

For the use of a Registered Medical Practitioner, Hospital or a Laboratory only.

Bupivacaine Hydrochloride in Dextrose Injection USP

BUPICAN™ HEAVY

Long acting local anaesthetic
For spinal anaesthesia

COMPOSITION

Each ml contains:

Bupivacaine Hydrochloride BP	
equivalent to anhydrous	
Bupivacaine Hydrochloride	5 mg
Dextrose Monohydrate USP	80 mg
Water for Injections BP	q.s.

PROPERTIES

BUPICAN™ HEAVY 0.5% 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 min. The duration of motor blockade does not exceed the duration of analgesia.

INDICATIONS

BUPICAN™ HEAVY 0.5% is indicated for spinal anaesthesia for urological and lower limb surgery lasting 2-3 hours, and abdominal surgery lasting 45-60 mins.

DOSAGE

2-3-4 ml (10-15-20 mg anhydrous Bupivacaine Hydrochloride). The doses should be regarded as a guide for use in the average adults. The effect of spinal administration of Bupivacaine spinal solution exceeding 20 mg have not yet been studied and can therefore not be recommended.

CONTRAINDICATIONS

Absolute: Sepsis or local infection at site of injection, severe shock and (Atrioventricular) heart block.

BUPICAN™ HEAVY is contraindicated in patients exhibiting hypersensitivity to local anaesthetics of the amide type.

Spinal anaesthesia is contraindicated or should only be used after careful consideration of alternatives in the following groups of patients: Uncooperative or unwilling patients, young children, shock, hypovolaemia, dehydration, hypotension, gross hypertension, severe IHD, toxemia, cerebral atheroma, severe valvular stenosis heart block, hydramnios, large ovarian and uterine tumours, patients who are breathless from any cause, abnormalities of the central nervous system, whether congenital or acquired, infective or degenerative, active or inactive/healed, raised intracranial pressure, chronic headache, gastrointestinal perforations, prostatic hypertrophy when this is not the reason for the surgery, renal failure, sepsis in the lumbar region, skeletal abnormalities of the back, clotting disorders or anticoagulant therapy; severe anaemia.

INJECTION TECHNIQUE

The technique for induction of spinal anaesthesia is the same as that normally followed with any other local anaesthetic used for this purpose. It can be administered in the right or left lateral position or in the sitting position. The addition of 7.5% glucose makes the solution hyperbaric which must be kept in mind when positioning the patient. When using this solution, barbotage is not recommended. Equilibrium (fixation) time for this solution is 5-10 minutes.

SIDE EFFECTS AND PRECAUTIONS

In the individual patient the height of the spinal anaesthetic block can be unpredictable and factors determining the height of the block are incompletely understood. There have been reports of unexpected cardiac arrests following induction of spinal anaesthesia in otherwise healthy patients.

The precautions required for administration of any spinal anaesthetic should be observed with special attention directed to proper positioning of the patient to avoid 'high spinal', selection of appropriate needle, correct site of injection, extent of analgesia, and availability of measures for control of possible complications of hypotension.

It is also important to be in constant readiness to cope with reactions due to the test dose or main dose, overdosage, individual patient idiosyncrasy, faulty technique and or inadvertent intravascular or subarachnoid injection. Adequate resuscitation equipment must be available whenever local anaesthesia is administered.

Side effects of **BUPICAN™ HEAVY** spinal solutions are rare but may occur in connection with extensive (total) spinal blockade. The first manifestation of CNS toxicity is drowsiness merging into unconsciousness and respiratory arrest. Cardiovascular reactions are depressant and may be characterized by hypotension, myocardial depression, bradycardia and possibly cardiac arrest. Systemic side effects are rarely associated with spinal anaesthesia but might occur in connection with accidental intravascular injection. Systemic side effects are characterized by numbness of tongue, lightheadedness, dizziness and tremor followed by convulsions.

TREATMENT OF SIDE EFFECTS

Treatment of extensive spinal blockade consists of ensuring and maintaining a patent airway and supporting ventilation using oxygen, if necessary by assisted or controlled ventilation. Should circulatory depression occur a vasopressor, preferably one with inotropic activity, ephedrine 5-10 mg, should be given intravenously. In case of inadvertent intravascular injection resulting in convulsions, this should be treated rapidly by intravenous injection of a short acting barbiturate e.g. thiopentone 100 mg to 200 mg or diazepam 5-10 mg.

STORAGE

Store in a cool place. Protect from light.

PRESENTATION

BUPICAN™ HEAVY is available in 4 ml glass ampoule.

Manufactured by :

Claris **Claris Lifesciences Limited**

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