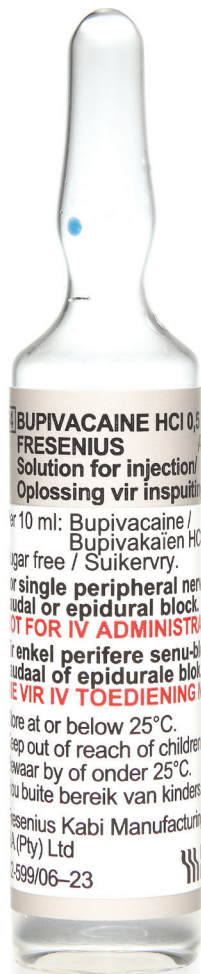




**FRESENIUS  
KABI**

caring for life



**NEW**

NAPPI code

3006585001 | Pack quantity: 10

## Bupivacaine HCl 0,5 % (10 ml) Fresenius Solution for injection

### Therapeutic Indications

Used as a peripheral nerve block, caudal or epidural block.

### Pharmacodynamic properties

Bupivacaine is an amide-type local anaesthetic medicine. Bupivacaine effects local anaesthetic action by preventing the initiation and transmission of neural impulses by stabilising the neuronal membrane.

The onset of action after administration is 10 - 40 minutes and the effect may last for several hours. Bupivacaine has a tendency to provide more sensory blockage than motor blockade.

#### 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

The area and vascularity of the tissue, the amount of neuronal segments to be blocked, the technique of anaesthesia as well as personal tolerance to BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS are factors that need to be taken into account when administering BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS.

When the correct dose of BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS is administered, complete sensory blockage will occur; however, motor blockade depends on the dose of BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS administered. The duration of anaesthesia is such that in most cases, a single dose will be sufficient.

The following dosages are recommended as a guide for use and have generally proved satisfactory in the average adult:

PROCEDURE	DOSE		ADDITIONAL INFORMATION
	ml	mg	
Trigeminal block	0,5 - 4	2,5 - 20	
Axillary block	15 - 30	75 - 150	
Intercostal block	3 - 5	15 - 25	Dose indicated for every segment
Epidural anaesthesia	10 - 20	50 - 100	
Continuous epidural anaesthesia		Starting dose of 10 ml followed by 3 ml - 5 ml - 8 ml every 4 - 6 hours. The dose depends on the number of segments to be rendered analgesic and the patient's age.	
Caudal anaesthesia	15 - 30	75 - 150	

The maximum recommended dose of BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS in a single injection is 150 mg and should not be exceeded unless there are special considerations present. Where dosage is calculated on the patient's weight, this should not exceed 2 mg/kg body weight up to a maximum of 150 mg.

### List of excipients

- Each 10 ml contains 50 mg bupivacaine hydrochloride
- 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 % (10 ml) Fresenius. Each 10 ml contains 50 mg bupivacaine hydrochloride. Reg. No.: W/4/335

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

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