DESCRIPTION:

Sensorcaine® (bupivacaine HCI) injections are sterile isotonic solutions that contain a local anesthetic agent with and without epinephrine (as bitartrate) 1:200,000, and are administered parenterally by injection. See INDICATIONS AND USAGE for specific uses. Solutions of bupivacaine HCl may be autoclaved if they do not contain epinephrine.

Sensorcaine injections contain bupivacaine HCl which is chemically designated as 2-piperidinecarboxamide, 1-hydroxy-N-(2,6-dimethylphenyl)-, monohydrochloride, monohydrate and has the following structural formula:

CH_3
\text{HN} \text{CH}_2\text{OH}
\text{CH}_3
\text{N} \text{CH}_2\text{OH}
\text{H}_2\text{O}

Epinephrine is (1:4,3-Dihydroxy-4-[methylamino]methyl)benzyl alcohol. It has the following structural formula:

\text{HO} \text{CH}_2\text{CH}_2\text{CH}_3
\text{NO}_2
\text{CH}_3
\text{OH}

The pKa of bupivacaine (8.1) is similar to that of lidocaine (7.86). However, bupivacaine possesses a greater degree of lipid solubility and is protein bound to a greater extent than lidocaine.

Bupivacaine is related chemically and pharmacologically to the aminoacyl local anesthetics. It is a homologue of mepivacaine and is chemically related to lidocaine. All three of these anesthetics contain an amide linkage between the aromatic nucleus and the amino or piperidine group. They differ in this respect from the procaine-type local anesthetics, which have an ester linkage.

Dosage forms listed as Sensorcaine-MPF indicates single dose solutions that are MethyLPARaben Free (MPF).

Sensorcaine-MPF is a sterile isotonic solution containing sodium chloride. Sensorcaine in multiple dose vials, each mL also contains 1 mg methylparaben as an antiseptic preservative. The pH of these solutions is adjusted to between 4.0 and 6.5 with sodium hydroxide and/or hydrochloric acid.

Sensorcaine-MPF with Epinephrine 1:200,000 (as bitartrate) is a sterile isotonic solution containing sodium chloride. Each mL contains bupivacaine hydrochloride and 0.005 mg epinephrine, with 0.5 mg sodium metabisulfite as an antioxidant and 0.2 mg citric acid (hydrated) as stabilizer. Sensorcaine with Epinephrine 1:200,000 (as bitartrate) in multiple dose vials, each mL also contains 1 mg methylparaben as an antiseptic preservative. The pH of these solutions is adjusted to between 3.3 to 5.5 with sodium hydroxide and/or hydrochloric acid. Filled under nitrogen.

Note: The user should have an appreciation and awareness of the formulations and their intended uses (see DOSAGE AND ADMINISTRATION).

CLINICAL PHARMACOLOGY:

Local anesthetics block the generation and the conduction of nerve impulses, presumably by increasing the threshold for action potentials 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 affected nerve fibers. Clinically, in order of loss of nerve function is as follows: (1) pain, (2) temperature, (3) touch, (4) proprioception, and (5) skeletal muscle tone.

Systemic absorption of local anesthetics produces effects on the cardiovascular and central nervous systems. At blood concentrations achieved with therapeutic doses, changes in cardiac conduct, excitability, refractoriness, contractility, and peripheral vascular resistance are minimal. However, toxic blood concentrations depress cardiac conduct and excitability, which may lead to atioventricular block, ventricular arrhythmias and cardiac arrest, sometimes resulting in fatalities. In addition, myocardial contractility is depressed and peripheral vasodilatation occurs, leading to decreased cardiac output and arterial blood pressure. Recent clinical reports and animal research suggest that these cardiovascular changes are more likely to occur after unintended intravascular injection of bupivacaine. Therefore, incremental dosing is necessary.

Following systemic absorption, local anesthetics can produce central nervous system depression, depression or depression of the respiration. Apparent central stimulation is usually manifested as restlessness, tremors and shivering progressing to convulsions, followed by depression and consequently progressing ultimately to respiratory arrest. However, the local anesthetics have a primary depressant effect on the medulla and on higher centers. The depressed stage may occur without a prior excited stage.

Pharmacokinetics:

The rate of systemic absorption of local anesthetics is dependent upon the total dose and concentration of drug administered, the route of administration, the vascularity of the administration site, and the presence or absence of epinephrine in the anesthetic solution. A dilute concentration of epinephrine (1:200,000) markedly reduces the rate of absorption and peak plasma concentration of bupivacaine, permitting the use of moderately larger total doses and sometimes the duration of action.

The onset of action with bupivacaine is rapid and anesthesia is long-lasting. The duration of anesthesia is significantly longer with bupivacaine than with any other commonly used local anesthetic. It has also been noted that there is a period of analgesia that persists after the return of sensation, during which time the need for potent analgesics is reduced.

Local anesthetics are bound to plasma proteins in varying degrees. Generally, the lower the plasma concentration of drug, the higher the percentage of drug bound to plasma proteins.

Local anesthetics appear in the placenta by passive diffusion. The rate and degree of diffusion is governed by: (1) the degree of protein binding, (2) the degree of ionization, and (3) the degree of lipid solubility. Fetal/maternal ratios of local anesthetics appear to be inversely related to the degree of plasma protein binding, because only the free, unbound drug is available for placental transfer. Bupivacaine, with a high protein binding capacity (96%), has a low fetal/maternal ratio (0.2 to 0.4). The extent of placental transfer is also dependent on the degree of ionization and lipid solubility of the drug.

Lipid soluble, nonionized drugs readily enter the fetal blood from the maternal circulation.

Depending upon the route of administration, local anesthetics are distributed to some extent to all body tissues, with high concentrations found in highly perfused organs and tissues. For example, local anesthetics are removed from the blood at a faster rate in the kidney and urinary tract than in the liver.

Pharmacokinetic studies on the plasma profile of bupivacaine after direct intravenous injection suggest a three-compartment model. The first compartment is represented by the rapid intravascular distribution of the drug. The second compartment represents the equilibrium of the drug throughout the highly perfused organs such as the brain, myocardium, lungs, kidneys, and liver. The third compartment represents an equilibrium of the drug with poorly perfused tissues, such as muscle and fat. The elimination of drug from tissues depends largely upon the ability of binding sites in the circulation to carry it to the liver where it is metabolized.

After injection of Sensorcaine (bupivacaine HCl) for caudal, epidural or peripheral nerve block in man, peak levels of bupivacaine in the blood are reached in 30 to 45 minutes, followed by a decline to insignificant levels during the first 3 to 6 hours.

Various pharmacokinetic parameters of the local anesthetics can be significantly altered by the presence of hepatic and/or renal diseases. The protein binding of bupivacaine, factors affecting urinary pH, renal blood flow, the route of drug administration, and the age of the patient. The half-life of bupivacaine in adults is 2.7 hours and in neonates 8.1 hours.

In clinical practice, elderly patients reached the maximal spread of analgesia and maximal motor blockade more rapidly than younger patients. Elderly patients also exhibited higher peak plasma concentrations following administration of this product. The total plasma clearance was decreased in these patients.

Amide-type local anesthetics such as bupivacaine are metabolized primarily in the liver via glucuronidation with glucuronic acid. Patients with hepatic disease, especially those with severe hepatic disease, may be more susceptible to the potential toxicities of the amide-type local anesthetics. Macrolactam derivatives of bupivacaine, the amine is the main excretory organ for most local anesthetics and their metabolites. Urinary excretion is affected by renal perfusion and factors affecting urinary pH. Only 6% of bupivacaine is excreted unchanged in the urine.

When administered in recommended doses and concentrations, Sensorcaine (bupivacaine HCI) does not ordinarily produce irritation or tissue damage and does not cause histologic damage.

INDICATIONS AND USAGE:

Sensorcaine (bupivacaine HCI) is indicated for the production of local or regional anesthesia or analgesia for surgery, oral surgery procedures, diagnostic and therapeutic procedures, and for obstetrical procedures. Only the 0.25% and 0.5% concentrations are indicated for obstetrical anesthesia (see WARNINGS). Experience with non-obstetrical surgical procedures in pregnant patients is not sufficient to recommend use of the 0.75% concentration of bupivacaine HCI in these patients. Sensorcaine is not recommended for intravenous regional anesthesia (Bier Block) (see WARNINGS).

The routes of administration and indicated Sensorcaine concentrations are:

- local infiltration: 0.25%, 0.5%
- peripheral nerve block 0.25%, 0.5%
- retrobulbar block 0.75%
- sympathetic block 0.25%
- lumbar epidural 0.25%, 0.5% and 0.75% (non-obstetrical)
- caudal
- epidural test dose (see PRECAUTIONS)
Locally anesthetic solutions containing a vasoconstrictor should be used cautiously in patients with restricted quantities in areas of the body supplied by end arteries or having otherwise compromised blood supply such as digit, toe, hand, or penis. Patients with hypertensive vascular disease may exhibit exaggerated vasoconstrictor response.

Because amide-type local anesthetics such as bupivacaine have high toxicity, benzocaine or other phenoxymethylcaine derivatives, especially in high concentrations, should be used with caution in patients with hepatic disease. Phenol, which is used to metabolize local anesthetics normally, is at a greater risk in chronic alcoholics or patients with liver cirrhosis. Local anesthetics should also be used with caution in patients with impaired cardiovascular function because they may be less capable of compensating for functional changes associated with the prolongation of A-V conduction periods.

Serious dose-related cardiac arrhythmias may occur if preparations containing a vasoconstrictor such as epinephrine are employed in large doses or if the administration of potent inhalation anesthetics, in conjunction with these products, is not interrupted if cardiac arrhythmias occur. The addition of epinephrine to the local anesthetic premixed solution may produce a synergistic effect that can result in a serious cardiac reaction. Therefore, epinephrine should not be added to a premixed solution.

LOCAL ANESTHETICS SHOULD ONLY BE EMPLOYED IN CLINICAL SETTINGS WHERE CAREFULLY VERIFIED IN DIAGNOSIS AND MANAGEMENT OF DOSE-RELATED TOXICITY AND OTHER ADVERSE REACTIONS IS POSSIBLE. IF THE BLOCK FROM THE BLOCK TO BE EMPLOYED, AND THERE IS NO ASSURANCE OF THE AVAILABILITY OF OXYGEN, OTHER RESUSCITATIVE DRUGS, CARDIOPULMONARY RESUSCITATION EQUIPMENT, AND PERSONNEL, RESOURCES NEEDED FOR PROPER MANAGEMENT OF MEDICAL EMERGENCIES (see also ADVERSE REACTIONS, PRECAUTIONS, AND OVERDOSE). DETAILED MANAGEMENT OF DOSE-RELATED TOXICITY, UNDERSYSTEMATIC CONTROL, AND THE PREDISPOSING FACETORS OF THE URINARY SENSITIVITY MAY LEAD TO THE DEVELOPMENT OF ACIDOSIS, CARDIAC ARREST AND, POSSIBLY, DEATH.

Local anesthetic solutions containing antimicrobial preservatives, ie, those supplied in multiple dose vials, should not be used for epidual or caudal anesthetic procedures or for intrathecal injection. The majority of reports of adverse reactions with regard to intrathecal injection, either intentional or unintentional, have been associated with the use of preservatives in the injectate. Intra-articular infusions of local anesthetics following arthroscopic and other surgical procedures is a well-recognized practice, and there have been post-marketing reports of chondrolysis in patients receiving these infusions. 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 may be associated with higher risk. However, local anesthetics should be used with caution in patients with chondrolysis due to glucocorticoid therapy and therapeutic procedures and some conditions, including obesity, pregnancy, and systemic disease. Local anesthetics may be used in patients who are undergoing gynecologic procedures, but they should be administered with caution in patients with a history of chondrolysis.

Injection of pure local anesthetic into the central nervous system (subarachnoid or intravenous) injection) should be avoided. Injection of local anesthetics into the intraventricular system should be performed only in patients with established brain stem integrity and a low risk of developing brain stem injury. Intra-articular and sympathetic ganglion injections are associated with rare reports of chondrolysis. These procedures should be avoided in patients with a history of chondrolysis.

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receiving monoamine oxidase inhibitors or tricyclic antidepressants may produce severe, prolonged hypotension. The potential use of these agents should generally be avoided. In situations in which concomitant use is necessary, careful patient monitoring is essential.

Concurrent administration of vasopressor drugs and local anesthetic drugs may cause severe, persistent hypertension or cerebral vascular accidents.

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

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Long-term studies in animals of most local anesthetics, including bupivacaine, to evaluate the carcinogenic potential of the drug have not been conducted. The mutagenic potential of the drug has not been determined. In an in vivo study to evaluate the teratogenic potential of bupivacaine (bupivacaine HCl) in rats, the drug did not cause cleft palate, cataract, or congenital anomalies. No relevant clinical data exist that bupivacaine (bupivacaine HCl) may be carcinogenic or mutagenic in humans.

Pregnancy Category C

Decreased pup survival in rats and embryofetal effects have also been observed with bupivacaine. It is not known if bupivacaine HCl is excreted in human breast milk. Because elderly patients are more likely to have decreased renal function, the dose of bupivacaine HCl should be carefully considered when dose in a patient, and it may be essential to monitor renal function (see CLINICAL PHARMACOLOGY).

ADVERSE REACTIONS:

Reactions to Sensorcaine (bupivacaine HCl) are characteristic of those associated with amide-type local anesthetics. The intensity of adverse reactions to this group of drugs is excessive plasma levels, which may be due to overdosage, unintentional intravascular injection or slow metabolic degradation.

Systemic

The most commonly encountered adverse reactions are changes in blood pressure and heart rate also should be monitored continuously, help prevent decreases in blood pressure. The fetal patient's legs and positioning her on her left side will pressure by the gravid uterus during administration.

In clinical studies, differences in various pharmacokinetic parameters have been observed between elderly and younger patients (see CLINICAL PHARMACOLOGY).

This product is known to be substantially excreted by the kidney, and the risk of toxic reactions by this drug may be increased in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, the dose of bupivacaine HCl should be carefully considered when dose in a patient, and it may be essential to monitor renal function (see CLINICAL PHARMACOLOGY).

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For specific techniques and procedures, refer to standard textbooks.

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

In recommended doses, Sensorcaine (bupivaca- cine HCl) produces complete sensory block, but the effect on motor function differs among the three concentrations.

- 0.25%—when used for caudal, epidural, or periph-
eral nerve block, produces incomplete motor block. Should be used for operations in which muscle relax-
ation is not important, or when another means of providing muscle relaxation is used concurrently. Opiate of action may be slower than with the 0.5% or 0.75% solutions.

- 0.5%—provides motor blockade for caudal, epi-
dural, or nerve block, but muscle relaxation may be inadequate for operations in which complete muscle relaxation is essential.

- 0.75%—produces complete motor block. Most useful for epidural block in abdominal operations requiring complete muscle relaxation, and for retro-
bulbar anesthesia. Not for obstetrical anesthesia.

The duration of anesthesia with Sensorcaine is such that for most indications, a single dose is sufficient.

Maximum dosage limit must be individualized in each case after evaluating the size and physical status of the patient, as well as the usual rate of sys-
temic absorption from a particular injection site. Most experience to date is with single doses of Sensor-
caine up to 225 mg with epinephrine 1:200,000 and 175 mg without epinephrine; more or less drug may be required depending on individualization of each case.

These doses may be repeated up to once every three hours. In clinical studies to date, total daily doses up to 400 mg have been reported. Until fur-
ther experience is gained, this dose should not be exceeded in 24 hours. The duration of anesthetic effect may be prolonged by the addition of epinephrine.

The dosages in Table 1 have generally proved satisfactory and are recommended as a guide for use in the average adult. These dosages should not be reduced for elderly or debilitated patients. Until further experience is gained Sensorcaine is not rec-
ommended for pediatric patients younger than 12 years. Sensorcaine is contraindicated for obstetrical para-
cervical blocks, and is not recommended for intravenous regional anesthesia (Bier Block).

**Use in Epidural Anesthesia**

During epidural administration of Sensorcaine, 0.25% solution should be administered in incremental doses of 3 mL to 5 mL with sufficient time between doses to detect toxic manifestations of unintentional intravascular or intrathecal injection. In obstetrics, only the 0.5% and 0.25% concentra-
tions should be used; incremental doses of 3 mL to 5 mL of the 0.5% solution not exceeding 50 mg to 100 mg at any dosing interval are recommended. Repeat doses should be preceded by a test dose containing epinephrine if not contraindicated. Use only the single dose ampules and single dose vials for caudal or epidural anesthesia; the multiple dose vials contain a preservative and therefore should not be used for these procedures.

**Test Dose for Caudal and Lumbar Epidural Blocks**

See PRECAUTIONS. Unused portions of solutions in single dose containers should be discarded, since this product form contains no preservatives.

**TABLE 1. DOSAGE RECOMMENDATIONS — SENSORCAINE (bupivacaine HCl) INJECTIONS**

<table>
<thead>
<tr>
<th>Type of Block</th>
<th>Cons. (mg)</th>
<th>Motor Block</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Infiltration</td>
<td>0.25%</td>
<td>up to max. up to max. —</td>
</tr>
<tr>
<td>Epidural</td>
<td>0.25%</td>
<td>10 to 20 75 to 150 complete</td>
</tr>
<tr>
<td></td>
<td>0.5%</td>
<td>10 to 20 50 to 100 moderate to complete</td>
</tr>
<tr>
<td></td>
<td>0.75%</td>
<td>10 to 20 25 to 50 moderate to complete</td>
</tr>
<tr>
<td>Caudal</td>
<td>0.5%</td>
<td>15 to 30 75 to 150 moderate to complete</td>
</tr>
<tr>
<td></td>
<td>0.5%</td>
<td>30 to 50 150 to 250 moderate to complete</td>
</tr>
<tr>
<td></td>
<td>0.75%</td>
<td>15 to 30 25 to 50 moderate to complete</td>
</tr>
<tr>
<td></td>
<td>0.75%</td>
<td>30 to 50 75 to 150 moderate to complete</td>
</tr>
<tr>
<td>Perineal Nerves</td>
<td>0.5%</td>
<td>5 to 10 25 to 50 moderate to complete</td>
</tr>
<tr>
<td>Retropubic</td>
<td>0.5%</td>
<td>5 to 10 25 to 50 moderate to complete</td>
</tr>
<tr>
<td></td>
<td>2 to 3</td>
<td>10 to 15 complete</td>
</tr>
<tr>
<td>Sympathetic</td>
<td>0.2%</td>
<td>20 to 50 150 to 250 complete</td>
</tr>
<tr>
<td></td>
<td>0.2%</td>
<td>20 to 50 250 to 500 complete</td>
</tr>
<tr>
<td>Epidural*</td>
<td>0.5%</td>
<td>2 to 3 10 to 15 complete</td>
</tr>
</tbody>
</table>

*With continuous (intermittent) techniques, repeat doses increase the degree of motor block. The first repeat dose of 0.5% may produce complete motor block. Intercostal nerve block with 0.25% may also produce complete motor block for intra-
abdominal surgery.

NOTE: Parenteral drug products should be inspected visually for particulate matter and discoul-
oration 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 SUPPLyED:**

**SOLUTIONS OF SENSORCAINE (BUPIVACAINE HYDROCHLORIDE) SHOULD NOT BE USED FOR THE PRODUCTION OF SPINAL ANESTHESIA (SUBARACHNOID BLOCK) BECAUSE OF INSUF-
ICIENT DATA TO SUPPORT SUCH USE.**

Sensorcaine-MPF (methylparaben free) is available in the following forms:

**With Epinephrine:**

<table>
<thead>
<tr>
<th>Product No.</th>
<th>NDC No.</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>460837</td>
<td>63323-468-37</td>
<td>0.25%</td>
</tr>
<tr>
<td>460817</td>
<td>63323-468-17</td>
<td>0.25%</td>
</tr>
<tr>
<td>460217</td>
<td>63323-462-17</td>
<td>0.5%</td>
</tr>
<tr>
<td>460237</td>
<td>63323-462-37</td>
<td>0.5%</td>
</tr>
<tr>
<td>460231</td>
<td>63323-462-31</td>
<td>0.5%</td>
</tr>
<tr>
<td>461037</td>
<td>63323-460-37</td>
<td>0.75%</td>
</tr>
</tbody>
</table>

**Without Epinephrine:**

<table>
<thead>
<tr>
<th>Product No.</th>
<th>NDC No.</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>460417</td>
<td>63323-464-17</td>
<td>0.25%</td>
</tr>
<tr>
<td>460437</td>
<td>63323-464-33</td>
<td>0.25%</td>
</tr>
<tr>
<td>460437</td>
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<td>0.25%</td>
</tr>
<tr>
<td>460431</td>
<td>63323-464-31</td>
<td>0.25%</td>
</tr>
<tr>
<td>460617</td>
<td>63323-466-17</td>
<td>0.5%</td>
</tr>
<tr>
<td>460637</td>
<td>63323-468-37</td>
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</tr>
<tr>
<td>460631</td>
<td>63323-468-31</td>
<td>0.5%</td>
</tr>
<tr>
<td>460637</td>
<td>63323-466-33</td>
<td>0.5%</td>
</tr>
<tr>
<td>470217</td>
<td>63323-472-17</td>
<td>0.75%</td>
</tr>
<tr>
<td>470237</td>
<td>63323-472-37</td>
<td>0.75%</td>
</tr>
<tr>
<td>470237</td>
<td>63323-472-33</td>
<td>0.75%</td>
</tr>
</tbody>
</table>

Sensorcaine (preserved with methylparaben) is available in the following forms:

**With Epinephrine:**

<table>
<thead>
<tr>
<th>Product No.</th>
<th>NDC No.</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>460157</td>
<td>63323-461-57</td>
<td>0.25%</td>
</tr>
<tr>
<td>460357</td>
<td>63323-463-57</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

**Without Epinephrine:**

<table>
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<tr>
<th>Product No.</th>
<th>NDC No.</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>460557</td>
<td>63323-465-57</td>
<td>0.25%</td>
</tr>
<tr>
<td>460757</td>
<td>63323-467-57</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

*Products manufactured for APP Pharmaceuticals, LLC.

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 since they have been related to incidents of swelling and edema.

When chemical disinfection of the container surface is desired, either isopropyl alcohol (91%) or ethyl alcohol (70%) is recommended. It is recommended that chemical disinfection be accomplished by wiping the ampule or vial stopper thoroughly with cotton or gauze that has been moistened with the recom-
manded alcohol just prior to use.

Solutions containing epinephrine should be pro-
tected from light.

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