

# Ropivacaine ReadyfusOR

## 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 Ropivacaine ReadyfusOR?

Ropivacaine ReadyfusOR contains the active ingredient ropivacaine hydrochloride. Ropivacaine ReadyfusOR is used in adults after surgery to treat post-operative pain.

For more information, see Section [1. Why am I using Ropivacaine ReadyfusOR?](#) in the full CMI.

### 2. What should I know before I use Ropivacaine ReadyfusOR?

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

### 3. What if I am taking other medicines?

Some medicines may interfere with Ropivacaine ReadyfusOR 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 do I use Ropivacaine ReadyfusOR?

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 in the Ropivacaine ReadyfusOR 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 do I use Ropivacaine ReadyfusOR?](#) in the full CMI.

### 5. What should I know while using Ropivacaine ReadyfusOR?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using Ropivacaine ReadyfusOR.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Be careful before you drive or use any machines or tools until you know how Ropivacaine ReadyfusOR affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>Do not drink alcohol while you are fitted with the Ropivacaine ReadyfusOR.</li></ul>

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) 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), dizziness, irregular or slow heartbeat, a tingling feeling ("pins and needles"), difficulty sleeping (insomnia), fever, back pain, headache, vomiting, difficulty passing urine, pain in the chest, shivering.

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 ReadyfusOR

Active ingredient: ropivacaine hydrochloride

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Ropivacaine ReadyfusOR. **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 ReadyfusOR.**

**Where to find information in this leaflet:**

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

## 1. Why am I using Ropivacaine ReadyfusOR?

Ropivacaine ReadyfusOR contains a local anaesthetic called ropivacaine hydrochloride, which is already inside the dispenser. The local anaesthetic is injected into the body where it makes the nerves unable to pass messages to the brain.

Depending on the amount used, it will either totally stop pain or will cause a partial loss of feeling.

**Ropivacaine ReadyfusOR is used in adults after surgery to treat post-operative pain.**

Your doctor will have explained why you are being treated with ropivacaine hydrochloride and will have told you about the length of time you will be treated and the 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 hydrochloride, the medicine in Ropivacaine ReadyfusOR, is not addictive.

## 2. What should I know before I use Ropivacaine ReadyfusOR?

### Warnings

**Do not use Ropivacaine ReadyfusOR if:**

- you are allergic to:

- ropivacaine hydrochloride
- 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:**

- have any allergies to other substances
- 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)

It may not be safe for you to use Ropivacaine ReadyfusOR if you have any of these conditions.

- have any other medical condition
- take any medicines for any other condition

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 Ropivacaine ReadyfusOR during pregnancy and breastfeeding.

## 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 ReadyfusOR and affect how it works. 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
- 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 ReadyfusOR.**

#### 4. How do I use Ropivacaine ReadyfusOR?

##### How much to use

- Your doctor will have had a lot of experience using ropivacaine hydrochloride 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 used

- Ropivacaine ReadyfusOR should only be used by or under the supervision of doctors experienced in regional anaesthesia.
- **Refer to the Package Insert for detailed instructions for use of the Ropivacaine ReadyfusOR product.**
- The Ropivacaine ReadyfusOR is intended for single use only, and the dispenser should be discarded after single use.
- The medicine in the Ropivacaine ReadyfusOR will be injected by your doctor into the skin, near a single nerve, or into the skin, near a single nerve, or into an area which contains a large number of nerves. It may also be directed into the surgical incision after surgery by a tube.
- This will result in an area of numbness at or near the site of administration.
- The medicine in Ropivacaine ReadyfusOR is ropivacaine hydrochloride and it should not be injected directly into the blood.

##### If you use too much Ropivacaine ReadyfusOR

**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.

If you think that you have been given too much Ropivacaine ReadyfusOR, 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 using Ropivacaine ReadyfusOR?

##### Things you should do

Remind any doctor, dentist, nurse or pharmacist you visit that you are using Ropivacaine ReadyfusOR.

##### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Ropivacaine ReadyfusOR affects you.**

Ropivacaine ReadyfusOR may cause dizziness in some people.

##### Drinking alcohol

**Do not drink alcohol while you are fitted with the Ropivacaine ReadyfusOR.**

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

##### Getting rid of any unwanted medicine

**Ropivacaine ReadyfusOR is for single use only.**

The Ropivacaine ReadyfusOR will be disposed of in a safe manner by your doctor or nurse after you have used it, even if there is some ropivacaine hydrochloride solution left in the dispenser.

Ropivacaine ReadyfusOR will only be used if the solution is clear, the package is undamaged and the use by (expiry) date marked on the pack has not been passed.

#### 6. Are there any side effects?

Ropivacaine ReadyfusOR will help relieve pain in most people, but it may have some unwanted 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.

**Tell your doctor or a nurse as soon as possible if you do not feel well while you are fitted with Ropivacaine ReadyfusOR.**

## Less serious side effects

Less serious side effects	What to do
<b>Gut related</b> <ul style="list-style-type: none"><li>• Nausea (feeling sick)</li><li>• Vomiting</li></ul> <b>Brain and nervous system related</b> <ul style="list-style-type: none"><li>• Headache</li><li>• Dizziness</li><li>• A tingling feeling ("pins and needles")</li><li>• Shivering</li><li>• Difficulty sleeping</li><li>• Nervousness</li><li>• Decreased feeling or sensitivity, especially in the skin</li></ul> <b>Heart related</b> <ul style="list-style-type: none"><li>• Irregular or slow heartbeat</li></ul> <b>Urine related</b> <ul style="list-style-type: none"><li>• Difficulty passing urine</li></ul> <b>Other</b> <ul style="list-style-type: none"><li>• Fever</li><li>• Back pain</li></ul>	<b>Tell your doctor or a nurse if you notice any of these less serious side effects and they worry you.</b>

## Serious side effects

Serious side effects	What to do
<b>Heart related</b> <ul style="list-style-type: none"><li>• Slow heartbeat</li></ul> <b>Brain and nervous system related</b> <ul style="list-style-type: none"><li>• Extreme dizziness</li></ul> <b>Lung and upper airways</b> <ul style="list-style-type: none"><li>• Difficulty breathing</li></ul> <b>General</b> <ul style="list-style-type: none"><li>• Stiff or twitching muscles</li><li>• Painful joints</li><li>• Pain in the chest</li><li>• Fits</li><li>• Loss of consciousness</li></ul>	<b>Tel your doctor or a nurse immediately if you notice any of these serious side effects.</b>

**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](http://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 ReadyfusOR contains

<b>Active ingredient (main ingredient)</b>	Ropivacaine hydrochloride
<b>Other ingredients (inactive ingredients)</b>	Sodium chloride Hydrochloric acid or sodium hydroxide for pH adjustment Water for injections
<b>Potential allergens</b>	N/A

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

### What Ropivacaine ReadyfusOR looks like

Ropivacaine ReadyfusOR containing 250 mL of the 0.2% ropivacaine hydrochloride solution is presented in the pre-filled dispenser. The ropivacaine hydrochloride solution is clear and colourless. (AUST R 267572).

### Who distributes Ropivacaine ReadyfusOR

#### Sponsor:

BioQ Pharma Pty Ltd  
225 George Street  
Sydney, NSW 2000  
Australia

#### Distributor:

STADA Pharmaceuticals Australia Pty Ltd  
40-42 Scott Street  
Dandenong, VIC 3175  
Australia

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