

Ropibam

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 using Ropibam?

Ropibam contains the active ingredient ropivacaine hydrochloride. Ropibam is used as an anaesthetic to stop the pain of surgery and/or to make childbirth less painful. It is also used after surgery to treat postoperative pain. For more information, see Section [1. Why am I using Ropibam?](#) in the full CMI.

2. What should I know before I am given Ropibam?

Do not use if you have ever had an allergic reaction to ropivacaine hydrochloride 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 Ropibam?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ropibam 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 Ropibam given?

- Ropibam will be injected by your doctor into the skin, near a single nerve, or into an area which contains a large number of nerves. Ropibam may also be directed into a surgical incision after surgery by a tube.
- The dosage you will be given will depend on your body size, age and the type of pain relief required.

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

5. What should I know while being given Ropibam?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist [add other health professionals as appropriate] you visit that you are using Ropibam.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery after you have been given Ropibam.• You may be drowsy, and your reflexes may be slow.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol while you are being given Ropibam.• If you drink alcohol while you are being given Ropibam your blood pressure may drop making you feel dizzy and faint.
Looking after your medicine	<ul style="list-style-type: none">• It will be stored by your doctor or pharmacist in a cool dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ropibam. Some of the mild side effects include nausea (feeling sick), vomiting, headache, dizziness, irregular or slow heartbeat, fever, a tingling feeling ("pins and needles"), shivering and difficulty passing urine. Some of the serious side effects include 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.

Ropibam

Active ingredient(s): *ropivacaine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ropibam. **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 Ropibam.**

Where to find information in this leaflet:

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

1. Why am I using Ropibam?

Ropibam contains the active ingredient ropivacaine hydrochloride which is a local anaesthetic.

It is injected into the body where it makes the nerves unable to pass messages to the brain.

Depending on the amount used, Ropibam will either totally stop pain or will cause a partial loss of feeling. Ropibam is used as an anaesthetic to stop the pain of surgery and/or to make childbirth less painful. It is also used after surgery to treat postoperative pain. Your doctor will have explained why you are being treated with Ropibam and told you what dose you will be given.

Your doctor may have prescribed this medicine for another reason. **Ask your doctor if you have any questions about why it has been prescribed for you.**

Ropibam is available only with a doctor's prescription.

Ropibam is not addictive.

2. What should I know before I am given Ropibam?

Warnings

You must not be given Ropibam if:

- you are allergic to ropivacaine hydrochloride, any other local anaesthetics, or any of the ingredients listed at the end of this leaflet.
- 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 injection.

Check with your doctor if you:

have had any medical conditions, especially the following:

- 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 possible risks and benefits of using Ropibam during pregnancy and breast-feeding.

If you have not told your doctor about any of the above, tell them before Ropibam is given to you.

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.

Tell any health professional who is prescribing a new medicine for you that you have been given Ropibam.

Some medicines and Ropibam may interfere with each other. These include:

- medicines that control your heartbeat
- medicines used to thin the blood, including aspirin
- low molecular weight heparin or other medicines used to prevent blood clots
- medicines used to treat depression, e.g. fluvoxamine and others
- 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.

The above medicines may be affected by Ropibam or may affect how well it works. You may need different amounts of Ropibam, or you may need to take different medicines. Your doctor and pharmacist have more information on

medicines to be careful with or avoid while using this medicine.

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

4. How is Ropibam 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 Ropibam 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

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

This will result in an area of numbness at or near the site of administration, or in an area that may seem unrelated to the site of administration. The latter will be the case if you are given an epidural injection (an injection around the spinal cord).

Ropibam should not be injected directly into the blood.

If you are given too much Ropibam

The doctor giving you Ropibam 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, or the dose is accidentally injected directly into your blood, you may develop problems with your sight or hearing, and get a numb feeling in or around 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.

If you think that you have used too much Ropibam, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given Ropibam?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Ropibam.

Driving or using machines

Be careful before you drive or use any machines or tools after you have been given Ropibam.

You may be drowsy, and your reflexes may be slow.

Drinking alcohol

Do not drink alcohol while you are being given Ropibam.

If you drink alcohol while you are being given Ropibam your blood pressure may drop, making you feel dizzy and faint.

Looking after your medicine

Ropibam will be stored by your doctor or pharmacist under the recommended storage conditions.

It should be kept in a cool dry place where the temperature stays below 25°C.

Getting rid of any unwanted medicine

Any Ropibam which has passed its expiry date, or is left in the container after use, 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
<ul style="list-style-type: none">• nausea (feeling sick)• vomiting• headache• dizziness• fever• a tingling feeling ("pins and needles")• shivering• difficulty passing urine• difficulty sleeping.	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>These side effects are usually mild.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">stiff or twitching musclespainful jointsdifficulty breathingextreme dizzinessirregular or slow heartbeatpain in the chestfits. On rare occasions you may lose consciousness.	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>You may need urgent medical attention.</p> <p>Serious side effects are rare.</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 Ropibam contains

Active ingredient (main ingredient)	ropivacaine hydrochloride <i>(refer to below description for strength & pack types)</i>
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">sodium chloridehydrochloric acid and sodium hydroxide (for pH adjustment)water for injections.

Ropibam does not contain lactose, sucrose, tartrazine or any other azo dyes.

Ropibam does not contain any preservatives.

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

What Ropibam looks like

Ropibam is a clear colourless solution for injection or infusion.

Ropibam 0.2%, 0.75% and 1% are available in 10 mL & 20 mL transparent polypropylene ampoules, each in a sterile plastic cover. A box contains 5 ampoules.

Ropibam 0.2% is also available in 100 mL & 200 mL transparent polypropylene infusion bags, each in a sterile plastic cover. A box contains 5 bags.

Australian Registration numbers:

Ropibam 0.2% (2 mg/mL) ampoules

10 mL: AUST R 186567

Ropibam 0.2% (2 mg/mL) ampoules

20 mL: AUST R 186566

Ropibam 0.2% (2 mg/mL) bags

100 mL: AUST R 186573

Ropibam 0.2% (2 mg/mL) bags

200 mL: AUST R 186571

Ropibam 0.75% (7.5 mg/mL) ampoules

10 mL: AUST R 186572

Ropibam 0.75% (7.5 mg/mL) ampoules

20 mL: AUST R 186569

Ropibam 1% (10 mg/mL) ampoules

10 mL: AUST R 186570

Ropibam 1% (10 mg/mL) ampoules

20 mL: AUST R 186568

Who distributes Ropibam

Boucher & Muir Pty Ltd
Level 9, 76 Berry Street
North Sydney NSW 2060

Distributed in NZ by:

BNM Group
39 Anzac Road
Browns Bay Auckland 0753

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