

Ropivacaine Actavis

Solution for injection

contains the active ingredient ropivacaine hydrochloride

Consumer Medicine Information

(Injection solutions for the production of local or regional anaesthesia)

NOT FOR INTRAVENOUS ADMINISTRATION UNDER ANY CIRCUMSTANCES

What is in this leaflet

This leaflet answers some common questions about ROPIVACAINE ACTAVIS.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

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

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

Keep this leaflet with your medicine. You may need to read it again.

What ROPIVACAINE ACTAVIS is used for

ROPIVACAINE ACTAVIS is a local anaesthetic (ana-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 ACTAVIS will either totally stop pain or will cause a partial loss of feeling.

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

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

Your doctor may have prescribed ROPIVACAINE ACTAVIS for another reason. Ask your doctor if you have any questions about why ROPIVACAINE ACTAVIS has been prescribed for you.

ROPIVACAINE ACTAVIS is available only with a doctor's prescription.

There is no evidence that ROPIVACAINE ACTAVIS is addictive.

Before you are given ROPIVACAINE ACTAVIS

When you must not use it

Do not use ROPIVACAINE ACTAVIS if you are allergic to medicines containing ropivacaine or any other local anaesthetics or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not use ROPIVACAINE ACTAVIS if you have:

- problems controlling your low blood pressure
- inflammation and/or an infection at the site of injection

Do not use ROPIVACAINE ACTAVIS if the expiry date (Exp.) printed on the pack has passed.

Do not use ROPIVACAINE ACTAVIS if the packaging is torn or shows signs of tampering.

Before you start to use it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking ROPIVACAINE ACTAVIS during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking ROPIVACAINE ACTAVIS when breastfeeding.

Tell your doctor if you have, any medical conditions, especially the following:

- problems with your blood pressure or circulation
- blood poisoning
- problems with 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)

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you start using ROPIVACAINE ACTAVIS.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by ROPIVACAINE ACTAVIS, or may affect how well it works. 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
- fluvoxamine, a medicine used to treat bacterial infections
- enoxacin, a medicine used to treat fungal infections
- cimetidine, a medicine used to treat stomach ulcers or heartburn
- medicines for depression

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

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using ROPIVACAINE ACTAVIS.

Using ROPIVACAINE ACTAVIS

How it will be given

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

Follow all directions given to you by your doctor and pharmacist carefully.

Overdose

The doctor giving you NAROPIN 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 ACTAVIS, 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 ACTAVIS

Things to be careful of

Be careful driving or operating machinery until you know how ROPIVACAINE ACTAVIS affects you.

ROPIVACAINE ACTAVIS may cause drowsiness, dizziness or lightheadedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

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

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

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

You may not experience any of them.

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 ACTAVIS.

Tell your doctor or 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.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using ROPIVACAINE ACTAVIS

Storage

ROPIVACAINE ACTAVIS 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 ACTAVIS 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 ACTAVIS is a clear colourless solution for injection or infusion.

ROPIVACAINE ACTAVIS comes in 4 strengths of concentrated solutions for injection:

- ROPIVACAINE ACTAVIS 0.2% w/v - clear concentrated solution, available as 20mg/10mL, 40mg/20mL polypropylene ampoules in blisters and 200mg/100mL, 400mg/200mL polypropylene bags in Medipeel pouches.
- ROPIVACAINE ACTAVIS 0.5% w/v - clear concentrated solution, available as 50mg/10mL and 100mg/20mL polypropylene ampoules in blisters.

- ROPIVACAINE ACTAVIS 0.75% w/v - clear concentrated solution, available as 75mg/10mL and 150mg/20mL polypropylene ampoules in blisters.
- ROPIVACAINE ACTAVIS 1.0% w/v - clear concentrated solution, available as 100mg/10mL and 200mg/20mL polypropylene ampoules in blisters.

Ingredients

The active ingredient in ROPIVACAINE ACTAVIS is ropivacaine hydrochloride.

- Each ROPIVACAINE ACTAVIS 0.2% w/v concentrated solution contains 2.0mg/mL of ropivacaine hydrochloride,
- ROPIVACAINE ACTAVIS 0.5% w/v concentrated solution contains 5.0mg/mL of ropivacaine hydrochloride,
- ROPIVACAINE ACTAVIS 0.75% w/v concentrated solution contains 7.5mg/mL of ropivacaine hydrochloride and
- ROPIVACAINE ACTAVIS 1.0% w/v concentrated solution contains 10.0mg/mL of ropivacaine hydrochloride.

The concentrated solution for injection also contains:

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

Supplier

Actavis Australia Pty Ltd

Upper Ground Floor
183 Melbourne Street
North Adelaide SA 5006
Australia
Tel: 1300 881 893



Australian Registration Numbers:

ROPIVACAINE ACTAVIS 0.2% w/v - AUST R 190558, 190541, 190549, 190561
ROPIVACAINE ACTAVIS 0.5% w/v - AUST R 190547, 190538
ROPIVACAINE ACTAVIS 0.75% w/v - AUST R 190540, 190568
ROPIVACAINE ACTAVIS 1.0% w/v - AUST R 190531, 190537

Date of preparation:
February 2013.