ROPIVACAINE PFIZER®

Ropivacaine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ROPIVACAINE PFIZER.

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 using Ropivacaine Pfizer against the benefits it is expected to 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 PFIZER is used for

ROPIVACAINE PFIZER is a local anaesthetic (an-a-set-ik). It is injected into the body where it makes the nerves unable to pass messages to the brain. Depending on the amount used, ROPIVACAINE PFIZER will either totally stop pain or will cause a partial loss of feeling.

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

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

Your doctor will have explained why you are being treated with ROPIVACAINE PFIZER 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 PFIZER is not addictive.

Before you are given ROPIVACAINE PFIZER

When you must not use it

ROPIVACAINE PFIZER 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 PFIZER during pregnancy and breastfeeding.

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

ROPIVACAINE PFIZER 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.

Some medicines may affect the way ROPIVACAINE PFIZER 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 any ROPIVACAINE PFIZER.

Using ROPIVACAINE PFIZER

How it will be given

ROPIVACAINE PFIZER 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 PFIZER 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 case if you are given an EPIDURAL injection (an injection around the spinal cord).

ROPIVACAINE PFIZER 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 PFIZER or other local anaesthetics and will choose the best dose for you. They will be willing to discuss this decision with you.

If you take too much (overdose)

The doctor giving you ROPIVACAINE PFIZER 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 PFIZER, 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 it

Things to be careful of

Be careful driving or operating machinery after you have been given ROPIVACAINE DELIZED

You may be drowsy and your reflexes may be

Do not drink alcohol while you are being given ROPIVACAINE PFIZER.

If you drink alcohol while you are being given ROPIVACAINE PFIZER 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 being given ROPIVACAINE PFIZER.

ROPIVACAINE PFIZER 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 PFIZER.

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

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 being given ROPIVACAINE PFIZER.

After being given ROPIVACAINE PFIZER

Storage

ROPIVACAINE PFIZER 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 30°C.

Disposal

Any ROPIVACAINE PFIZER 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 PFIZER is a clear colourless solution for injection or infusion.

Ingredients

ROPIVACAINE PFIZER contains 2.0 mg/mL ropivacaine hydrochloride as the active ingredient.

It also contains:

- sodium chloride
- hydrochloric acid
- · sodium hydroxide
- · water for injections

Ropivacaine Pfizer 200 mg solution for infusion is presented in 100 mL bags with 200 mg of ropivacaine hydrochloride; pack of 5.

Ropivacaine Pfizer 400 mg solution for infusion is presented in 200 mL bags with 400 mg of ropivacaine hydrochloride; pack of 5.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

ROPIVACAINE PFIZER is supplied in Australia by

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Australia

Toll Free number: 1800 675 229

Australian Registration Numbers

 ROPIVACAINE PFIZER 400 mg/200 mL hag.

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ROPIVACAINE PFIZER 200 mg/100 mL

AUST R 206687

Date of preparation

This leaflet was prepared in October 2014.