

Bupivacaine Hydrochloride in Dextrose Injection USP

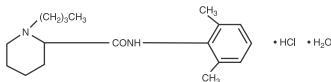
For Spinal Anaesthesia

Composition:

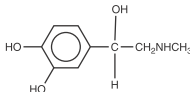
Each mL contains:
Bupivacaine Hydrochloride USP
equiv. to anhydrous
Bupivacaine Hydrochloride 5 mg
Dextrose USP (monohydrate) 80 mg
Water for Injection USP q.s.

Description:

Bupivacaine hydrochloride is 1-butyl-N-(2,6-dimethylphenyl)-2-piperidinecarboxamide monohydrochloride monohydrate, a white crystalline powder that is freely soluble in 95 percent ethanol, soluble in water, and slightly soluble in chloroform or acetone. It has the following structural formula:



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



Bupivacaine hydrochloride is available in sterile isotonic solutions with and without epinephrine (as bitartrate) 1:200,000 for injection via local infiltration, peripheral nerve block, and caudal and lumbar epidural blocks. Bupivacaine Hydrochloride solutions may be autoclaved if they do not contain epinephrine. The solutions are clear and colorless. Bupivacaine is chemically and pharmacologically related to the aminoacyl local anesthetics. It is a homolog 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. In this respect, they differ from procaine-type local anesthetics, which possess an ester linkage. Bupivacaine hydrochloride injection, USP is available in sterile isotonic solutions containing bupivacaine hydrochloride in water for injection.

characteristics as follows:

Bupivacaine Hydrochloride Injection, USP (without epinephrine)		
Concentration	Bupivacaine Hydrochloride mg/mL	Sodium Chloride mg/mL
0.25%	2.5	8.6
0.5%	5	8.1
0.75%	7.5	7.6

Indications and Use:

Bupivacaine Hydrochloride is indicated for the production of local or regional anesthesia or analgesia for surgery, dental and oral surgical procedures, diagnostic and therapeutic procedures, and obstetric procedures. Only the 0.25% and 0.5% concentrations are indicated for obstetric anesthesia.

Dosage and Administration:

(For additional information) Standard textbooks should be consulted to determine accepted procedures and techniques for the administration of Bupivacaine Hydrochloride.

Contraindications:

Bupivacaine Hydrochloride is contraindicated for paracervical block in obstetric anesthesia. Its use in this technique has resulted in fetal bradycardia and death. Bupivacaine Hydrochloride is contraindicated in patients with known hypersensitivity to it, to any amide-type local anesthetic agent, or to other components of Bupivacaine Hydrochloride solutions.

Precautions: General:

The safety and efficacy of local anesthetics depend on proper dosage, correct technique, adequate precautions, and readiness for emergencies. Resuscitation equipment, oxygen, and other resuscitative drugs must be available for immediate use.

Storage:

Store below 25°C. Protect from light.

Keep medicines out of the reach of children.

Caution:

Discard the injection if visible particles appear.

Presentation: 10 x 4 mL ampoules.

Manufactured in India:

