

SCHEDULING STATUS

S4

Ropivacaine 2 mg/mL B. Braun, solution for injection/infusion

Ropivacaine 5 mg/mL B. Braun, solution for injection

Ropivacaine 7,5 mg/mL B. Braun, solution for injection

Ropivacaine 10 mg/mL B. Braun, solution for injection

Active pharmaceutical ingredient: Ropivacaine hydrochloride (as Ropivacaine hydrochloride monohydrate).

Sugar free

Read all of this leaflet carefully before you are given ROPIVACAINE B BRAUN

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| <ul style="list-style-type: none">- Keep this leaflet. You may need to read it again.- If you have further questions, please ask your doctor, nurse, pharmacist or other healthcare provider. |
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What is in this leaflet

- 1: What **ROPIVACAINE B BRAUN** is and what it is used for
- 2: What you need to know before you use **ROPIVACAINE B BRAUN**
- 3: How to use **ROPIVACAINE B BRAUN**
- 4: Possible side effects
- 5: How to store **ROPIVACAINE B BRAUN**
- 6: Contents of the pack and other information

1: What ROPIVACAINE B BRAUN is and what it is used for

The active substance is ropivacaine hydrochloride.

1 ampoule of 10 mL or 20 mL solution for injection contains 50 mg or 100 mg ropivacaine hydrochloride as ropivacaine hydrochloride.

ROPIVACAINE B BRAUN belongs to a group of medicines called local anaesthetics (numbing medicine).

ROPIVACAINE B BRAUN is used to anaesthetise parts of the body for surgical operations and also for pain relief. Its most important uses are described below:

- to anaesthetise the area of the body where surgery is to be performed
- to provide pain relief in labour and after surgery or acute injury.

ROPIVACAINE B BRAUN works by preventing the nerves in the injected area from transmitting sensations of pain, heat or cold. However, you may still experience sensations such as pressure and touch.

In this way the part of the body in the area of the nerve(s) is numbed and prepared for surgery. In many cases this means that the nerves to the muscles in the area will also be blocked, causing temporary loss of sensation to the involved area.

2: What you need to know before ROPIVACAINE B BRAUN is administered to you

ROPIVACAINE B BRAUN must not be administered to you:

- If you are allergic (hypersensitive) to ropivacaine hydrochloride or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, difficulty of breathing or swelling of the face, lips, throat or tongue.
- If you are allergic to any other local anaesthetics of the same class (e.g. lidocaine or bupivacaine).
- For injection into a blood vessel to numb a specific area of your body, or into the neck of the womb to relieve pain during childbirth.
- If you have been told that you have decreased volume of blood (hypovolaemia).

ROPIVACAINE B BRAUN is not recommended in children under the age of 1 year.

ROPIVACAINE 7,5 mg/mL and 10 mg/mL B. BRAUN should not be used in children below the age of 12 years as safety and efficacy have not been established.

If you are not sure if any of the above applies to you, talk to your doctor before you are given **ROPIVACAINE B BRAUN**.

Take special care with ROPIVACAINE B BRAUN

Tell your doctor or health care provider before being given the injection:

- if you have heart, liver or kidney problems. Your doctor may need to adjust the dose of **ROPIVACAINE B**

BRAUN

- if you have ever been told that you have a rare disease of the blood called "porphyria" (this is where a red blood pigment build up in your blood) or if anyone in your family has it. Your doctor may need to give you a different anaesthetic medicine.

- if you are in poor health due to advanced age or other reasons about any diseases or medical conditions that you have or had in the past.

Your doctor, nurse or health care provider will take special care in monitoring your heart and lung vital signs as well as state of consciousness after receiving **ROPIVACAINE B BRAUN** injection. It should be kept in mind that at such times restlessness, anxiety, tinnitus, dizziness, blurred vision, tremors, depression or drowsiness may be early warning signs of CNS toxicity.

Children

Your doctor will take special care:

- with children up to and including 12 years as some injections of ropivacaine given in order to numb parts of the body are not established in younger children.

Your doctor will adjust the required dose for your child carefully and will monitor your child thoroughly.

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Other medicines and ROPIVACAINE B BRAUN

Always tell your doctor, nurse, pharmacist or other healthcare provider if you are taking, have recently taken or might take any other medicines (this includes all complimentary or traditional medicines). This is especially important with the following medicines, which can make the effects of **ROPIVACAINE B BRAUN** stronger:

- Other local anaesthetics (e.g. lidocaine)
- Strong pain relievers (e.g. morphine)
- Medicines used to treat irregular heart beat (e.g. amiodarone, mexiletine).
- Prolonged use of ropivacaine should be avoided if you are receiving:
- Medicines used to treat depression (e.g. fluvoxamine)
- Antibiotics used to treat infections caused by bacteria (e.g. enoxacin).

It may still be all right for you to receive **ROPIVACAINE B BRAUN**. Your doctor needs to know about these medicines to be able to decide what is suitable for you.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine. It is not known whether ropivacaine can pass into breast milk or if it could harm a nursing baby.

Driving and using machines

ROPIVACAINE B BRAUN may make you feel sleepy and affect the speed of your reactions. After you have been given this medicine, you must not drive, operate machinery, or work in dangerous situations until the next day.

3: How to use ROPIVACAINE B BRAUN

ROPIVACAINE B BRAUN will be given to you by your doctor.

The usual dose is:

ROPIVACAINE B BRAUN will be given to you as an injection or as an infusion. The part of the body where it will be used depends on why you are being given this medicine.

Your doctor will give you this medicine in one of the following places:

- The part of the body that needs to be numbed.

- Near to the part of the body that needs to be numbed.
- In an area away from the part of the body that needs to be numbed. This is the case if you are given an epidural injection or infusion into your middle or lower back near your spine.
- You will be watched closely by health care professionals while you are receiving **ROPIVACAINE B BRAUN**.
- This medicine stops the nerves from being able to pass pain messages to the brain. It will stop you feeling pain, heat or cold in where it is used but you may still have other feelings like pressure or touch.

Dosage

Your doctor will decide on the dose of ROPIVACAINE B BRAUN you will be given.

The dosage depends on the type of pain relief that you need and other factors such as body size, age, and physical condition.

If you receive more ROPIVACAINE B BRAUN than you should

Since this medicine will be given to you by a doctor under carefully controlled conditions, it is unlikely that you will be given too much or that you will miss a dose.

Serious side effects from getting too much **ROPIVACAINE B BRAUN** need special treatment and the doctor treating you is trained to deal with these situations.

The first signs of being given too much of **ROPIVACAINE B BRAUN** are usually as follows:

- feeling dizzy or light-headed
- numbness of the lips and around the mouth
- numbness of the tongue
- hearing problems
- problems with your sight (vision)
- Speech disorder where you struggle to speak properly
- Stiff muscles or twitching of the muscles, tremors, trembling, fits
- Slow or irregular heartbeat
- Loss of consciousness

This may be signs and symptoms of very serious conditions called cardiac arrest (where your heart stops) of breathing arrest (where you stop breathing)

Your doctor will stop giving you this medicine as soon as these signs appear to reduce the risk of serious side effects. This means that if any of these happen to you, or you think you received too much of **ROPIVACAINE B BRAUN**, tell your doctor immediately.

More serious side effects from being given too much of this medicine includes problems with your speech, twitching of your muscles, tremors, trembling, fits (seizures), and loss of consciousness.

Since health care provider will administer **ROPIVACAINE B BRAUN**, he/she will control the dosage.

However in the event of overdosage your doctor will manage the overdose.

4: POSSIBLE SIDE EFFECTS

ROPIVACAINE B BRAUN, can have side effects.

Not all side effects reported for **ROPIVACAINE B BRAUN**, are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking please consult your health care provider for advice.

All medicines including **ROPIVACAINE B BRAUN** can cause life-threatening allergic reactions, although this does not happen frequently.

You should tell your doctor immediately if you experience any of the following symptoms after receiving this medicine:

--sudden onset of rash, itching or hives;

--swelling of the eyelids, face, lips, tongue, throat or other parts of the body;

--breathing difficulties, sudden wheeziness, dizziness.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction and may require urgent medical attention.

Other possible side effects:

Frequent

- low blood pressure (hypotension) (you may feel dizzy or light-headed)
- feeling sick (nausea)
- pins and needles
- dizziness
- being sick (vomiting)
- slow or fast heart rate (bradycardia, tachycardia)
- high blood pressure (hypertension)
- high body temperature (fever) or stiffness (chills)
- back pain
- headache
- difficulty in passing urine

Less Frequent

- anxiety
- fainting
- difficulty breathing
- low body temperature (hypothermia)
- Heart attack (cardiac arrest)
- Irregular heart beat (arrhythmia)
- Horner syndrome, an affection of the eyelids, eye muscles and iris.

Some symptoms can occur if the injection is accidentally given into a blood vessel or if too much

ROPIVACAINE B BRAUN is administered (see also "*If you receive more **ROPIVACAINE B BRAUN** than you should*" above). These include convulsions, fits (seizures), feeling dizzy or light-headed, numbness of the lips and around the mouth, numbness of the tongue, hearing problems, problems with your sight (vision), problems with your speech, stiff muscles, decreased sensitivity or feeling in the skin, and trembling.

Frequency Unknown

-- Jerky movements (dyskinesia)

If you notice any side effects not mentioned, please inform your doctor or pharmacist.

Possible side effects seen with other local anaesthetics which might also be caused by **ROPIVACAINE B BRAUN**.

Damaged nerves. Rarely this may cause permanent problems.

The whole body may get numbed (anaesthetised), if too much **ROPIVACAINE B BRAUN** is injected into the spinal fluid.

Children

In children, the side effects are the same as in adults except for low blood pressure which happens less often in infants and children and being sick which happens more often in children.

Reporting of side effects

If you get side effects. Talk to your doctor, or pharmacist or nurse. You can also report side effects to SAHPRA via 6.04 Adverse Drug Reaction Reporting Form found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/index/8/>. By reporting side effects, you can help provide more information on the safety of **ROPIVACAINE B BRAUN**.

5: How to store ROPIVACAINE B BRAUN.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Your doctor or pharmacist is responsible for storing this medicine. They are also responsible for disposing of any unused medicine correctly.

Do not use this medicine after the expiry date which is stated on the carton and label after “EXP.”. The expiry date refers to the last day of that month.

Do not freeze.

Store at or below 30 °C.

6: Contents of the pack and other information

What **ROPIVACAINE B BRAUN** contains

The active substance is ropivacaine hydrochloride.

Ropivacaine 2 mg/mL B. Braun solution for injection/infusion:

1 mL solution for injection/infusion contains 2 mg ropivacaine hydrochloride (as ropivacaine hydrochloride monohydrate).

Ropivacaine 5 mg/mL B. Braun solution for injection:

1 mL solution for injection contains 5 mg ropivacaine hydrochloride (as Ropivacaine hydrochloride monohydrate).

Ropivacaine.5 mg/mL B. Braun solution for injection:

1 mL solution for injection contains 7.5 mg ropivacaine hydrochloride (as Ropivacaine hydrochloride monohydrate).

Ropivacaine 10 mg/mL B. Braun solution for injection:

1 mL solution for injection contains 10 mg ropivacaine hydrochloride (as Ropivacaine hydrochloride monohydrate).

The other ingredients are sodium chloride, hydrochloric acid 0.36% (for pH adjustment) and sodium hydroxide 0.4% (for pH adjustment), and water for injections.

What **ROPIVACAINE B BRAUN** looks like and the contents of the pack:

ROPIVACAINE B BRAUN is a clear, colourless solution for injection/infusion, available as follows:

Ropivacaine 2 mg/mL , 5 mg/mL , 7,5 mg/mL and 10 mg/mL B. Braun :

- 10 mL polyethylene ampoules in packs of 20
- 20 mL polyethylene ampoules in packs of 20

Ropivacaine 2 mg/mL B. Braun :

- 100 mL polyethylene bottles in packs of 1 and 10
- 200 mL polyethylene bottles in packs of 1 and 10
- 400 mL polyethylene bottles in packs of 1 and 10
- 500 mL polyethylene bottles in packs of 1 and 10

Not all pack sizes may be marketed.

Holder of Certificate of Registration

B. Braun Medical (Pty) Ltd,
253 Aintree Road,
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Gauteng, South Africa

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8. REGISTRATION NUMBER:

Ropivacaine 2mg/ml: 48/4/0349

Ropivacaine 5mg/ml: 48/4/0350

Ropivacaine 7,5mg/ml: 48/4/0351

Ropivacaine 10mg/ml: 48/4/0352