

Ropibam

Solution for injection 0.2%, 0.75% and 1%

Ropivacaine hydrochloride

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you are given Ropibam.

This leaflet answers some common questions about Ropibam. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.ebs.tga.gov.au.

Reading this leaflet 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 Ropibam against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may want to read it again.

What Ropibam is used for

Ropibam contains 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 post-

operative 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.

Before you are given Ropibam

Ropibam is not suitable for everyone.

When you must not be given it

Ropibam must not be given if you:

- are allergic to any medicine containing ropivacaine, any other local anaesthetics, or any of the ingredients listed at the end of this leaflet
- have problems controlling your low blood pressure
- have inflammation and/or an infection at the site of injection.

Ropibam must not be used after the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering. The solution must be clear before use.

If you are not sure whether you should be given Ropibam, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or 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).

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

Tell your doctor if you are pregnant, are breast-feeding or intend to breast-feed.

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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 heart beat
- 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.

How Ropibam is given

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.

How much will be 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.

While you are being given it

Things to be careful of

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

You may be drowsy and your reflexes may be slow.

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.

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

In case of overdose

If you are given too much

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

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.

Immediately tell your doctor if you think that you or anyone else may have been given too much Ropibam.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are being given Ropibam.

Like all medicines, Ropibam may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor to answer any questions you may have.

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

- nausea (feeling sick)
- vomiting
- headache
- dizziness
- fever
- a tingling feeling ("pins and needles")
- shivering
- difficulty passing urine
- difficulty sleeping.

These side effects are usually mild.

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

- stiff or twitching muscles
- painful joints
- difficulty breathing
- extreme dizziness
- irregular or 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.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After being given it

Storage

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.

Disposal

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.

Product description

What it 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.

Ingredients

Active ingredient:

- ropivacaine hydrochloride

Inactive ingredients:

- sodium chloride
- hydrochloric 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.

Ropibam 1% (10 mg/mL) ampoules 10 mL:

AUST R 186570

Ropibam 1% (10 mg/mL) ampoules 20 mL:

AUST R 186568

Date of preparation

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Sponsor details

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North Sydney NSW 2060

Distributed in NZ by:

BNM Group

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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