

ROPIVACAINE KABI

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given ROPIVACAINE KABI?

ROPIVACAINE KABI contains the active ingredient ropivacaine hydrochloride. ROPIVACAINE KABI is used as an anaesthetic to stop the pain of surgery and/or to make childbirth less painful. ROPIVACAINE KABI is also used after surgery to treat post-operative pain.

For more information, see Section [1. Why am I being given ROPIVACAINE KABI?](#) in the full CMI.

2. What should I know before I am given ROPIVACAINE KABI?

Do not use if you have ever had an allergic reaction to ROPIVACAINE KABI or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given ROPIVACAINE KABI?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ROPIVACAINE KABI and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is ROPIVACAINE KABI given?

Your doctor will have had a lot of experience using ropivacaine hydrochloride or other local anaesthetics and will choose the best dose for you.

Your doctor will inject the medicine into the skin, near a single nerve, or into an area which contains a large number of nerves. It may also be directed into a surgical incision after surgery by a tube.

More instructions can be found in Section [4. How is ROPIVACAINE KABI given?](#) in the full CMI.

5. What should I know after being given ROPIVACAINE KABI?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you have been given ROPIVACAINE KABI.
Driving or using machines	<ul style="list-style-type: none">Be careful before you drive or use any machines or tools until you know how ROPIVACAINE KABI affects you.
Drinking alcohol	<ul style="list-style-type: none">Do not drink alcohol while you are being given or after being given ROPIVACAINE KABI.

For more information, see Section [5. What should I know after being given ROPIVACAINE KABI?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary.

The most common side effects are nausea (feeling sick), vomiting, headache, dizziness, irregular or slow heartbeat, fever, a tingling feeling ("pins and needles"), shivering, difficulty passing urine, stiff or twitching muscles, painful joints, difficulty breathing, extreme dizziness, slow heartbeat, pain in the chest and fits.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ROPIVACAINE KABI

Active ingredient: *Ropivacaine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ROPIVACAINE KABI. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ROPIVACAINE KABI.**

Where to find information in this leaflet:

- [1. Why am I being given ROPIVACAINE KABI?](#)
- [2. What should I know before I am given ROPIVACAINE KABI?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is ROPIVACAINE KABI given?](#)
- [5. What should I know after being given ROPIVACAINE KABI?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given ROPIVACAINE KABI?

ROPIVACAINE KABI contains the active ingredient **ropivacaine hydrochloride**. ROPIVACAINE KABI is a local anaesthetic (an-es-thet-ic). It is injected into the body where it makes the nerves unable to pass messages to the brain. Depending on the amount used, ropivacaine will either totally stop pain or will cause a partial loss of feeling.

ROPIVACAINE KABI is used as an anaesthetic to stop the pain of surgery and/or to make childbirth less painful.

ROPIVACAINE KABI is also used after surgery to treat post-operative pain.

Your doctor will have explained why you are being treated with ROPIVACAINE KABI and told you what dose you will be given.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Ropivacaine Kabi is not addictive.

2. What should I know before I am given ROPIVACAINE KABI?

Warnings

Do not use ROPIVACAINE KABI if:

- you are allergic to

- ropivacaine hydrochloride, or any of the ingredients listed at the end of this leaflet
- any other local anaesthetics

Always check the ingredients to make sure you can use this medicine.

- you have problems controlling your low blood pressure
- you have inflammation and/or an infection at the site of the injection

Check with your doctor if you:

- you have any allergies to other substances
- you have any of these medical conditions
 - problems with your blood pressure or circulation
 - blood poisoning
 - problems with the clotting of your blood
 - acidosis, or too much acid in the blood
 - nerve problems
 - liver, kidney or heart problems
 - disease of the brain or spine, including meningitis, polio, cancer or infections
 - muscle disease or weakness (e.g. myasthenia gravis)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the risks and benefits of using ROPIVACAINE KABI if you are pregnant or breast-feeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ROPIVACAINE KABI and affect how it works.

Medicines that may affect the way ROPIVACAINE KABI works include:

- medicines that control your heart beat
- medicines used to thin the blood, including aspirin

- low molecular weight heparin or other medicines used to prevent blood clots
- fluvoxamine, a medicine used to treat depression.
- enoxacin, a medicine used to treat bacterial infections.
- ketoconazole, a medicine used to treat fungal infections
- cimetidine, a medicine used to treat stomach ulcers or heartburn
- medicines for depression

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ROPIVACAINE KABI.

4. How is ROPIVACAINE KABI given?

How much is given

The dosage you will be given will depend on your body size, age and the type of pain relief required. Your doctor will have had a lot of experience using ROPIVACAINE KABI or other local anaesthetics and will choose the best dose for you. They will be willing to discuss this decision with you.

How it will be given

ROPIVACAINE KABI will be injected by your doctor into the skin, near a single nerve, or into an area which contains a large number of nerves. ROPIVACAINE KABI may also be directed into a surgical incision after surgery by a tube.

If you are given too much

The doctor giving you ropivacaine hydrochloride will be experienced in the use of local anaesthetics, so it is unlikely that you will be given too much.

However, if you are particularly sensitive to ropivacaine hydrochloride, or the dose is accidentally injected directly into your blood, you may develop problems with your sight, hearing, and get a numb feeling in or around the mouth, feel dizzy or stiff, or have twitchy muscles.

In rare cases, these effects may be followed by drowsiness and fits. In extreme cases you may have problems with your breathing or your heart and you may become unconscious.

5. What should I know after being given ROPIVACAINE KABI?

Things you should do

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ROPIVACAINE KABI affects you.

ROPIVACAINE KABI may cause dizziness in some people. You may be drowsy and your reflexes may be slow.

Drinking alcohol

Do not drink alcohol while you are being given or after being given Ropivacaine Kabi, if you drink alcohol your blood pressure may drop making you feel dizzy and faint.

Getting rid of any unwanted medicine

Any ROPIVACAINE KABI which is not used, and which is left in the container, will be disposed of in a safe manner by your doctor, nurse or pharmacist.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gut related <ul style="list-style-type: none"> • Nausea (feeling sick) • Vomiting Brain and nervous system related <ul style="list-style-type: none"> • Headache • Dizziness • A tingling feeling ("pins and needles") • Shivering Heart related <ul style="list-style-type: none"> • Irregular or slow heartbeat Urine related <ul style="list-style-type: none"> • Difficulty passing urine Other <ul style="list-style-type: none"> • Fever 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
Heart related <ul style="list-style-type: none"> • Slow heartbeat Brain and nervous system related <ul style="list-style-type: none"> • Extreme dizziness Lung and upper airways <ul style="list-style-type: none"> • Difficulty breathing General <ul style="list-style-type: none"> • Stiff or twitching muscles • Painful joints • Pain in the chest • Fits 	<p>Tell your doctor or nurse straight away, or if you have already left the hospital or surgery, go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ROPIVACAINE KABI contains

Active ingredient (main ingredient)	Ropivacaine hydrochloride
Other ingredients (inactive ingredients)	Sodium chloride Hydrochloric acid and/or sodium hydroxide for pH adjustment Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What ROPIVACAINE KABI looks like

ROPIVACAINE KABI is a clear colourless, sterile and isotonic ready- to-use solution for injection.

ROPIVACAINE KABI is available as

- 2 mg/mL in 10 mL ampoule: AUST R 195796
- 2 mg/mL in 20 mL ampoule: AUST R 195804
- 5 mg/mL in 10 mL ampoule: AUST R 195805
- 7.5 mg/mL in 10 mL ampoule: AUST R 195806
- 7.5 mg/mL in 20 mL ampoule: AUST R 195807
- 10 mg/mL in 10 mL ampoule: AUST R 195808
- 10 mg/mL in 20 mL ampoule: AUST R 195809
- 2 mg/mL in 100 mL **freeflex**[®] bag AUST R 195810
- 2 mg/mL in 200 mL **freeflex**[®] bag AUST R 195811

Who distributes ROPIVACAINE KABI

Fresenius Kabi Australia Pty Limited

Level 2, 2 Woodland Way

Mount Kuring-gai NSW 2080

Australia

Telephone: (02) 9391 5555

This leaflet was prepared in December 2022.