

Ropivacaine Kabi

Ropivacaine hydrochloride Solution for Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Ropivacaine Kabi. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Ropivacaine Kabi is used for

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.

Before you are given Ropivacaine Kabi

When you must not take it

Ropivacaine Kabi 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 take 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 Kabi during pregnancy and breast-feeding.

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

Ropivacaine Kabi 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 Ropivacaine Kabi works.

Your doctor or pharmacist 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 are given Ropivacaine Kabi.

Using Ropivacaine Kabi

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.

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).

Ropivacaine Kabi should not be injected directly into the blood.

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.

Overdose

The doctor giving you Ropivacaine Kabi 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 Kabi, 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 being given Ropivacaine Kabi

Things to be careful of

Be careful driving or operating machinery after you have been given Ropivacaine Kabi.

You may be drowsy and your reflexes may be slow.

Do not drink alcohol while you are being given Ropivacaine Kabi.

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

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

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ropivacaine Kabi.

Ropivacaine Kabi 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 or pharmacist to answer any questions you may have.

Tell your doctor 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 Kabi.

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.

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may get other side effects while taking Ropivacaine Kabi.

This leaflet was updated in Feb, 2016.

After using Ropivacaine Kabi

Storage

Ropivacaine Kabi 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.

Disposal

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.

Product Description

What it looks like

Ropivacaine Kabi (ropivacaine hydrochloride solution for injection) is a clear colourless, sterile and isotonic ready-to-use solution for injection.

The solution is filled into 100 mL or 250 mL (filling volume 200 mL) polyolefin bags (freeflex®) or into 10 mL or 20 mL polypropylene ampoules (Ovalia).

Ingredients

The active ingredient is ropivacaine hydrochloride.

Excipients:

- Sodium chloride
- Hydrochloric acid (for pH adjustment)
- Sodium hydroxide (for pH adjustment)
- Water for injections

Sponsor

Supplied in Australia by:

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way
Mount Kuring-gai NSW 2080
Australia
Telephone: (02) 9391 5555

Supplied in New Zealand by:

Fresenius Kabi New Zealand Limited
60 Pavilion Drive
Airport Oaks, Auckland
New Zealand
Freecall: 0800 144 892

Australian Registration Numbers

- 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

® = Registered Trademark