



**FRESENIUS
KABI**

caring for life



NAPPI code

3005365001 | Pack quantity: 5

Levobupivacaine 5 mg/ml Fresenius

Therapeutic indications

LEVOBUPIVACAINE FRESENIUS is indicated in adults for:

- **Surgical anaesthesia**

Major: Epidural (including for caesarean section), intrathecal, peripheral nerve block.

Minor: Local infiltration, peribulbar block in ophthalmic surgery.

- **Pain management**

Continuous epidural infusion, single or multiple bolus epidural administration for post-operative, labour or chronic pain.

For continuous epidural analgesia, LEVOBUPIVACAINE FRESENIUS may be administered in combination with epidural fentanyl, morphine or clonidine.

LEVOBUPIVACAINE FRESENIUS is indicated in children for infiltration analgesia. No data are available in paediatric population < 6 months of age.

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Dosage Recommendations

	Concentration (%)	Dose (ml)	Dose (mg)	Motor block
Surgical anaesthesia				
Epidural for surgery	0,5 - 0,75	10 - 20	50 - 150	Moderate to complete
Epidural for Caesarean section	0,5	15 - 30	75 - 150	Moderate to complete
Peripheral nerve	0,25 - 0,5	1 - 40	Maximum 150	Moderate to complete
Intrathecal	0,5	3	15	Moderate to complete
Ophthalmic	0,75	5 - 15	37,5 - 112,5	Moderate to complete
Local infiltration - Adults	0,25	1 - 60	Maximum 150	Not applicable
Local infiltration - Children < 12 years	0,25 - 0,5	0,25 - 0,50 ml/kg	1,25 - 2,5 mg/kg	Not applicable
Dental	0,5 - 0,75	5 - 10	25 - 75	Not applicable
Pain^(a,b) management				
Labour analgesia (epidural bolus)	0,25	10 - 20	25 - 50	Minimal to moderate
Labour analgesia (epidural infusion)	0,125 ^(c)	4 - 10 ml/h	5 - 12,5 mg/h	Minimal to moderate
Post-operative pain (epidural infusion)	0,125 ^(c)	10 - 15 ml/h	12,5 - 18,75 mg/h	Minimal to moderate
	0,25	5 - 7,5 ml/h	12,5 - 18,75 mg/h	

a In pain management LEVOBUPIVACAINE FRESENIUS can be used epidurally with fentanyl, morphine or clonidine.

b In cases where LEVOBUPIVACAINE FRESENIUS is combined with other medicines e.g. opioids in pain management, the LEVOBUPIVACAINE FRESENIUS dose should be reduced as use of a lower concentration (e.g. 1,25 mg/ml) is preferable.

c Dilutions of LEVOBUPIVACAINE FRESENIUS standard solutions should be made with preservative free 0,9 % saline according to standard hospital procedures for sterility.

The doses in the table are those considered to be necessary to produce a successful block and should be regarded as guidelines for use. Individual variations in onset and duration occur.

The maximum single dose recommended is 2 mg/kg (150 mg).

The maximum dose in 24 hours for intra-operative block and post-operative pain management is 6 mg/kg (400 mg).

In children, the maximum recommended dose for infiltration analgesia (ilioinguinal-iliohypogastric block) is 1,25 mg/kg/side.

Method of administration

LEVOBUPIVACAINE FRESENIUS is indicated for epidural use, intrathecal use, perineural use (peripheral nerve blocks) and for infiltration.

The rapid injection of a large volume of LEVOBUPIVACAINE FRESENIUS solution should be avoided and fractional (incremental) doses should always be used.

Shelf life

24 months, stored at or below 30 °C.

Shelf life after first opening: The product should be used immediately.

Shelf life after dilution in sodium chloride solution 0,9 %:

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless the dilution and admix have taken place in controlled and validated aseptic conditions.

Container

10 ml polypropylene ampoules (Ovalia), in sterile blister packs.

For single use only. Discard any unused solution.

[S4] Levobupivacaine 5 mg/ml Fresenius. Each 1 ml solution contains 5 mg levobupivacaine (as levobupivacaine hydrochloride). Reg. No.: 50/4/0738

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

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