**Bupivacaine & Adrenaline Injection B.P. 0.25% w/v 1 in 200,000**

Last Updated on eMC 25-Apr-2014 [View changes](https://www.medicines.org.uk/emc/history/22179)  | Amdipharm Mercury Company Limited [Contact details](https://www.medicines.org.uk/emc/medicine/22179#companyDetails)

1. Name of the medicinal product

Bupivacaine and Adrenaline (Epinephrine) Injection 0.25% w/v, 1 in 200,000

2. Qualitative and quantitative composition

Each 10ml of solution contains Bupivacaine Hydrochloride B.P. 26.375mg equivalent to anhydrous Bupivacaine Hydrochloride 25mg, Adrenaline Acid Tartrate B.P. 0.091mg equivalent to Adrenaline 0.05mg

3. Pharmaceutical form

Solution for injection. Colourless or almost colourless, aqueous, solution.

4. Clinical particulars

4.1 Therapeutic indications

Bupivacaine 0.25% and 0.5% solutions are used for the production of local anaesthesia by percutaneous infiltration, peripheral nerve block(s) and central neural block (caudal or epidural), that is, for specialist use in areas where prolonged anaesthesia is indicated. Bupivacaine is particularly useful for pain relief e.g. during labour, as its sensory nerve block is more marked than its motor block. A list of indications and suggested dose and strength of solution appropriate for each are shown in the table under 4.2 below.

• Surgical anaesthesia in adults and children above 12 years of age.

• Acute pain management in adults, infants and children above 1 year of age

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| --- |
| *Note:*  *From the reviewed literature only evidence for the use of bupivacaine 1.25 - 2.5 mg/ml + 2.5 - 5μg/ml adrenaline for caudal epidural block in children > 1 year of age could be derived.*  *Regarding other anaesthetic techniques, the investigated paediatric population were mostly very small and a variety of different applications were studied, so that no reliable recommendations can be derived from the literature.*  ***As for other local anaesthetics, recommendations for the adolescent population above 12 years remain included in the information for adults.*** |

4.2 Posology and method of administration

Great care must be taken in order to prevent an accidental intravascular injection, always including careful aspirations. For epidural anaesthesia, a test dose of 3 - 5ml of bupivacaine containing adrenaline should be administered, since an intravascular injection of adrenaline will be quickly recognised by an increase in heart rate. Verbal contact and frequent measurements of the heart rate, preferably by electrographic (ECG) monitoring, should be maintained throughout a period of 5 minutes following the test dose.

Aspiration should be repeated prior to the administration of the total dose. The main dose should be injected slowly, 25 - 50mg/min., in incremental doses under constant contact with the patient. If mild toxic symptoms develop, the injection must be immediately stopped.

The lowest dosage required to achieve effective anaesthesia should be given. However, the dose will vary and will be dependent on the area to be anaesthetised, the vascularity of the tissues, the number of neuronal segments to be blocked, individual tolerance and the technique of anaesthesia used. For most indications, the duration of anaesthesia with bupivacaine solutions is such that a single dose is sufficient.

The maximum dosage must be determined by evaluating the size and physical status of the patient and considering the usual rate of systemic absorption from a particular injection site. Experience to-date indicates a single dose of up to 150mg bupivacaine hydrochloride. Doses of up to 50mg 2-hourly may subsequently be used. The dosages in the following table are recommended as a guide for use in the average adult. For young, elderly or debilitated patients, these doses should be reduced.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of block | %  Conc. | Each dose | | Motor block+ |
| ml | mg |  |
| LOCAL INFILTRATION | 0.25 | Up to 60 | Up to 150 | - |
| LUMBAR EPIDURAL  Surgical operations | 0.50 | 10 to 20 | 50 to 100 | Moderate to complete |
| Analgesia in labour | 0.50 | 6 to 12 | 30 to 60 | Moderate to complete |
| 0.25 | 6 to 12 | 15 to 30 | Minimal |
| CAUDAL EPIDURAL  Surgical operations | 0.50 | 15 to 30 | 75 to 150 | Moderate to complete |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of block | %  Conc. | Each dose | | Motor block+ |
| ml | mg |  |
| Analgesia in labour | 0.50 | 10 to 20 | 50 to 100 | Moderate to complete |
| 0.25 | 10 to 20 | 25 to 50 | Moderate |
| PERIPHERAL NERVES | 0.50 | Up to 30 | Up to 150 | Moderate to complete |
| 0.25 | Up to 60 | Up to 150 | Slight to Moderate |
| SYMPATHETIC BLOCKS | 0.25 | 20 to 50 | 50 to 125 | - |
|  |  |  |  |

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

Paediatric patients

Paediatric patients 1 to 12 years of age

Paediatric regional anaesthetic procedures should be performed by qualified clinicians who are familiar with this population and the technique.

The doses in the table should be regarded as guidelines for use in paediatrics. Individual variations occur. In children with a high body weight a gradual reduction of the dosage is often necessary and should be based on the ideal body weight. Standard textbooks should be consulted for factors affecting specific block techniques and for individual patient requirements. The lowest dose required for adequate analgesia should be used.

The duration may be prolonged with the adrenaline-containing solutions.

N.B. Risk of systemic effects of adrenaline with large volumes of adrenaline containing solutions should be considered.

Table : Dosage recommendations for children 1 to 12 years of age

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Conc. mg/ml | Volume ml/kg | Dose mg/kg | Onset min | Duration of effect hours |
| ACUTE PAIN MANAGEMENT (per-and postoperative) |  |  |  |  |  |
| Caudal, lumbar and thoracic Epidural Administration | 2.5 | 0.6-0.8 | 1.5-2 | 20-30 | 2-6 |

In order to avoid intravascular injection, aspiration should be repeated prior to and during administration of the main dose. This should be injected slowly in incremental doses, particularly in the lumbar and thoracic epidural routes, constantly and closely observing the patient's vital functions. Thoracic epidural blocks need to be given by incremental dosage until the desired level of anaesthesia is achieved.

The safety and efficacy of Bupivacaine and Adrenaline (Epinephrine) Injection 0. 25% w/v, 1 in 200,000 in children < 1 year of age have not been established. Only limited data are available.

Safety and efficacy of intermittent epidural bolus injection or continuous infusion have not been established. Only limited data is available.

4.3 Contraindications

Bupivacaine hydrochloride solutions are contraindicated in patients with a known hypersensitivity to local anaesthetic agents of the amide group or to other components of the injectable formulation.

Solutions of bupivacaine hydrochloride are contraindicated for intravenous regional anaesthesia (Bier's block). Solutions containing adrenaline are contraindicated in patients with thyrotoxicosis or severe heart disease particularly when tachycardia is present.

Solutions of bupivacaine containing adrenaline should not be used in connection with anaesthesia in areas of the body supplied by end arteries or otherwise having a compromised blood supply such as digits, nose, external ear or genitalia owing to the risk of tissue necrosis.

Epidural anaesthesia, regardless of the local anaesthetic used, has its own contraindications which include: Active disease of the central nervous system such as meningitis, poliomyelitis, intracranial haemorrhage, subacute combined degeneration of the cord due to pernicious anaemia and cerebral or spinal tumours. Tuberculosis of the spine. Pyogenic infection of the skin at or adjacent to the site of lumbar puncture. Cardiogenic or hypovolaemic shock. Coagulation disorders or ongoing anticoagulant therapy. Epidural anaesthesia is contraindicated in patients with an expanding cerebral lesion, a tumour, cyst or abscess, which may, if the intracranial pressure is suddenly altered, cause obstruction to the cerebrospinal fluid or blood circulation (the pressure cone).