Only for the use of Medical Professionals

# Pivacain D®

Bupivacaine Hydrochloride & Dextrose

**Description**

Pivacain-D® is a preparation of Bupivacaine Hydrochloride and Dextrose. Bupivacaine is a long acting anaesthetic agent of the amide type. Pivacain-D® has a rapid onset of action and long duration. The duration of analgesia in the T10-T12 segments is 2-3 hours. Bupivacaine Hydrochloride produces a moderate muscular relaxation of the lower extremities lasting 2-2.5 hours. The motor blockade of the abdominal muscles makes the solution suitable for performance of abdominal surgery lasting 45-60 minutes.

**Indications**

Pivacain-D® is indicated in spinal anaesthesia for

- Urological surgery (lasting 2-3 hours)
- Lower limb surgery (lasting 2-3 hours)
- Abdominal surgery (lasting 45-60 minutes)

**Dosage and administration**

**Use in Adult:** Intrathecal anaesthesia (recommended site of injection is below L3) for surgery: 2-4ml (10-20mg Bupivacaine Hydrochloride). The dose should be reduced in the elderly and in patients in the late stages of pregnancy.

Note: The effects of injections of Pivacain-D® exceeding 4ml have not yet been studied and such volumes can therefore not be recommended. The spread of anaesthesia obtained with Pivacain-D® depends on several factors including the volume of solution and the position of the patient during and following the injection. When injected at the L3-L4 intervertebral space, with the patient in the sitting position, 3ml of Pivacain-D® spreads to the T7-T10 spinal segments. With the patient receiving the injection in the horizontal position and then turned supine, the blockade spreads to T4-T7 spinal segments. It should be understood that the level of spinal anaesthesia achieved with any local anaesthetic can be unpredictable in a given patient.

**Use in elderly and renal impairment:** Patients in poor general condition due to ageing or other compromising factors such as partial or complete heart conduction block, advanced liver or renal dysfunction require special attention, although regional anesthesia may be the optimal choice for surgery in these patients.

**Use in children:** Bupivacaine Hydrochloride is not recommended in patients younger than 18 years of age.

**Use in pregnancy and lactation**

There is no evidence of untoward effects in human pregnancy. In large doses there is evidence of decreased pup survival in rats and an embryological effect in rabbits if Bupivacaine is administered in pregnancy. Bupivacaine should not therefore be given in early pregnancy unless the benefits are considered to outweigh the risks. It should be noted that the dose should be reduced in patients in the late stages of pregnancy. Bupivacaine enters the mother's milk, but in such small quantities that there is generally no risk of affecting the child at therapeutic dose levels.

**Side-effects**
The adverse reaction profile for Bupivacaine is similar to those for other long acting local anaesthetics used for intrathecal anaesthesia. Serious systemic adverse reactions are rare, the adverse reactions are dizziness, paraesthesia, or drowsiness (particularly if injection too rapid); other CNS effects include confusion, respiratory depression and convulsions; hypotension and bradycardia (may lead to cardiac arrest). Ventricular arrhythmia, ventricular fibrillation, sudden cardiovascular collapse has been reported in connection with high systemic concentrations of Bupivacaine rarely hypersensitivity reactions including anaphylaxis. Severe hypotension may result from hypovolaemia due to haemorrhage or dehydration, or aorto-caval occlusion in patients with massive ascites, large abdominal tumours or late pregnancy.

**Contraindications**
Bupivacaine is contra-indicated in patients with hypersensitivity to local anaesthetic agents of the amide type or to any of the excipients. Intrathecal anaesthesia, regardless of the local anaesthetic used, has its own contra-indications which include: Active disease of the central nervous system such as meningitis, poliomyelitis, intracranial haemorrhage, sub-acute combined degeneration of the cord due to pernicious anaemia and cerebral and spinal tumours. Spinal stenosis and active disease (e.g. spondylitis, tuberculosis, tumour) or recent trauma (e.g. fracture) in the vertebral column. It is also contraindicated in septicaemia, pyogenic infection of the skin at or adjacent to the site of lumbar puncture, cardiogenic or hypovolaemic shock and coagulation disorders or ongoing anticoagulation treatment.

**Precautions**
Bupivacaine should be given cautiously to the elderly, the debilitated patients and to children, to patients with epilepsy, respiratory impairment, impaired cardiac conduction, bradycardia, severe shock; porphyria; myasthenia gravis. Myocardial depression may be more severe and more resistant to treatment.

**Drug Interactions**
Bupivacaine should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type local anaesthetics, e.g. certain anti-arrhythmics, such as lidocane. It is also used with caution in patients who receiving beta blocker (propranolol).

**Overdosage**
Bupivacaine Hdrochloride, used as recommended, is not likely to cause blood levels high enough to cause systemic toxicity. However, if other local anaesthetics are concomitantly administered, toxic effects are additive and may cause systemic toxic reactions. Systemic toxicity is rarely associated with spinal anaesthesia but might occur after accidental intravascular injection. Systemic adverse reactions are characterized by numbness of the tongue, light-headedness, dizziness and tremors, followed by convulsions and cardiovascular disorders.

**Treatment of systemic toxicity:** No treatment is required for milder symptoms of systemic toxicity but if convulsions occur then it is important to ensure adequate oxygenation and to arrest the convulsions if they last more than 15-30 seconds. Oxygen should be given by face mask and the respiration assisted or controlled if necessary. Convulsions can be arrested by injection of thiopentone 100-150mg intravenously or with diazepam 5-10mg intravenously. Alternatively, succinylcholine

50-100mg intravenously may be given but only if the clinician has the ability to perform endotracheal intubation and to manage a totally paralyzed patient.

**Pharmaceutical precautions**
Store in a cool and dry place. Protect from light.

**Presentation**
Pivacain-D®Injection: Sterile, clear, colorless solution. Each ml contains Bupivacaine Hydrochloride BP 5 mg and Dextrose USP 80 mg.

**Package quantities**
Pivacain-D® Injection: Carton of 4 ml x 10's ampoules.

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