoxyllidide monohydrochloride monohydrate, a white powder freely soluble in water. It has the following structural formula:



Epinephrine, USP is a sympathomimetic (adrenergic) agent designated chemically as 4-[1-hydroxy-2-(methylamino) ethyl]-1,2 benzenediol, a white, microcrystalline powder. It has the following structural formula:



Clinical Pharmacology

Mechanism of Action

Lidocaine HCl stabilizes the neuronal membrane by inhibiting the ionic fluxes required for the initiation and conduction of impulses thereby effecting local anesthetic action.

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.

Pharmacokinetics and Metabolism

Information derived from diverse formulations, concentrations and usages reveals that lidocaine HCl is completely absorbed following parenteral administration, its rate of absorption depending, for example, upon various factors such as the site of administration and the presence or absence of a vasoconstrictor agent. Except for intravascular administration, the highest blood levels are obtained following intercostal nerve block and the lowest after subcutaneous administration.

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

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

Lidocaine HCl 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 monoethylglycinexylidide and glycinexylidide. The pharmacological/toxicological actions of these metabolites are similar to, but less potent than, those of lidocaine HCl. Approximately 90% of lidocaine HCl 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.

The elimination half-life of lidocaine HCl following an intravenous bolus injection is typically 1.5 to 2 hours. Because of the rapid rate at which lidocaine HCl is metabolized, any condition that affects liver function may alter lidocaine HCl kinetics. The half-life may be prolonged two-fold or more in patients with liver dysfunction.

Renal dysfunction does not affect lidocaine HCl 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 HCl required to produce overt systemic effects. Objective adverse manifestations become increasingly apparent with increasing venous plasma levels above 6 mcg free base per mL. In the rhesus monkey arterial blood levels of 18 to 21 mcg/mL have been shown to be threshold for convulsive activity.

Indications and Usage

Lidocaine Hydrochloride and Epinephrine Injection, USP is indicated for production of local or regional anesthesia by infiltration techniques such as percutaneous injection, 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.

Contraindications

Lidocaine HCl is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type.

Warnings

LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION, USP FOR INFILTRATION AND NERVE BLOCK 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 FROM THE BLOCK TO BE EMPLOYED 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.

Cases of methemoglobinemia have been reported in association with local anesthetic use. Although all patients are at risk for methemoglobinemia, patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, infants under 6 months of age, and concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing clinical manifestations of the condition. If local anesthetics must be used in these patients, close monitoring for symptoms and signs of methemoglobinemia is recommended.

Signs of methemoglobinemia may occur immediately or may be delayed some hours after exposure, and

are characterized by a cyanotic skin discoloration and/or abnormal coloration of the blood. Methemoglobin levels may continue to rise; therefore, immediate treatment is required to avert more serious CNS and cardiovascular adverse effects, including seizures, coma, arrhythmias, and death. Discontinue lidocaine HCl and any other oxidizing agents. Depending on the severity of the signs and symptoms, patients may respond to supportive care, i.e., oxygen therapy, hydration. A more severe clinical presentation may require treatment with methylene blue, exchange transfusion, or hyperbaric oxygen.

Intra-articular infusions of local anesthetics following arthroscopic and other surgical procedures is an unapproved use, and there have been post-marketing reports of chondrolysis in patients receiving such infusions. The majority of reported cases of chondrolysis have involved the shoulder joint; cases of gleno-humeral chondrolysis have been described in pediatric and adult patients following intra-articular infusions of local anesthetics with and without epinephrine for periods of 48 to 72 hours. There is insufficient information to determine whether shorter infusion periods are not associated with these findings. The time of onset of symptoms, such as joint pain, stiffness and loss of motion can be variable, but may begin as early as the 2nd month after surgery. Currently, there is no effective treatment for chondrolysis; patients who experienced chondrolysis have required additional diagnostic and therapeutic procedures and some required arthroplasty or shoulder replacement.

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.

Lidocaine Hydrochloride and Epinephrine Injection contains 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 non-asthmatic people.

Anaphylactic reactions may occur following administration of lidocaine hydrochloride (see **ADVERSE REACTIONS**).

In the case of severe reaction, discontinue the use of the drug.

Adverse Reactions

Systemic

Adverse experiences following the administration of lidocaine HCl 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 or inadvertent intravascular injection, or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature. The following types are those most commonly reported:

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 manifestations 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 HCl 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 multiple dose vials. Allergic reactions, including anaphylactic reactions, may occur as a result of sensitivity to lidocaine, 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 hydrochloride and procainamide or between lidocaine hydrochloride and quinidine.

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. In a prospective review of 10,440 patients who received lidocaine HCl for spinal anesthesia, the incidences of adverse reactions were reported to be about 3 percent each for positional headaches, hypotension and backache; 2 percent for shivering; and less than 1 percent 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.

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 of 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.

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

Hematologic

Methemoglobinemia.

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 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 thiamylal) or a benzodiazepine (such as diazepam) may be administered intravenously. The clinician should be familiar, prior to 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 LD₅₀ 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 I (Recommended Dosages) summarizes the recommended volumes and concentrations of Lidocaine Hydrochloride Injection, USP 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, USP 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, USP may result in a more profound fall in blood pressure when used in epidural anesthesia. Although the incidence of side effects with lidocaine HCl 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.

Epidural Anesthesia

For an epidural test dose, only the following **available** specific product of Lidocaine Hydrochloride and Epinephrine Injection, USP by Hospira is recommended:

1.5% with epinephrine 1:200,000.....5 mL single-dose ampuls

For epidural anesthesia, only the following **available** specific products of Lidocaine Hydrochloride and Epinephrine Injection, USP by Hospira are recommended:

1% with epinephrine 1:200,000 30 mL single-dose vials

1.5% with epinephrine 1:200,000 30 mL single-dose vials

2% with epinephrine 1:200,000 20 mL single-dose vials

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 to 3 mL of the indicated concentration per dermatome).

Caudal and Lumbar Epidural Block

As a precaution against the adverse experiences sometimes observed following unintentional penetration of the subarachnoid space, a test dose such as 2 to 3 mL of 1.5% lidocaine HCl 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 to 15 mcg 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 anesthesia after administration of each test dose. The rapid injection of a large volume of Lidocaine Hydrochloride and Epinephrine Injection, USP 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 Hydrochloride and Epinephrine Injection, USP 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 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. 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 non-obstetrical procedures, more drug may be administered if required to produce adequate anesthesia.

The maximum recommended dose per 90 minute period of lidocaine hydrochloride for paracervical block in obstetrical patients 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**).

Children

It is difficult to recommend a maximum dose of any drug for pediatric patients, since this varies as a function of age and weight. For children over 3 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 5 years weighing 50 lbs., the dose of lidocaine HCl should not exceed 75 to 100 mg (1.5 to 2 mg/lb). The use of even more dilute solutions (i.e., 0.25 to 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.

FOR EPIDURAL USE ONLY.

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

Table 1
Recommended Dosages
Lidocaine Hydrochloride
Injection, USP (without Epinephrine)

| Procedure | Conc. (%) | Vol. (mL) | Total Dose (mg) |
|---------------------------------------|-----------|-----------|-----------------|
| Infiltration | | | |
| Percutaneous | 0.5 or 1 | 1 to 60 | 5 to 300 |
| Intravenous regional | 0.5 | 10 to 60 | 50 to 300 |
| Peripheral Nerve Blocks, e.g. | | | |
| 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 |
| Paracervical | | | |
| Obstetrical analgesia (each side) | 1 | 10 | 100 |
| Sympathetic Nerve Blocks, e.g. | | | |
| Cervical (stellate ganglion) | 1 | 5 | 50 |
| Lumbar | 1 | 5 to 10 | 50 to 100 |
| Central Neural Blocks | | | |
| Epidural* | | | |
| Thoracic | 1 | 20 to 30 | 200 to 300 |
| Lumbar | | | |
| Analgesia | 1 | 25 to 30 | 250 to 300 |
| Anesthesia | 1.5 | 15 to 20 | 225 to 300 |
| | 2 | 10 to 15 | 200 to 300 |
| Caudal | | | |
| Obstetrical analgesia | 1 | 20 to 30 | 200 to 300 |
| Surgical anesthesia | 1.5 | 15 to 20 | 225 to 300 |

*Dose determined by number of dermatomes to be anesthetized (2 to 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 EXCEEDED.

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. It is recommended that chemical disinfection be accomplished by wiping the vial stopper or ampul thoroughly with cotton or gauze that has been moistened with the recommended alcohol just prior to use.

Do not autoclave.

How Supplied

Lidocaine Hydrochloride and Epinephrine Injection, USP is supplied in single-dose and multiple-dose containers as shown below:

**Table 1
Recommended Dosages**

| Procedure | Lidocaine Hydrochloride Injection, USP (without Epinephrine) | | |
|--|--|-----------|-----------------|
| | Conc. (%) | Vol. (mL) | Total Dose (mg) |
| Infiltration Percutaneous Intravenous regional | 0.5 or 1 | 1 to 60 | 5 to 300 |
| | 0.5 | 10 to 60 | 50 to 300 |
| Peripheral Nerve Blocks, e.g. Brachial Dental Intercostal Paravertebral Pudendal (each side) <u>Paracervical</u> Obstetrical analgesia (each side) | 1.5 | 15 to 20 | 225 to 300 |
| | 2 | 1 to 5 | 20 to 100 |
| | 1 | 3 | 30 |
| | 1 | 3 to 5 | 30 to 50 |
| | 1 | 10 | 100 |
| | 1 | 10 | 100 |
| | 1 | 10 | 100 |
| Sympathetic Nerve Blocks, e.g. Cervical (stellate ganglion) Lumbar | 1 | 5 | 50 |
| | 1 | 5 to 10 | 50 to 100 |
| Central Neural Blocks Epidural [†] Thoracic Lumbar Analgesia Anesthesia Caudal Obstetrical analgesia Surgical anesthesia | 1 | 20 to 30 | 200 to 300 |
| | 1 | 25 to 30 | 250 to 300 |
| | 1.5 | 15 to 20 | 225 to 300 |
| | 2 | 10 to 15 | 200 to 300 |
| | 1 | 20 to 30 | 200 to 300 |
| | 1.5 | 15 to 20 | 225 to 300 |
| | 1 | 20 to 30 | 200 to 300 |
| | 1.5 | 15 to 20 | 225 to 300 |

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] **Protect from light.**

Distributed by Hospira, Inc., Lake Forest, IL 60045 USA

LAB-1298-1.0

Revised: 08/2019

Sample Package Label

NDC # 52584 - 182 - 01
ITEM# :2480237
LOT # XXXXXXXXX
EXP : mm - dd - yy

Packaged By
General Injectables and Vaccines, Inc
80 Summit View Lane
Bastian, VA 24314

**LIDOCAINE HCL 2% AND
EPINEPHRINE 1:100,000**

INJECTION, USP

20 ML

MULTIPLE DOSE

SEE MANUFACTURER'S INSERT
FOR COMPLETE PRODUCT AND
PRESCRIBING INFORMATION

PROTECT FROM LIGHT. RETAIN IN CARTON UNTIL
CONTENTS ARE USED. DO NOT AUTOCLAVE. FOR
INFILTRATION AND NERVE BLOCK. NOT FOR EPIDURAL
OR CAUDAL USE. STERILE, NONPYROGENIC. DO NOT
USE THE INJECTION IF ITS COLOR IS PINKISH OR
DARKER THAN SLIGHTLY YELLOW OR IF IT
CONTAINS A PRECIPITATE.

Keep out of children's reach.
Store at controlled room
temperature 68F to 77F.

MANUFACTURER INFORMATION

Mfr: Hospira

ORIG MFG LOT: XX - XXX - XX

NDC:0409 - 3182 - 01



(10)XXXXXX

(17)XXXXXXXX

(01)XXXXXXXXXXXX

(21)XXXXXXXXXXXX

RX ONLY

NDC # 52584 - 182 - 02
ITEM# :2485394
LOT # XXXXXXXXX
EXP : mm - dd - yy

Packaged By
General Injectables and Vaccines, Inc
80 Summit View Lane
Bastian, VA 24314

**LIDOCAINE HCL 2% and
EPINEPHRINE 1:100,000**

INJECTION, USP
MULTIPLE DOSE

30 ML

SEE MANUFACTURER'S INSERT
FOR COMPLETE PRODUCT AND
PRESCRIBING INFORMATION

PROTECT FROM LIGHT. FOR INFILTRATION AND NERVE
BLOCK. NOT FOR EPIDURAL OR CAUDAL USE. DO NOT
AUTOCLAVE. RETAIN IN CARTON UNTIL CONTENTS ARE
USED. STERILE, NONPYROGENIC. DO NOT USE THE
INJECTION IF ITS COLOR IS PINKISH OR DARKER THAN
SLIGHTLY YELLOW OR IF IT CONTAINS A
PRECIPITATE.

Keep out of children's reach.
Store at controlled room
temperature 68F to 77F.



MANUFACTURER INFORMATION

Mfr: Hospira

ORIG MFG LOT: XX - XXX - XX

NDC:0409 - 3182 - 02

(10)XXXXXX

(17)XXXXXXXX

(01)XXXXXXXXXXXX

(21)XXXXXXXXXXXX

RX ONLY

NDC # 52584 - 182 - 03
 ITEM# :2481961
 LOT # XXXXXXXXX
 EXP : mm - dd - yy

Packaged By
 General Injectables and Vaccines, Inc
 80 Summit View Lane
 Bastian, VA 24314

**LIDOCAINE HCL 2% and
 EPINEPHRINE 1:100,000**
 INJECTION, USP
 50 mL MULTIPLE DOSE FLIPTOP VIAL

SEE MANUFACTURER'S INSERT
 FOR COMPLETE PRODUCT AND
 PRESCRIBING INFORMATION

PROTECT FROM LIGHT. RETAIN IN BAG UNTIL CONTENTS
 ARE USED. DO NOT AUTOCLAVE. FOR INFILTRATION AND
 NERVE BLOCK. NOT FOR EPIDURAL OR CAUDAL USE.
 STERILE, NONPYROGENIC. DO NOT USE THE INJECTION IF
 ITS COLOR IS PINKISH OR DARKER THAN SLIGHTLY
 YELLOW OR IF IT CONTAINS A PRECIPITATE.

Keep out of children's reach.

Store at 20 to 25C (68 to 77F). (See
 Controlled Room Temperature.)



MANUFACTURER INFORMATION
 Mfr: Hospira
 ORIG MFG LOT: XX - XXX - XX
 NDC:0409 - 3182 - 03

(10)XXXXXX
 (17)XXXXXXXX
 (01)XXXXXXXXXXXX
 (21)XXXXXXXXXXXX
 RX ONLY

LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE
 lidocaine hydrochloride and epinephrine injection, solution

| Product Information | | | |
|-------------------------|--------------------------|--------------------|------------------------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:52584-182(NDC:0409-3182) |
| Route of Administration | INFILTRATION, PERINEURAL | | |

| Active Ingredient/Active Moiety | | |
|--|-----------------------------------|---------------|
| Ingredient Name | Basis of Strength | Strength |
| Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987) | LIDOCAINE HYDROCHLORIDE ANHYDROUS | 20 mg in 1 mL |
| Epinephrine (UNII: YKH834O4BH) (Epinephrine - UNII:YKH834O4BH) | Epinephrine | 10 ug in 1 mL |

| Inactive Ingredients | |
|--------------------------|----------|
| Ingredient Name | Strength |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:52584-182-01 | 1 in 1 BAG | 03/01/2010 | |
| 1 | | 20 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 2 | NDC:52584-182-02 | 1 in 1 BAG | 03/01/2010 | |
| 2 | | 30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |
| 3 | NDC:52584-182-03 | 1 in 1 BAG | 03/01/2010 | |
| 3 | | 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA089646 | 03/01/2010 | |

Labeler - General Injectables & Vaccines (108250663)

Revised: 9/2020

General Injectables & Vaccines