

Ropivacaine ReadyfusOR

0.2% Ropivacaine Hydrochloride Solution for Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about the Ropivacaine ReadyfusOR, and the medicine inside the dispenser.

All medicines have risks and benefits. Your doctor will have weighed the risks of you using the Ropivacaine ReadyfusOR against the benefits they expect it will have for you.

If you have any concerns about using the medicine in this product, ask your doctor.

Keep this leaflet.

You may need to read it again.

What Ropivacaine ReadyfusOR is used for

Ropivacaine ReadyfusOR contains a local anaesthetic (anas-thet-ik) 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.

The 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.

Before you use Ropivacaine ReadyfusOR

When you must not use it

Ropivacaine ReadyfusOR must not be used if:

- 1. you have any allergies to**
 - any ingredient listed at the end of this leaflet
 - any other local anaesthetics
- 2. you have problems controlling your low blood pressure**
- 3. you have inflammation and/or an infection at the site of injection**

Before you start to use it

- You must tell your doctor if:
- 1. you have any allergies to other substances**
 - 2. 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)
- 3. you are pregnant, are breast feeding or intend to breast-feed.**

Your doctor will discuss the possible risks and benefits of using Ropivacaine ReadyfusOR during pregnancy and breast-feeding.

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

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.

Taking other medicines

You must tell your doctor if you are taking any other medicines, including

- 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
- medicines that you buy at the pharmacy, supermarket or health food shop.

These medicines may affect the way the ropivacaine hydrochloride in the Ropivacaine ReadyfusOR works.

Your doctor can tell you what to do if you are taking any of these medicines.

If you have not told your doctor about any of these things, tell them before you use the Ropivacaine ReadyfusOR.

Using the Ropivacaine ReadyfusOR

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 an area which contains a large number of nerves. It 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.

The medicine in Ropivacaine ReadyfusOR is ropivacaine hydrochloride and it should not be injected directly into the blood.

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.

Overdose

The doctor giving you ropivacaine hydrochloride will be experienced in the use of local anaesthetics, so it 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.

While you are using it

Things to be careful of

Be careful driving or operating machinery after use of the Ropivacaine ReadyfusOR.

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.

Please talk to your doctor about these possibilities if you think they may bother you.

Side effects

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

Ropivacaine hydrochloride will help relieve pain in most people, but it may have unwanted side-effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

You may need medical treatment if you get some of the side effects.

Ask your doctor to answer any questions you may have.

Tell your doctor or a nurse if you notice any of the following and they worry you:

- nausea (feeling sick)
- vomiting
- headache
- dizziness
- irregular or slow heart beat
- fever
- a tingling feeling ("pins and needles")
- shivering
- difficulty passing urine

These are all mild side effects of ropivacaine hydrochloride.

Tell your doctor or a nurse immediately if you notice any of the following:

- stiff or twitching muscles
- painful joints
- difficulty breathing
- extreme dizziness
- slow heart beat
- pain in the chest
- fits

On rare occasions you may lose consciousness.

These are all serious side effects.

You may need urgent medical attention.

Serious side effects are rare.

Some people may get other side effects while taking ropivacaine hydrochloride.

After using it

Ropivacaine ReadyfusOR is for single use only.

Disposal

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.

Product description

Ropivacaine ReadyfusOR: 0.2% Ropivacaine Hydrochloride Solution for Injection in the pre-filled dispenser. The ropivacaine hydrochloride solution is clear and colourless.

The active ingredient is ropivacaine hydrochloride, plus

- sodium chloride
- hydrochloric acid or sodium hydroxide for pH adjustment
- water for injections.

The product is presented as the Ropivacaine ReadyfusOR, containing 250 mL of the 0.2% ropivacaine hydrochloride solution for injection in the pre-filled dispenser.

Supplier

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

Australian registration number:

AUST R 267572

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