Prescribing Information

Carbocaine 1%

10 mg/mL, Mepivacaine Hydrochloride Injection, USP

Carbocaine 2%

20 mg/mL, Mepivacaine Hydrochloride Injection, USP

Local Anesthetic

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Local Anesthetic

Pharmacology: Mepivacaine stabilizes the neuronal membrane and prevents the initiation and transmission of nerve impulses, thereby effecting local anesthesia. Its pharmacological properties are somewhat similar to those of lidocaine, which it resembles chemically. Its action is more rapid in onset and somewhat more prolonged than that of lidocaine. It has been employed for all types of infiltration and regional nerve block anesthesia.

Onset of anesthesia is rapid, the time of onset for sensory block ranging from about 3 to 20 minutes depending upon such factors as the anesthetic technique, the type of block, the concentration of the solution and the individual patient. The degree of motor blockade produced is dependent on the concentration of the solution. The 1% concentration will block sensory and sympathetic conduction without loss of motor function and will be effective in small superficial nerve blocks. The 2% concentration of mepivacaine will produce complete sensory and motor block of any nerve group.

The duration of anesthesia also varies depending upon the technique and type of block, the concentration and the individual. Mepivacaine will normally provide anesthesia which is adequate for 2 to 2½ hours of surgery. It has been reported that vasoconstrictors do not significantly prolong anesthesia with mepivacaine, but epinephrine (1:200 000) may be added to the mepivacaine solution to promote local hemostasis and to delay systemic absorption of the anesthetic.

The drowsiness and lassitude seen with lidocaine have not been commonly noted with mepivacaine. Mepivacaine has shown excellent tissue compatibility: irritation or tissue damage has not been observed.

Indications: For production of local or regional anesthesia by local infiltration, peripheral nerve block techniques, and central neural techniques including epidural and caudal blocks.

Contraindications: Hypersensitivity to mepivacaine or amide-type local anesthetics or to other components of mepivacaine solutions.

Warnings: Local anesthetics should only be employed by clinicians who are well versed in diagnosis and management of related toxicity and other acute emergencies which might arise from the block to be employed, and then only after insuring the immediate availability

of oxygen, resuscitative drugs, cardiopulmonary resuscitative equipment, and the personnel resources needed for proper management of toxic reactions and related emergencies (see also Adverse Effects and Precautions). Delay in proper management of dose-related toxicity, underventilation from any cause, and/or altered sensitivity may lead to acidosis, cardiac arrest and, possibly death.

Local anesthetic solutions containing antimicrobial preservatives (i.e., those supplied in multiple-dose vials) should not be used for epidural or caudal anesthesia because safety has not been established with regard to intrathecal injection, either intentionally or inadvertently, of such preservatives.

It is essential that aspiration for blood or cerebrospinal fluid (where applicable) be done prior to injecting any local anesthetic, both the original dose and all subsequent doses, to avoid intravascular or subarachnoid injection. However, a negative aspiration does not ensure against an intravascular or subarachnoid injection.

Mepivacaine with epinephrine or other vasopressors should not be used concomitantly with ergot-type oxytocic drugs, because a severe persistent hypertension may occur. Likewise, solutions of mepivacaine containing a vasoconstrictor, such as epinephrine, should be used with extreme caution in patients receiving monoamine oxidase inhibitors (MAOI) or antidepressants of the triptyline or imipramine types, because severe prolonged hypertension may result.

Local anesthetic procedures should be used with caution when there is inflammation and/or sepsis in the region of the proposed injection.

Mixing or the prior or intercurrent use of any local anesthetic with mepivacaine cannot be recommended because of insufficient data on the clinical use of such mixtures.

These solutions are not intended for spinal anesthesia or dental use.

Precautions: General: During major regional nerve block, the patient should have i.v. fluids running via an indwelling catheter to assure a functioning i.v. pathway. Injections should be made slowly, with frequent aspirations before and during the injection to avoid intravascular injection. Current opinion favors fractional administration with constant attention to the patient rather than rapid bolus injection. Syringe aspirations should also be performed before and during each supplemental injection in continuous (intermittent) catheter techniques. An intravascular injection is still possible even if aspirations for blood are negative.

During the administration of epidural anesthesia, it is recommended that a test dose be administered initially and the effects monitored before the full dose is given. When using a continuous catheter technique, test doses should be given prior to both the original and all reinforcing doses, because plastic tubing in the epidural space can migrate into a blood vessel or through the dura. When clinical conditions permit an effective test dose should contain epinephrine (10 to 15 μg have been suggested) to serve as a warning of unintended intravascular injection. If injected into a blood vessel, this amount of epinephrine is likely to produce an epinephrine response within 45 seconds, consisting of an increase of pulse and 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/minute for 15 or more seconds. Therefore,

following the test dose, the heart rate should be monitored for a heart rate increase. The test dose should also contain an amide anesthetic to detect an unintended intrathecal administration. This will be evidenced within a few minutes by signs of spinal block. A negative outcome from the test dose does not guarantee that the epidural needle is accurately placed.

Injection of repeated doses of local anesthetics may cause significant increases in plasma levels with each repeated dose due to slow accumulation of the drug or its metabolites or to slow metabolic degradation. Tolerance to elevated blood levels varies with the status of the patient. Debilitated elderly patients and acutely ill patients should be given reduced doses commensurate with their age and physical status. Local anesthetics should also be used with caution in patients with severe disturbances of cardiac rhythm, shock heart block or hypotension.

Local anesthetic solutions containing a vasoconstrictor should be used cautiously and in carefully restricted quantities in areas of the body supplied by end arteries or having otherwise compromised blood supply such as digits, nose, external ear, penis. Patients with hypertensive vascular disease may exhibit exaggerated vasoconstrictor response. Ischemic injury or necrosis may result.

Mepivacaine should be used with caution in patients with known allergies and sensitivities.

Use mepivacaine cautiously in patients with hepatic and renal disease, and in patients with impaired cardiovascular function.

Serious dose-related cardiac arrhythmias may occur if preparations containing a vasoconstrictor such as epinephrine are employed in patients during or following the administration of potent inhalation anesthetics. In deciding whether to use these products concurrently in the same patient, the combined action of both agents upon the myocardium, the concentration and volume of vasoconstrictor used, and the time since injection, when applicable, should be taken into account If epinephrine is used, a 1:200 000 concentration is preferred.

Many drugs used during the conduct of anesthesia are considered potential triggering agents for familial malignant hyperthermia. Because it is not known whether amide-type local anesthetics may trigger this reaction and because the need for supplemental general anesthesia cannot be predicted in advance, it is suggested that a standard protocol for management should be available.

Head and Neck Area: Small doses of local anesthetics injected into the head and neck area may produce adverse reactions similar to systemic toxicity seen with unintentional intravascular injections of larger doses. The injection procedures require the utmost care.

Pregnancy Obstetrical anesthesia: Animal reproduction studies have not been conducted with mepivacaine. There are no adequate well-controlled studies in pregnant women of the effect of mepivacaine on the developing fetus. Mepivacaine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. This does not preclude the use of mepivacaine at term for obstetrical anesthesia or analgesia.

Maternal hypotension has resulted from regional anesthesia. Local anesthetics produce vasodilation by blocking sympathetic nerves.

Epidural, paracervical, caudal, or pudendal anesthesia may alter the forces of parturition through changes in uterine contractibility 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. Epidural anesthesia has 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 to 30% of patients receiving paracervical 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. Added risk appears to be present in prematurity, postmaturity, toxemia of pregnancy, and fetal distress. The physician should weigh the possible advantages against dangers when considering paracervical block in these conditions. 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 or paracervical or pudendal block or both.

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

It is extremely important to avoid aortocaval compression by the gravid uterus during administration of regional block to parturients and the patient must be maintained in the left lateral decubitus position.

Lactation: It is not known whether local anesthetic drugs are excreted in human milk.

Adverse Effects: Reactions to mepivacaine are characteristic of those associated with other amide-type local anesthetics: A major cause of adverse reactions to this group of drugs is excessive plasma levels, which may be due to overdosage, inadvertent intravascular injection or slow metabolic degradation. Transient slight stinging on injection has been noted occasionally.

CNS reactions are characterized by excitation and/or depression. Disorientation, restlessness, anxiety, dizziness, tinnitus, blurred vision or tremors may occur, possibly proceeding to convulsions. However, excitement may be transient or absent, with depression being the first manifestation of an adverse reaction. This may quickly be followed by drowsiness merging into unconsciousness and respiratory arrest Other CNS effects may be nausea, vomiting, chills and constriction of the pupils.

High doses or inadvertent intravascular injection may lead to high plasma levels and related depression of the myocardium, decreased cardiac output, heart block hypotension (or sometimes hypertension) bradycardia, ventricular arrhythmias and possibly cardiac arrest.

Allergic-type reactions are rare and may occur as a result of sensitivity to the local anesthetic or to other formulation ingredients, such as the antimicrobial preservative methylparaben, contained in multiple-dose vials. Cross-sensitivity among members of amide-type local anesthetic group has been reported. The usefulness of screening for sensitivity has not been definitely established.

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

Overdose: Symptoms and Treatment: Toxic effects of local anesthetics require symptomatic treatment there is no specific cure. The physician should be prepared to maintain an airway and to support ventilation with oxygen and assisted or controlled respiration as required. Supportive treatment of the cardiovascular system includes i.v. fluids and, when appropriate, vasopressors (preferably those that stimulate the myocardium).

Convulsions may be controlled with oxygen and i.v. administration, in small increments, of a barbiturate or muscle relaxant, as follows: preferably, an ultra short-acting barbiturate such as thiopental or thiamylal: if this is not available, a short-acting barbiturate (e.g. secobarbital or pentobarbital) or a short-acting muscle relaxant (succinylcholine). I.V. muscle relaxants and barbiturates should only be administered by those familiar with their use.

Dosage: The dose of any local anesthetic administered varies with the anesthetic procedure, the area to be anesthetized, the vascularity of the tissues, the number of neuronal segments to be blocked, the depth of anesthesia and degree of muscle relaxation required, the duration of anesthesia desired, individual tolerance and the physical condition of the patient. The recommended single adult dose for unsedated, healthy, normal-sized individuals should not usually exceed 400 mg. The following dosages have generally proved satisfactory and are therefore suggested as a guide. The smallest dose and concentration required to produce the desired result should be administered. The recommended dosage is based on requirements for the average adult and should be reduced for elderly or debilitated patients.

Nerve block (e.g. cervical, brachial, intercostal, pudendal): From 5 to 40 mL of a 1% solution, or 5 to 20 mL of a 2% solution, depending on the area and extent of block Pudendal block: one half of total dose injected each side.

Paracervical block: Maximum of up to 20 mL of a 1% solution (half-dose injected slowly each side, 5 minutes between sides) per 90-minute period.

Transvaginal block: Up to 30 mL of a 1% solution (half-dose injected each side).

Caudal and Epidural block: From 15 to 30 mL of a 1% solution, from 10 to 20 mL of a 2% solution containing no preservative.

Infiltration: Up to 40 mL of a 1% solution (or an equivalent amount in a more dilute solution, depending on the area of the operative field).

Therapeutic block (in management of pain): From 1 to 5 mL of a 1 or 2% solution.

Pediatric doses should be measured as a percentage of total adult dose based on body weight (not exceeding 5 to 6 mg/kg). In children under 3 years of age or weighing less than 14 kg, 1% solutions should be employed.

Mepivacaine solution may be diluted with an equal part of sodium chloride injection USP. Dosages in excess of the aforementioned amounts have been administered without serious side effects. Due caution should be exercised in the use of larger dosages and in general a total dosage of 7 mg/kg should not be exceeded. Under no circumstances should administration be repeated at intervals less than 1.5 hours. The total dose for 24 hours should not exceed 1000 mg.

Supplied: Infiltration and Nerve block: Each mL of solution contains: mepivacaine HCl 10 mg in water for injection. Nonmedicinal ingredients: sodium chloride and methylparaben. May also contain sodium hydroxide and/or hydrochloric acid (for pH adjustment). Gluten-, lactose- and sulfite-free; Multiple dose vials of 50 mL (1%), boxes of 5.

Caudal and Epidural block: Each ml of solution contains: mepivacaine HCI 10 mg in water for injection. Nonmedicinal ingredients: calcium chloride (dihydrate), potassium chloride and sodium chloride. May also contain sodium hydroxide and/or hydrochloric acid (for pH adjustment). Gluten-, lactose-, preservative- and sulfite-free. Single dose vials of 30 mL (1%), boxes of 5.

Caudal and Epidural block: Each ml of solution contains: mepivacaine HCI 20 mg in water for injection. Nonmedicinal ingredients: calcium chloride (dihydrate), potassium chloride and sodium chloride. May also contain sodium hydroxide and/or hydrochloric acid (for pH adjustment). Gluten-, lactose-, preservative- and sulfite-free. Single dose vials of 20 mL (2%), boxes of 5.