SEPTOCaine®...
Articaine hydrochloride 4% with Epinephrine 1:100,000 and 1:200,000 Injection

Predictable pain control for your patients.

Peace of mind for you.

Discover what Septocaine, the #1 branded injectable dental anesthetic in the U.S.*, can do for you and your patients.

* Based on total 4th Quarter 2009 U.S. sales data by Strategic Dental Marketing, Inc.

Septocaine® is indicated for local, infiltrative, or conductive anesthesia in both simple and complex dental procedures. Septocaine® with epinephrine 1:100,000 is preferred during operative or surgical procedures when improved visualization of the surgical field is desirable. Reactions to Septocaine® (pain and headache, for example, or convulsions or respiratory arrest following accidental intravascular injection) are characteristic of those associated with other amide-type local anesthetics. Septocaine® 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. Accidental intravascular injection may be associated with convulsions, followed by central nervous system or cardiorespiratory depression and coma, progressing ultimately to respiratory arrest. Dental practitioners and/or clinicians who employ local anesthetic agents should be well versed in diagnosis and management of emergencies that may arise from their use. Resuscitative equipment, oxygen, and other resuscitative drugs should be available for immediate use. Septocaine® along with other local anesthetics, is capable of producing methemoglobinemia. The clinical signs of methemoglobinemia are cyanosis of the nail beds and lips, fatigue and weakness. If methemoglobinemia does not respond to administration of oxygen, administration of methylene blue intravenously 1-2 mg/kg body weight over a 5 minute period is recommended. Please see Package Insert on the next following pages for prescribing information.

Some lead... others follow.
• Onset Time: 1 - 9 Minutes
• Epinephrine: 1:100,000 / 1:200,000
• Maximum Dose of Articaine: 3.2 mg/lb | 7 mg/kg
• Articaine per Cartridge: 68 mg
• Cartridge Fill Volume: 1.7 mL
• Package Size: 50 cartridges per box

INDICATIONS AND USAGE
Septocaine® is indicated for local, infiltrative, or conductive anesthesia in both simple and complex dental procedures.

Septocaine® with epinephrine 1:100,000 is preferred during operative or surgical procedures when improved visualization of the surgical field is desirable.

Use in pediatric patients under 4 years of age is not recommended.

Septocaine® is indicated for local, infiltrative, or conductive anesthesia in both simple and complex dental procedures. Septocaine® with epinephrine 1:100,000 is preferred during operative or surgical procedures when improved visualization of the surgical field is desirable. Reactions to Septocaine® (pain and headache, for example, or convulsions or respiratory arrest following accidental intravascular injection) are characteristic of those associated with other amide-type local anesthetics. Septocaine® 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. Accidental intravascular injection may be associated with convulsions, followed by central nervous system or cardiorespiratory depression and coma, progressing ultimately to respiratory arrest. Dental practitioners and/or clinicians who employ local anesthetic agents should be well versed in diagnosis and management of emergencies that may arise from their use. Resuscitative equipment, oxygen, and other resuscitative drugs should be available for immediate use. Septocaine® along with other local anesthetics is capable of producing methemoglobinemia. The clinical signs of methemoglobinemia are cyanosis of the nail beds and lips, fatigue and weakness. If methemoglobinemia does not respond to administration of oxygen, administration of methylene blue intravenously 1-2 mg/kg body weight over a 5 minute period is recommended.

Please see Package insert on the next page for prescribing information.

ORDERING INFORMATION
Septocaine® with epinephrine 1:200,000
Item No. 01-A1200

Septocaine® with epinephrine 1:100,000
Item No. 01-A1400
Articaine HCl is a member of the amino amide class of local anesthetics. Local anesthetics block the generation and conduction of nerve impulses, presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential. In general, the progression of anesthesia is related to the diameter, myelination and conduction velocity of the affected nerve fibers. Clinically, the order of loss of nerve function is as follows: (1) pain, (2) temperature, (3) touch, (4) proprioception, and (5) skeletal muscle tone. Epinephrine is administered with articaine HC1 with epinephrine results in a 3- to 5-fold increase in plasma epinephrine concentrations compared to baseline; however, in healthy adults it does not appear to be associated with marked increases in blood pressure or heart rate.

PHARMACOKINETICS
Absorption: Following dental injection by the submucosal route of an articaine solution containing 1:200,000 epinephrine, articaine reaches peak blood concentration about 25 minutes after a single dose injection and 48 minutes after three doses. Peak plasma levels of articaine achieved after 68 and 204 mg doses are 385 and 900 ng/mL, respectively. Following intravenous administration of a near maximum dose of 476 mg, articaine reaches peak blood concentrations of 2037 and 2145 ng/mL for articaine solution containing 1:100,000 and 1:200,000 epinephrine, respectively, approximately 22 minutes post-dose.

Distribution: Approximately 60 to 80% of articaine HC1 is bound to human serum albumin and g-globulins at 37°C in vitro.

Metabolism: Articaine HC1 is rapidly metabolized by plasma carboxylesterase to its primary metabolite, articainic acid, which is inactive. In vitro studies show that the human liver microsome P450 isozyme system metabolizes approximately 5% to 10% of available articaine with nearly quantitative conversion to articainic acid.

Excretion: At the dose of 476 mg of articaine, the elimination half-life was 43.8 minutes and 44.4 minutes for articaine solution containing 1:100,000 and 1:200,000 epinephrine, respectively. Articaine is excreted primarily through urine with 53 - 57% of the administered dose eliminated in the first 24 hours following submucosal administration. Articainic acid is the main metabolite in urine. A minor metabolite, articaine acid glucuronide, is also excreted in urine. Articaine constitutes only 2% of the total dose excreted in urine.

SPECIAL POPULATIONS
Effect of Age: No studies have been performed to evaluate the pharmacokinetics of Septocaine® injection in pediatric subjects.

Race: There is insufficient information to determine whether the pharmacokinetics of Septocaine® injection differs by race.

Renal and Hepatic Insufficiency: No studies have been performed with Septocaine® injection in patients with renal or hepatic dysfunction.

PHARMACODYNAMICS
Mechanism of Action: Articaine HC1 is a member of the amino amide class of local anesthetics. Local anesthetics block the generation and conduction of nerve impulses, presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential. In general, the progression of anesthesia is related to the diameter, myelination and conduction velocity of the affected nerve fibers. Clinically, the order of loss of nerve function is as follows: (1) pain, (2) temperature, (3) touch, (4) proprioception, and (5) skeletal muscle tone. Epinephrine is a vasoconstrictor added to articaine HC1 to slow absorption into the general circulation and thus prolong maintenance of an active tissue concentration.

The onset of anesthesia, following administration of Septocaine®, has been shown to be within 1 to 9 minutes of injection. Complete anesthesia lasts approximately 1 hour for infiltrations and up to approximately 2 hours for nerve block.

Administration of articaine HC1 with epinephrine results in a 3- to 5-fold increase in plasma epinephrine concentrations compared to baseline; however, in healthy adults it does not appear to be associated with marked increases in blood pressure or heart rate, except in the case of accidental intravascular injection (see WARNINGS).

CLINICAL TRIALS
Three randomized, double-blind, active-controlled studies were designed to evaluate effectiveness of Septocaine® with epinephrine 1:100,000 as a dental anesthetic. Patients ranging in age from 4 years to over 65 years old underwent simple dental procedures such as single uncomplicated extractions, routine operative procedures, single apical resections, and single crown procedures, and simple dental procedures such as multiple extractions, multiple crowns and/or bridge procedures, multiple apical resections, and extraoral surgical procedures. Septocaine® with epinephrine 1:100,000 was administered as submucosal infiltration and/or nerve block. Efficacy was measured immediately following the procedure by having the patient and investigator rate the patient’s procedural pain using a 10 cm visual analog scale (VAS), in which a score of zero represented no pain, and a score of 10 represented the worst pain imaginable. Mean patient and investigator VAS pain scores were 0.3 - 0.4 cm for simple procedures and 0.3 - 0.6 cm for complex procedures.

Four randomized, double blind, active-controlled studies were performed comparing Septocaine® with epinephrine 1:100,000 versus Septocaine® with epinephrine 1:200,000. The first two studies used electric pulp testers (EPT) to evaluate the success rate (maximum EPT value within 10 minutes), onset, and duration of Septocaine® with epinephrine 1:100,000 versus Septocaine® with epinephrine 1:200,000 as well as articaine solution without epinephrine in healthy adults between 18 and 65 years old. Results indicated that the anesthetic characteristics of the 1:100,000 and 1:200,000 formulations are not significantly different. A third study compared the difference in visualization of the surgical field after administration of Septocaine® with epinephrine 1:100,000 versus Septocaine® with epinephrine 1:200,000 during bilateral maxillary periodontal surgeries in patients ranging from 21 to 65 years old. Septocaine® with epinephrine 1:100,000 provided better visualization of the surgical field and less blood loss during the procedures. In a fourth study, when administration of the maximum dose of each formulation was used, no clinically relevant differences in blood pressure or heart rate were observed.

INDICATIONS AND USAGE
Septocane® is indicated for local, infiltrative, or conductive anesthesia in both simple and complex dental procedures. Septocaine® with epinephrine 1:100,000 is preferred during operative or surgical procedures when improved visualization of the surgical field is desirable.

CONTRAINDICATIONS
Septocaine® is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type, or in patients with known hypersensitivity to sodium metabisulfite.

WARNINGS
Accidental intravascular injection may be associated with convulsions, followed by central nervous system or cardiopulmonary depression and coma, progressing ultimately to respiratory arrest. Dental practitioners and/or clinicians who employ local anesthetic agents should be well versed in diagnosis and management of emergencies that may arise from their use. Resuscitation equipment, oxygen, and other re-structive drugs should be available for immediate use.

Intravenous injections should be avoided. To avoid intravenous injection, aspiration should be performed before Septocaine® 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 intravenous injection has been avoided.

Septocaine® contains epinephrine that can cause local tissue necrosis or systemic toxicity. Usual precautions for epinephrine administration should be observed.

Septocaine® 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
Septocaine®, along with other local anesthetics, is capable of producing methemoglobinemia. The clinical signs of methemoglobinemia are cyanosis of the nail beds and lips, fatigue and weakness. If methemoglobinemia does not respond to administration of oxygen, administration of methylene blue intravenously 1-2 mg/kg body weight over a 5 minute period is recommended.

The American Heart Association has made the following recommendation regarding the use of local anesthetics with vasoconstrictors in patients with ischemic heart disease. "Vasoconstrictor agents should be used in local anesthesia solutions during dental anesthesia for adults. If there is evidence that these procedures will be shortened or the analgesia rendered more profound. If a vasoconstrictor is indicated, extreme care should be taken to avoid intravascular injection. The minimum possible amount of vasoconstrictor should be used."

PHYSICAL PROPERTIES

Local anesthetic solutions, such as Septocaine®, containing a vasoconstrictor should be used cautiously. Patients with peripheral vascular disease and those with hypertensive vascular disease may exhibit exaggerated vasoconstrictor response. Ischemic injury or necrosis may result. Septocaine® 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.

Systemic absorption of local anesthetics can produce effects on the central nervous and cardiovascular systems. At blood concentrations achieved with therapeutic doses, changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance are minimal. However, toxic blood concentrations depress cardiac conduction and excitability, which may lead to atrioventricular block, ventricular arrhythmias, and cardiac arrest, possibly resulting in fatalities. In addition, myocardial contractility is depressed and peripheral vasodilation occurs, leading to decreased cardiac output and arterial blood pressure.

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

In vitro studies show that about 5% to 10% of articaine is metabolized by the human liver microsomal P450 isoenzyme system. However, because no studies have been performed in patients with liver dysfunction, caution should be used in patients with severe hepatic disease.

Septocaine® 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 A-V conduction produced by these drugs.

Small doses of local anesthetic injected in dental 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 central nervous system. Patients receiving these blocks should be observed constantly. Resuscitative equipment and personnel for treating adverse reactions should be immediately available.

DOSAGE AND ADMINISTRATION

Information for Patients:

- The patient should be informed in advance of the possibility of temporary loss of sensation and muscle function following infiltration and nerve block injections.
- Patients should be instructed not to eat or drink until normal sensation returns.

Clinically Significant Drug Interactions:

The administration of local anesthetic solutions containing epinephrine to patients receiving monoamine oxidase inhibitors, nonselective beta adrenergic antagonists or tri cyclic antidepressants may produce severe, prolonged hypertension. Phenothiazines and butyrophenones may reduce or reverse the pressor effect of epinephrine. Concurrent use of these agents should generally be avoided. In situations when concurrent therapy is necessary, careful patient monitoring is essential.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Studies to evaluate the carcinogenic potential of articaine HCI in animals have not been conducted. Five standard mutagenicity tests, including three in vitro tests (the nonmammalian Ames test, the mammalian Chinese hamster ovary chromosomal aberration test and a mammalian gene mutation test with articaine HCI) and two in vivo mouse micronucleus tests (one with Septocaine® with epinephrine 1:100,000 and one with articaine HCI alone) showed no mutagenic effects. No effects on male or female fertility were observed in rats for Septocaine® with epinephrine 1:100,000 administered subcutaneously in doses up to 80 mg/kg/day (approximately two times the maximum male and female recommended human dose on a mg/m² basis).

Pregnancy: Teratogenic Effects—Pregnancy Category C.

In developmental studies, no embryo-fetal toxicities were observed when Septocaine® with epinephrine 1:100,000 was administered subcutaneously throughout organogenesis at doses up to 40 mg/kg in rabbits and 80 mg/kg in rats (approximately 2 times the maximum recommended human dose on a mg/m² basis). In rabbits, 80 mg/kg (approximately 4 times the maximum recommended human dose on a mg/m² basis) did cause fetal death and increase fetal skeletal variations, but these effects were not evident at the severe maternal toxicity, including maternal deaths, observed at this dose.

When articaine hydrochloride was administered subcutaneously to rats throughout gestation and lactation, 80 mg/kg (approximately 2 times the maximum recommended human dose on a mg/m² basis) increased the number of stillbirths and adversely affected passive avoidance, a measure of learning, in pups. This dose also produced severe maternal toxicity in some animals. A dose of 40 mg/kg (approximately equal to the maximum recommended human dose on a mg/m² basis) did not produce these effects. A similar study using Septocaine® with epinephrine 1:100,000 rather than articaine hydrochloride alone produced maternal toxicity, but no effects on offspring.

There are no adequate and well-controlled studies in pregnant women. Animal reproduction studies are not always predictive of human response. Septocaine® should be used during pregnancy only if the potential benefits justify the potential risk to the fetus.

Nursing Mothers:

It is not known whether articaine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Septocaine® is administered to a nursing woman.

Pediatric Use: In clinical trials, 61 pediatric patients between the ages of 4 and 16 years received Septocaine® with epinephrine 1:100,000. Among these pediatric patients, doses from 0.76 mg/kg to 5.65 mg/kg (0.9 to 5.1 mL) were administered safely to 51 patients for simple procedures and doses between 0.37 mg/kg and 7.48 mg/kg (0.7 to 3.9 mL) were administered safely to 10 patients for complex procedures. However, there was insufficient exposure to Septocaine® with epinephrine 1:100,000 at doses greater than 7.00 mg/kg in order to assess its safety in pediatric patients. No unusual adverse reactions were noted in these patients. Approximately 13% of these pediatric patients required additional injections of anesthetic for supplementation. Safety and effectiveness in pediatric patients below the age of 4 years have not been established. Dosages in pediatric patients should be reduced, commensurate with age, body weight, and physical condition.

See DOSAGE AND ADMINISTRATION.

Geriatric Use: In clinical trials, 54 patients between the ages of 65 and 75 years, and 11 patients 75 years and over received Septocaine® with epinephrine 1:100,000. Among all patients between 65 and 75 years, doses from 0.43 mg/kg to 4.76 mg/kg (0.9 to 1.19 mL) were administered safely to 35 patients for simple procedures and doses from 1.05 mg/kg to 4.27 mg/kg (1.3 to 6.8 mL) were administered safely to 19 patients for complex procedures. Among the 11 patients 75 years of age or older doses from 0.78 mg/kg to 4.76 mg/kg (1.3 to 11.9 mL) were administered safely to 7 patients for simple procedures and doses of 1.12 mg/kg to 2.17 mg/kg (1.3 to 5.1 mL) were safely administered to 4 patients for complex procedures.

No overall differences in safety or effectiveness were observed between elderly subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Approximately 6% of patients between the ages of 65 and 75 years and none of the 11 patients 75 years of age or older required additional injections of anesthetic for complete anesthesia compared with 11% of patients between 17 and 65 years did who required additional injections.

ADVERSE REACTIONS

Reactions to Septocaine® are characteristic of those associated with other amide-type local anesthetics. Adverse reactions to this group of drugs may also result from excessive plasma levels (which may be due to overdosage, unintentional intravascular injection, or slow metabolic degradation), injection technique, volume of injection, hypersensitivity, or may be idiosyncratic.

The reported adverse events are derived from clinical trials in the US and UK. Table 1 displays the adverse events reported in clinical trials where 882 individuals were exposed to Septocaine® with epinephrine 1:100,000 and 179 individuals were exposed to Septocaine® with epinephrine 1:200,000.

<table>
<thead>
<tr>
<th>Event</th>
<th>Subjects with epinephrine 1:100,000 (%)</th>
<th>Number of patients exposed to drug</th>
<th>Number of patients that reported any adverse event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>47 (7.8%)</td>
<td>35</td>
<td>33</td>
</tr>
<tr>
<td>Headache</td>
<td>9 (1.3%)</td>
<td>9 (1.3%)</td>
<td>9 (1.3%)</td>
</tr>
<tr>
<td>Vision</td>
<td>6 (0.9%)</td>
<td>6 (0.9%)</td>
<td>6 (0.9%)</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>6 (0.9%)</td>
<td>6 (0.9%)</td>
<td>6 (0.9%)</td>
</tr>
<tr>
<td>Numbness and tingling</td>
<td>5 (0.7%)</td>
<td>5 (0.7%)</td>
<td>5 (0.7%)</td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>2 (0.3%)</td>
<td>2 (0.3%)</td>
<td>2 (0.3%)</td>
</tr>
<tr>
<td>Dysphasia</td>
<td>2 (0.3%)</td>
<td>2 (0.3%)</td>
<td>2 (0.3%)</td>
</tr>
<tr>
<td>Positive blood aspiration into syringe</td>
<td>2 (0.3%)</td>
<td>2 (0.3%)</td>
<td>2 (0.3%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event</th>
<th>Subjects with epinephrine 1:200,000 (%)</th>
<th>Number of patients exposed to drug</th>
<th>Number of patients that reported any adverse event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>14 (7.8%)</td>
<td>14 (7.8%)</td>
<td>14 (7.8%)</td>
</tr>
<tr>
<td>Headache</td>
<td>9 (1.3%)</td>
<td>9 (1.3%)</td>
<td>9 (1.3%)</td>
</tr>
<tr>
<td>Vision</td>
<td>6 (0.9%)</td>
<td>6 (0.9%)</td>
<td>6 (0.9%)</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>6 (0.9%)</td>
<td>6 (0.9%)</td>
<td>6 (0.9%)</td>
</tr>
<tr>
<td>Numbness and tingling</td>
<td>5 (0.7%)</td>
<td>5 (0.7%)</td>
<td>5 (0.7%)</td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>2 (0.3%)</td>
<td>2 (0.3%)</td>
<td>2 (0.3%)</td>
</tr>
<tr>
<td>Dysphasia</td>
<td>2 (0.3%)</td>
<td>2 (0.3%)</td>
<td>2 (0.3%)</td>
</tr>
<tr>
<td>Positive blood aspiration into syringe</td>
<td>2 (0.3%)</td>
<td>2 (0.3%)</td>
<td>2 (0.3%)</td>
</tr>
<tr>
<td>Common side effects</td>
<td>1 (0.5%)</td>
<td>1 (0.5%)</td>
<td>1 (0.5%)</td>
</tr>
</tbody>
</table>

Septocaine Sellsheet:Layout 1  9/20/10  3:57 PM  Page 4
The following list includes adverse and intercurrent events that were recorded in 1 or more patients, but occurred at an overall rate of less than one percent, and were considered clinically relevant.

- **Body as a Whole:** abdominal pain, accidental injury, asthenia, back pain, injection site pain, burning sensation above injection site, malaise, neck pain.
- **Cardiovascular System:** angina, dyspnea, syncope, tachycardia, elevated blood pressure.
- **Dietary System:** constipation, diarrea, dyspepsia, glossitis, gum hemorhage, mouth ulceration, nausea, stomatitis, tongue edema, tooth disorder, vomiting.
- **Hemic and Lymphatic System:** ecchymosis, lymphadenopathy.
- **Metabolism and Nutritional System:** edema, thirst.
- **Musculoskeletal System:** arthralgia, myalgia, osteomyelitis.
- **Nervous System:** dizziness, dry mouth, facial paralysis, hyperesthesia, increased salivation, nervousness, neuropathy, paresthesia, somnolence, exacerbation of Kearns-Sayre Syndrome.
- **Respiratory System:** pharyngitis, rhinitis, sinus pain, sinus congestion.
- **Skin and Appendages:** pruritus, skin disorder.
- **Special Senses:** ear pain, taste perversion.
- **Urogenital System:** dysmenorrhea.

Persistent paresthesias of the lips, tongue, and oral tissues have been reported with use of articaine hydrochloride, with slow, incomplete, or no recovery. These post-marketing events have been reported chiefly following nerve blocks in the mandible and have involved the trigeminal nerve and its branches.

**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 **WARNINGs, PRECAUTIONS; General** and **ADVERSE REACTIONS**).

**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 hypoventilation, consists of immediate attention to the maintenance of a patent airway and assisted or controlled ventilation as needed. The adequacy of the circulation should be assessed. Should convulsions persist despite adequate respiratory support, treatment with appropriate anticonvulsant therapy is indicated. The practitioner should be familiar with the use of anticonvulsant drugs. Supportive treatment of circulatory depression may require administration of intravenous fluids and, when appropriate, a vasopressor.

If not treated immediately, both convulsions and cardiovascular depression can result in hypoxia, acidosis, bradycardia, arrhythmias and cardiac arrest. If cardiac arrest should occur, standard cardiopulmonary resuscitative measures should be instituted.

**DOSEAGE AND ADMINISTRATION**

Table 3 (Recommended Dosages) summarizes the recommended volumes and concentrations of Septocaine® for various types of anesthetic procedures. The dosages suggested in this table are for normal healthy adults, administered by submucosal infiltration and/or nerve block.

For most routine dental procedures Septocaine® with epinephrine 1:200,000 is preferred. However, when more pronounced hemostasis is required, Septocaine® with epinephrine 1:100,000 may be used.

Table 3. Recommended Dosages

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Septocaine® Injection Volume (mL)</th>
<th>Total dose of articaine HCl (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infiltration</td>
<td>0.5 - 2.5</td>
<td>20 - 100</td>
</tr>
<tr>
<td>Nerve Block</td>
<td>0.5 - 3.4</td>
<td>20 - 136</td>
</tr>
<tr>
<td>Oral surgery</td>
<td>1.0 - 5.1</td>
<td>40 - 204</td>
</tr>
</tbody>
</table>

The above suggested volumes serve only as a guide. Other volumes may be used provided the total maximum recommended dose is not exceeded.

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

**MAXIMUM RECOMMENDED DOSAGES**

- **Adults:** For normal healthy adults, the maximum dose of articaine HCl administered by submucosal infiltration and/or nerve block should not exceed 7 mg/kg (0.175 mL/kg) or 3.2 mg/lb (0.0795 mL/lb) of body weight, e.g., 7 mL (1.19 mL) for a 150lb patient.
- **Pediatric Patients:** Use in pediatric patients under 4 years of age is not recommended. The quantity to be injected should be determined by the age and weight of the child and the magnitude of the operation. For children of less than 10 years 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. In any case, the maximum dose of 4% articaine HCl should not exceed the equivalent of 7 mg/kg (0.175 mL/kg) or 3.2 mg/lb (0.0795 mL/lb) of body weight.

**STERILIZATION, STORAGE, AND TECHNICAL PROCEDURES**

For chemical disinfection of the carpule, either isopropyl alcohol (91%) or ethyl alcohol (70%) is recommended. Many commercially available brands of isopropyl (rubbing) alcohol, as well as solutions of ethyl alcohol not of U.S.P. grade, contain denaturants that are injurious to rubber and therefore are not to be used.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

**HOW SUPPLIED**

Septocaine® (articaine HCl 4% with epinephrine 1:100,000 or 1:200,000 injection) is available in 1.7 mL glass cartridges, in boxes of 50 cartridges. The product is formulated with a 15% overage of epinephrine.

- NDC 0362-9049-02 Septocaine® with epinephrine 1:200,000 Box of 50 cartridges
- NDC 0362-9049-02 Septocaine® with epinephrine 1:100,000 Box of 50 cartridges

Store at controlled room temperature, below 25°C (77°F) with brief excursions permitted between 15° and 30°C (59°F-86°F) (see USP controlled room temperature). Protect from light. DO NOT PERMIT TO FREEZE.

Manufactured for SEPTODONT Louisville, CO 80027
by Novocaid Pharmaceutical of Canada Inc.
Cambridge, Ontario, Canada N1R 6X3
Rev. 05/06 (2552-1)
ACCESSORY PRODUCTS

SEPTODONT ASPIRATING SYRINGES

Septodont aspirating syringes are lightweight and durable. Available in three distinct sizes to fit your specific injection style.

**Septodont Standard (gold)** is equipped with a larger thumb ring and regular plunger length for improved comfort. **01N2110**

**Septodont Fusion (titanium)** is the perfect blend of our Standard and Petite syringe. The perfect “in between” size. **01N2105**

**Septodont Petite (blue and pink)** is designed for smaller handed dentists or hygienists. Its compact design provides a smaller thumb ring and shorter plunger length making it easier to control and more comfortable when aspirating. **Blue - 01N2100, Pink - 01N2120**

SEPTODONT ECO SYRINGES

Stainless steel aspirating syringes - winged and wingless. Lightweight, durable and contain no removable parts. **Wingless - 01N2200, Winged - 01N2210**

SEPTOJECT NEEDLES WITH BEVEL INDICATOR.

Plastic Hub ~ Easier Threading ~ No metal to metal contact.

**Sharpness you can see!**

The Septoject needles offer you a Bevel Indicator to help you orient the needle for different injections.

- **Magnified triple-beveled tip**
- **Pre-threaded Plastic Hub** offers you the same easy assembly. Septoject needles attach like metal hub needles with less risk of damage to syringes.

**Cannula is siliconized to ensure smooth insertion.**

**Description** | **Item #**
--- | ---
25 guage long - red | 01N1252
27 guage short - orange | 01N1271
27 guage long - yellow | 01N1272
30 guage extra short - purple | 01N1300
30 guage short - blue | 01N1301

For more information call Septodont at 800-872-8305. To order contact your local dental dealer.