









NAPPI code 3005424002 | Pack quantity: 5

Ropivacaine 2 mg/ml Infusion Fresenius (100 ml)

NAPPI code 3009282001 | Pack quantity: 5

Ropivacaine 2 mg/ml Infusion Fresenius (200 ml)

NAPPI code 3005426001 | Pack quantity: 5

Ropivacaine 7,5 mg/ml Injection Fresenius

NAPPI code 3005427001 | Pack quantity: 5

Ropivacaine 10 mg/ml Injection Fresenius

Indications

Surgical anaesthesia in adults:

- Epidural block for surgery, including Caesarean section
- Minor nerve block and infiltration anaesthesia
- · Major nerve block

Acute pain management in adults:

- 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

Acute pain management in paediatrics (children 1 - 12 years of age):

- · Caudal epidural block
- · Peripheral nerve block for pre- and postoperative pain management

ROPIVACAINE FRESENIUS should not be administered intravenously

Ropivacaine Fresenius

In general, surgical anaesthesia (e.g. epidural administration) requires the use of the higher concentrations and doses.

For analgesia, the 2 mg/ml concentration is generally recommended.

ROPIVACAINE FRESENIUS is not recommended for children under the age of 1 year and in patients under 60 kg for major nerve block anaesthesia, as safety and efficacy have not been established.

Dosage recommendations in adults:

PROCEDURE	Conc. (mg/ml)	Volume (ml)	Dose (mg)	Onset (minutes)	Duration (hours)
SURGICAL ANAESTHESIA					
Lumbar epidural administration:					
Surgery	7,5	15 to 25	113 to 188	10 - 20	3 to 5
	10,0	15 to 20	150 to 200	10 - 20	4 to 6
Lumbar epidural administration:					
Caesarean section	7,5	15 to 20	113 to 150	10 - 20	3 to 5
Thoracic epidural administration:					
To establish block for postoperative pain relief	7,5	5 to 15 Depending or level of injection		10 - 20	n/a
Minor nerve block and infiltration anaesthesia:					
(e.g. minor nerve blocks and infiltration)	7,5	1 to 30	7,5 to 225	1 - 15	2 to 6
Major nerve block:					
(e.g. brachial plexus)	7,5	10 to 40	75 to 300*	10 - 25	6 to 10
ACUTE PAIN MANAGEMENT					
Lumbar epidural administration:					
Bolus	2,0	10 to 20	20 to 40	10 - 15	0,5 to 1,5
Intermittent injections (top-up) (e.g. labour pain management)	2,0	10 to 15 (minimum interval 30 min.	20 to 30	-	-
Lumbar epidural administration:					
Continuous infusion (e.g. labour pain)	2,0	6 to 10 ml/h	12 to 20 mg/h	n/a	n/a
Postoperative pain management	2,0	6 to 14 ml/h	12 to 28 mg/h	n/a	n/a
There is enidered administration.					
Thoracic epidural administration: Continuous infusion (e.g. postoperative pain management)	2.0	6 to 1/1 ml/h	12 to 28 mg/h	n/a	n/a
	2,0	0 to 14 1111/11	12 to 20 mg/m	11/4	11/a
Minor nerve block and infiltration anaesthesia:					
(e.g. minor nerve blocks and infiltration)	2,0	1 to 100	2 to 200 mg/h	1-5	2 to 6
Peripheral nerve block:					
(Femoral or interscalene block) Continuous infusion or intermittent injections (e.g. postoperative pain management)	2,0	5 to 10 ml/h	10 to 20 mg/h	n/a	n/a

Dosage recommendations for paediatric patients 1 - 12 years of age:

initial to its for pacellatine patients 1 12 years of age.	Conc. (mg/ml)	Volume (ml/kg)	Dose (mg/kg)	
ACUTE PAIN MANAGEMENT (pre- and postoperative)				
Single caudal epidural block administration: Blocks below T12, in children with a body weight up to 25 kg	2,0	1	2	
Peripheral nerve block: (e.g. ilioinguinal nerve block)	5,0	0,6	3	

^{*} Exercise caution when using the 300 mg dose

Individual variations occur. In children with a high body weight, a gradual reduction of the dosage is often necessary and should be based on the ideal body weight.

Paediatric population

The safety and efficacy of ROPIVACAINE FRESENIUS 2 mg/ml for field block in children up to and including 12 years has not been established. The safety and efficacy of ROPIVACAINE FRESENIUS 7,5 mg/ml and 10 mg/ml in children up to and including 12 years has not been established. The safety and efficacy of ropivacaine 2 mg/ml for peripheral nerve blocks in infants below 1 year has not been established.

Shelf life before opening

- 3 years (solution for injection) polypropylene ampoule 2 years (solution for infusion) *Freeflex*® bags

Shelf life after first opening

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. Store at or below 25 °C. Protect from light.

- 54 Ropivacaine 2 mg/ml Infusion Fresenius. Each 1 ml solution contains 2 mg ropivacaine hydrochloride. Reg. No.: 46/4/0899
- 54 Ropivacaine 7,5 mg/ml Injection Fresenius. Each 1 ml solution contains 7,5 mg ropivacaine hydrochloride. Reg. No.: 46/4/0902
- 54 Ropivacaine 10 mg/ml Injection Fresenius. Each 1 ml solution contains 10 mg ropivacaine hydrochloride. Reg. No.: 46/4/0903

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



