



**FRESENIUS
KABI**

caring for life



NEW

NAPPI code

3006584001 | Pack quantity: 10

Bupivacaine HCl 0,5 % Spinal (4 ml) Fresenius Solution for injection

Therapeutic Indications

Induction of spinal anaesthesia.

Mechanism of action

Bupivacaine is a long acting (up to 8 hours) local anaesthetic of amide-type with an intermediate, to slow onset (about 15 minutes) of action.

Shelf life

- 24 months
- **In-use shelf life**
Use immediately after opening

Special precautions for storage

- Store at or below 25 °C
- Any unused portion should be discarded

Posology

Dosages of local anaesthetics used for spinal anaesthesia vary according to the volume of the subarachnoid space (i.e. the height of the patient), the segmental level of anaesthesia desired, and the duration of anaesthesia required.

BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS is given in doses of 10 to 20 mg (2 to 4 ml) for the average adult.

The smallest effective dose should be used. Smaller doses are usually needed in the elderly, in children, in debilitated patients, in cardiac disease, and in hepatic disease.

Meticulous attention to technique is essential. Special care should be taken to avoid fast bolus injection.

The spread of anaesthesia obtained with BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS is dependent upon several factors, the most important being volume of solution injected, and the age and position of the patient.

The difference in spread between a 10 mg and 20 mg dose is approximately two segments.

The larger dose gives a half to 1 hour longer duration of anaesthesia in the lumbar segments and longer lasting motor blockade.

When injected into the sub-arachnoid space via the L₃/L₄ interspace with the patient in a sitting position, 3 ml of BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS spreads to between the T₄ and T₅ segments.

If the patient is in the supine horizontal position the blockade spreads to between the T₅ and T₇ segments.

List of excipients

- Each 1 ml contains 5 mg bupivacaine hydrochloride (anhydrous)
- Sodium chloride
- Water for injection

Pharmaceutical form

- Solution for injection
- A clear colourless and odourless solution
- The pH of the solution is between 4,0 and 6,5
- The osmolality is between 270 and 330 mOsmol/kg

Incompatibilities

- Should not be mixed with other medicines

[S4] Bupivacaine HCl 0,5 % Spinal (4 ml) Fresenius. Each 1 ml contains 5 mg bupivacaine hydrochloride (anhydrous). Reg. No.: 29/4/0558

For full prescribing information refer to professional information approved by the South African Health Products Regulatory Authority.

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