FRESENIUS KABI

Local Anaesthetics Portfolio

The full offering

	Ropivacaine Fresenius[1]	Levobupivacaine Fresenius[1]	Bupivacaine Fresenius[1]
Indication	**ADULTS** **Surgical anaesthesia:** • Epidural block for surgery, including Caesarean section • Minor nerve block and infiltration anaesthesia • Major nerve block **Acute pain management:** • Continuous epidural infusion or intermittent bolus administration e.g. postoperative or labour pain • Minor nerve block and infiltration analgesia • Continuous peripheral nerve block infusion or intermittent injections, e.g. postoperative pain management **PAEDIATRICS** **(1 - 12 years of age): 2 mg/mL** **Acute pain management:** • Caudal epidural block • Peripheral nerve block for pre- and postoperative pain management	**ADULTS** **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 **PAEDIATRICS** Indicated in children for infiltration analgesia.	**4 mL spinal:** Induction of spinal anaesthesia. Give with caution to children. **10 mL:** Peripheral nerve block, caudal or epidural block. Not recommended for children younger than 12 years.
Method of administration	Epidural.	Epidural, intrathecal, perineural, infiltration.	**4 mL:** intrathecal injection. **10 mL:** nerve plexus, caudal/epidural.
Maximum (max.) dose	300 mg in adult patients of 60 kg or more. Data on patients under 60 kg is not available.	Maximum single dose recommended is 2 mg/kg (150 mg). Maximum dose in 24 hours for intra-operative block & post-operative pain management is 6 mg/kg (400 mg). In children, the max. recommended dose for infiltration analgesia is 1,25 mg/kg/side.	**4 mL:** 10 to 20 mg (2 to 4 mL) for the average adult. **10 mL:** 2 mg/kg up to a max. of 150 mg.
Onset time	10 - 20 min for lumbar & thoracic epidural administration. 10 - 25 min for major nerve blocks. 1 - 15 min for minor nerve block & infiltration anaesthesia. 10 - 15 min for bolus lumbar epidural administration for pain management. 1 - 5 min for minor nerve block & infiltration analgesia pain management.	Up to 15 mins.[2] Individual variations occur.[1]	**4 mL:** About 15 mins (intermediate to slow onset). **10 mL:** 10 - 40 mins.
Duration of action	Dose dependent. Ranges from 2 to 10 hours for surgical anaesthesia, and 0,5 to 6 hours for acute pain management.	Similar to Bupivacaine.[2] Individual variations occur.[1]	Up to 8 hours (long acting).
Formulations available from Fresenius Kabi within South Africa	2 mg/mL 100 mL solution for infusion; 7,5 mg/mL 10 mL solution for injection; 10 mg/mL 10 mL solution for injection.	5 mg/mL 10 mL only.	5 mg/mL spinal (4 mL); 5 mg/mL 10 mL.

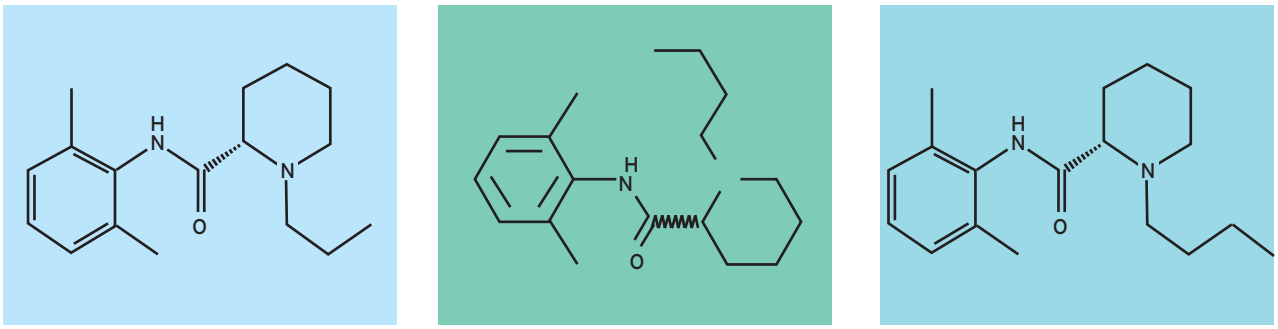
Toxicity

Systemic toxicity of local anaesthetics may occur due to **unwanted intravascular or intrathecal injection**, or after the administration of an **excessive dose** of these medicines.[3]

Toxicity from local anaesthetics typically affect the **central nervous system (CNS)** first, followed by involvement of the **cardiovascular system**.[3,4] This order of progression is due to the fact that the CNS is generally more sensitive to the effects of local anesthetics compared to the cardiovascular system.[3,4]

Bupivacaine differs from other local anaesthetics in that it has a narrower margin between the dose or plasma concentrations required to cause toxicity.[4] **Ropivacaine and Levobupivacaine** have been developed to offer an alternative to Bupivacaine as they have the same desirable blocking properties with reduced toxic potential.[3,4]

Figure 1: Structure of the three local anaesthetics. Adapted from Leone et al, 2008



Ropivacaine | Bupivacaine | Levobupivacaine

Bupivacaine is a racemic solution containing both (R+)- and (S-)-enantiomers, while ropivacaine and levobupivacaine are optically pure and contain only the (S-)-enantiomer. The (S-)-enantiomer tends to have reduced toxic potential than the (R+)-enantiomer.[3]

References:
1) SA Professional Information: Bupivacaine Fresenius, Levobupivacaine Fresenius, Ropivacaine Fresenius
2) Foster RH. Markam A. Drugs 2000;59(3):551-79.
3) Leone S, *et al*. Acta Biomed 2008;79:92-105.
4) Casati A, *et al*. Best Pract. Res. Clin. Anaesthesiol. 2005;9(2):247-268.

S4 Bupivacaine HCl 0,5 % (10 ml) Fresenius. Each 10 ml contains 50 mg bupivacaine hydrochloride. Reg. No.: W/4/335
S4 Bupivacaine HCl 0,5 % Spinal (4 ml) Fresenius. Each 1 ml contains 5 mg bupivacaine hydrochloride (anhydrous). Reg. No.: 29/4/0558
S4 Ropivacaine 2 mg/ml Infusion Fresenius. Each 1 ml solution contains 2 mg ropivacaine hydrochloride. Reg. No.: 46/4/0899
S4 Ropivacaine 7,5 mg/ml Injection Fresenius. Each 1 ml solution contains 7,5 mg ropivacaine hydrochloride. Reg. No.: 46/4/0902
S4 Ropivacaine 10 mg/ml Injection Fresenius. Each 1 ml solution contains 10 mg ropivacaine hydrochloride. Reg. No.: 46/4/0903
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 the latest professional information approved by the South African Health Products Regulatory Authority.

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FRESENIUS KABI

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