

**BUCAINE®****BUCAINE® With Adrenaline**

(Bupivacaine HCl)

ACTION

Bucaine is a local anesthetic of the amide-type available in sterile isotonic solution with and without adrenaline (as tartrate).

Local anesthetics block the generation and the 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.

Bucaine 0.25% and 0.5% solutions are used for the production of local anesthesia by percutaneous infiltration, peripheral nerve block (s) and central neural block (caudal or epidural), that is, for specialist use in situations where prolonged anesthesia is required. Because sensory nerve block is more marked than motor block, Bucaine is especially useful in the relief of pain, e.g. during labour. At blood concentrations achieved with normal therapeutic doses, changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance are minimal.

The onset of action with Bucaine is rapid and anesthesia is long lasting (3-10 hours; via nerveblock, even longer). The duration of anesthesia is significantly longer with Bucaine than with any other commonly used local anesthetic. The onset of action following dental injections is usually 2 to 10 minutes and anesthesia may last two or three times longer with Bucaine than lidocaine and mepivacaine; for dental use, in many patients up to 7 hours. The duration of anesthetic effect is prolonged by the addition of adrenaline 1:200,000.

INDICATIONS

Bucaine is indicated for the production of local or regional anesthesia or analgesia for surgical, dental and oral surgery procedures, diagnostic and therapeutic procedures and for obstetrical procedures. Bucaine is not recommended for intravenous regional anesthesia.

DOSEAGE AND ADMINISTRATION

The utmost care should be taken to prevent an accidental intravascular injection always including careful aspiration. For epidural anesthesia, a test dose of 3-5 ml of Bucaine containing adrenaline should be administered, since an intravascular injection of adrenaline will be quickly recognised by an increase in heart rate. Aspiration should be repeated prior to administration of the total dose. The main dose should be injected slowly, 25-50 mg/min, in incremental doses under constant contact with the patient. If mild toxic symptoms occur, the injection should be stopped immediately.

The dosage varies and depends upon the area to be anesthetised, the vascularity of the tissue, the number of neuronal segments to be blocked, individual tolerance and the technique of anesthesia used. The lowest dosage needed to provide effective anesthesia should be administered. For most indications, the duration of anesthesia with Bucaine solutions is such that a single dose is sufficient.

The maximum dosage: Experience to date indicates single dose up to 150 mg Bupivacaine HCl. Doses of up to 50 mg 2-hourly may subsequently be used. Dosages of Bucaine should be reduced for elderly and debilitated patients with cardiac and/or liver diseases. Dosage in children under 12 years has not been established.

Recommended Concentration and Doses of Bucaine

Type of Block	Conc.	(ml)	Dose (mg)	Motor Block
Local infiltration	0.25%	upto 60 ml	upto 150 mg	-
Epidural	0.5%	10-20	50-100	moderate to complete
	0.25%	10-20	25-50	partial to moderate
Caudal	0.25%	15-30	37.5-75	partial
	0.5%	15-30	75-150	moderate
Peripheral nerves	0.5%	upto 30	upto 150	moderate to complete
	0.25%	upto 60	upto 150	moderate to complete
Sympathetic	0.25%	20-50	50-125	
Dental	0.5%	1.8-3.6	9-18	
	w/aden.	per site	per site	
Epidural test dose	0.5%	2-3	10-15	
	w/aden.			

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.

CONTRAINDICATIONS

Bupivacaine is contraindicated in obstetrical paracervical block anesthesia. And in patients with a known hypersensitivity to it or to any local anesthetic agent of the amide-type.

WARNINGS

Pregnancy and lactation: Safety for use in pregnant women other than labour, has not been established. Local anesthetics rapidly cross placenta. Safety for use in nursing mother has not been established. Careful adherence to recommended dosage is extremely important.

Maternal hypotension has resulted from regional anesthesia. Local anesthetics may alter the forces of parturition. (Bupivacaine is FDA pregnancy category B)

PRECAUTIONS

Use local anesthetic with caution when there is inflammation or sepsis in the region of proposed injection. Monitor cardiovascular and respiratory vital signs and early signs of CNS toxicity. Use with caution in elderly, debilitated patients, children and obstetric patients. For epidural and caudal anesthesia use with extreme caution in pediatric patients and in persons with existing neurological diseases, septicemia and severe hypertension.

Use solutions containing adrenaline with extreme caution in patients whose medical history and physical evaluation suggest the existence of hypertension, diabetes, cerebral vascular insufficiency, heart block, arrhythmias, heart disease and peripheral vascular diseases.

Since amide-type anesthetics are metabolized primarily in the liver, use cautiously in patients with severe hepatic diseases.

SIDE EFFECTS

May result from excessive plasma levels, which may be due to overdosage, unintentional intravascular injection, or slow metabolic degradation. Side effects of Bupivacaine HCl are characteristic of amide-type local anesthetics. Most commonly related to CNS and cardiovascular systems, these are generally dose-related.

CNS: Restlessness, anxiety, tremor, blurred vision, nausea, vomiting, crills, pupil constriction and tremors may occur, possibly proceeding to convulsions.

Respiratory: Impairment or paralysis (spinal) and allergic type reactions may occur.

Cardiovascular: Myocardial depression, peripheral vasoconstriction, hypotension (secondary to spinal block), hypertension, ventricular myocardial arrhythmia, heartblock and cardiac arrest.

OVERDOSAGE

In case of overdosage with local anesthetic the following should be considered: Securing and maintaining a patent airway and assist or control ventilation.

For circulatory depression, administer a vasopressor and I.V. fluids. For convulsions, administer a benzodiazepine.

PRESENTATION

Vials

BUCAINE 0.25%

Bupivacaine HCl 2.5 mg/ ml

BUCAINE 0.5%

Bupivacaine HCl 5 mg/ ml

Ampoules

BUCAINE 0.25% with adrenaline

Bupivacaine HCl BP 2.5 mg/ ml

+ Adrenaline BP 1:200,000 (5 µg/ ml)

BUCAINE 0.5% with adrenaline

Bupivacaine HCl , BP 5 mg/ ml

+ Adrenaline BP 1:200,000 (5 µg/ ml)

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

