Package Leaflet: Information For The Patient
ROPIVACAINE READYFUSOR
Ropivacaine Hydrochloride 0.2% Solution for Injection
bottle in dispenser device (infusion pump)
Ropivacaine Hydrochloride Monohydrate

Read all of this leaflet carefully before this medicine is given to you because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in the leaflet. See section 4.

What is in this leaflet

1. What Ropivacaine Hydrochloride 0.2% is and what it is used for

The name of your medicine is "Ropivacaine Hydrochloride 0.2% Solution for Injection, bottle in dispenser device (infusion pump)". It contains an active substance called ropivacaine hydrochloride monohydrate. It belongs to a group of medicines called local anaesthetics. Ropivacaine Hydrochloride 0.2% is used in adults for acute pain management. It numbs (anaesthetises) parts of the body, e.g. after surgery.

2. What you need to know before Ropivacaine Hydrochloride 0.2% is given to you.

You must not be given Ropivacaine Hydrochloride 0.2%:
- If you are allergic to ropivacaine hydrochloride monohydrate or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to any other local anaesthetics of the same class (such as lidocaine or bupivacaine).
- If you have been told that you have decreased volume of blood (hypovolaemia).
- Into a blood vessel, spine, or joint to numb a specific area of your body, or into the neck of the womb to relieve pain during childbirth.

If you are not sure if any of the above applies to you, talk to your doctor before you are given Ropivacaine Hydrochloride 0.2%.

Warnings and precautions

Talk to your doctor or nurse before Ropivacaine Hydrochloride 0.2% is given to you, especially:
- If you have heart, liver or kidney problems.
- If you have ever been told that you have a rare disease of the blood pigment called "porphyria" or if anyone in your family has it, because your doctor may need to give you a different medicine.
- If you have any diseases or medical conditions.

Other medicines and Ropivacaine Hydrochloride 0.2%

Tell your doctor if you are taking, or have recently taken any other medicines. This is because Ropivacaine Hydrochloride 0.2% can affect the way some medicines work and some medicines can have an effect on Ropivacaine Hydrochloride 0.2%.
In particular, tell your doctor if you are taking any of the following medicines:
- Other local anaesthetics.
- Strong pain killers, such as morphine or codeine.
- Drugs used to treat an uneven heart beat (arrhythmia), such as lidocaine and mexiletine.

Your doctor needs to know about these medicines to be able to assess if Ropivacaine Hydrochloride 0.2% may be administered to you. Also tell your doctor if you are taking any of the following medicines:
- Medicines to treat depression (such as fluvoxamine)
- Antibiotics to treat infections caused by bacteria (such as enoxacin).

This is because your body takes longer to get rid of Ropivacaine Hydrochloride 0.2% if you are taking these medicines.
If you are taking either of these medicines, prolonged use of Ropivacaine Hydrochloride 0.2% should be avoided.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.
It is not known if ropivacaine hydrochloride affects pregnancy or passes into breast milk.
As a precautionary measure, it is preferable to avoid the use of Ropivacaine Hydrochloride 0.2% during pregnancy.
Breast-feeding should be temporarily interrupted during treatment with Ropivacaine Hydrochloride 0.2%. The milk should be pumped and discarded for this period.

Driving and using machines

Ropivacaine Hydrochloride 0.2% may make you feel sleepy and affect the speed of your reactions. After you have been given Ropivacaine Hydrochloride 0.2% you should not drive or use tools or machines until the next day.

Ropivacaine Hydrochloride 0.2% contains sodium

Ropivacaine Hydrochloride 0.2% contains up to 3.7 milligrams (mg) of sodium in each millilitre (ml) of solution. If you are on a sodium controlled diet you will need to take this into account.

3. How Ropivacaine Hydrochloride 0.2% is given to you

Ropivacaine Hydrochloride 0.2%will be given to you by a doctor.
Ropivacaine Hydrochloride 0.2%will be given to you as an infusion to reduce pain after surgery. During surgery, your doctor will place a tube in the wound, which can be connected to the so called "ROPIVACAINE READYFUSOR".
The ROPIVACAINE READYFUSOR is a dispensing device that contains the solution for infusion and has a tube permanently connected to it that can be attached to the tube in the wound.
Your doctor or nurse will activate the ROPIVACAINE READYFUSOR and connect it to the tube in the wound.
You will not need to do anything to the ROPIVACAINE READYFUSOR.
After its activation the ROPIVACAINE READYFUSOR will continuously administer a defined dose of the active substance, sufficient for the relief of your pain.

Warnings
- Kinking of the tube must be avoided.
- Do not place tight wrappings around the tube.
- Do not use the ROPIVACAINE READYFUSOR if any part has been damaged or cracked, or if the port on the tubing appears broken, cracked, or damaged in any way.
- Do not reconnect the ROPIVACAINE READYFUSOR, if it is accidentally disconnected from the tubing during medication delivery, as this may cause an infection. Contact your doctor or nurse to let them know that the ROPIVACAINE READYFUSOR has disconnected.
- Do not bathe or shower with the ROPIVACAINE READYFUSOR, or while the tubing is still in place under your skin, as this could cause an infection.
- Do not tamper with the wound dressings or with the tubing under your skin as this could cause an infection.

If you have been given too much Ropivacaine Hydrochloride 0.2%

As the ROPIVACAINE READUFSOR continuously administers a defined dose of the active substance, serious side effects from getting too much Ropivacaine Hydrochloride 0.2% are very unlikely.
Should the dose be too high, you will need special treatment and the doctor treating you is trained to deal with these situations.
The first signs of being given too much Ropivacaine Hydrochloride 0.2% are usually as follows:
- Feeling dizzy or light-headed.
- Numbness of the lips and around the mouth.
- Numbness of the tongue.
- Hearing problems.
- Problems with your sight (vision).

To reduce the risk of serious side effects, your doctor will stop the administration of Ropivacaine Hydrochloride 0.2% as soon as these signs appear. This means that if any of these happen to you, or you think you have received too much Ropivacaine Hydrochloride 0.2% **tell your doctor immediately.**
If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Important side effects to look out for

Sudden life-threatening allergic reactions (such as anaphylaxis) are rare, affecting 1 to 10 users in 10,000. Possible symptoms include sudden onset of rash, itching or lumpy rash (hives); swelling of the face, lips, tongue or other parts of the body; and shortness of breath, wheezing or difficulty breathing. **If you think that Ropivacaine Hydrochloride 0.2% is causing an allergic reaction, tell your doctor immediately.**

Other possible side effects

Very common *(may affect more than 1 in 10 people)*
- Low blood pressure (hypotension). This might make you feel dizzy or light-headed.
- Feeling sick (nausea).

Common *(may affect up to 1 in 10 people)*
- Pins and needles.
- Feeling dizzy.
- Headache.
- Slow or fast heart beat (bradycardia, tachycardia).
- High blood pressure (hypertension).
- Being sick (vomiting).
- Difficulty in passing urine.
- High temperature (fever) or shivering (chills).
- Back pain.

Uncommon *(may affect up to 1 in 100 people)*
- Anxiety.
- Decreased sensitivity or feeling in the skin.
- Fainting.
- Difficulty breathing.
- Low body temperature (hypothermia).
- Some symptoms can happen if you have been given too much Ropivacaine Hydrochloride 0.2% (see also "If you have been given too much Ropivacaine Hydrochloride 0.2%" above). These include fits (seizures), feeling dizzy or light-headed, numbness of the lips and around the mouth, numbness of the tongue, hearing problems, problems with your sight (vision), problems with your speech, stiff muscles, and trembling.

Rare *(may affect up to 1 in 1,000 people)*
- Heart attack (cardiac arrest).
- Uneven heart beat (arrhythmias).

Not known *(cannot be estimated from the available data)*
- Involuntary muscle movements (dyskinesia).

Possible side effects seen with other local anaesthetics which might also be caused by Ropivacaine Hydrochloride 0.2%

Rare *(may affect up to 1 in 1,000 people)*
- Damaged nerves. This may cause permanent problems.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ropivacaine Hydrochloride 0.2%

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the label after "EXP". The expiry date refers to the last day of that month.
This medicinal product should be stored below 30°C.
Your doctor or the hospital will normally store Ropivacaine Hydrochloride 0.2% and they are responsible for the quality of the product. The medicinal product should be visually inspected prior to use. The solution should only be used if it is clear, practically free from particles and if the container is undamaged.
They are also responsible for disposing of any unused Ropivacaine Hydrochloride 0.2% correctly.

6. Contents of the pack and other information

What Ropivacaine Hydrochloride 0.2% Contains
- The active substance is ropivacaine hydrochloride monohydrate. Each ml contains 2 mg ropivacaine hydrochloride monohydrate.
- The other ingredients are sodium chloride, sodium hydroxide solution or hydrochloric acid for pH adjustment, and water for injections.

What Ropivacaine Hydrochloride 0.2% looks like and contents of the pack

Ropivacaine Hydrochloride 0.2% is a clear, colourless solution for infusion.
The ROPIVACAINE READYFUSOR is an orange cylinder with black caps on each side. The ROPIVACAINE READYFUSOR is designed to contain a transparent HDPE bellows bottle with 250 ml ropivacaine hydrochloride monohydrate solution for infusion. A latex free tube with Luer lock fitting is permanently connected to the ROPIVACAINE READYFUSOR.
There are three presentations of the pack: without catheter, with 6.5cm catheter and with 15cm catheter. Each pack contains one ROPIVACAINE READYFUSOR and a carrying pouch. A pack may also include a latex free fenestrated catheter for placement (6.5cm or 15cm) in the wound

Marketing Authorisation Holder	**Manufacturer of Dosage Form**	**Batch Release Site**
BioQ Pharma Pty Ltd Sydney, Australia	Holopack Verpackungstechnik GmbH Bahnhofstrasse 20b 73453 Abtsgemünd-Untergröningen Germany	Geryon Pharma Limited 18 Owen Drive Liverpool L24 1YL United Kingdom

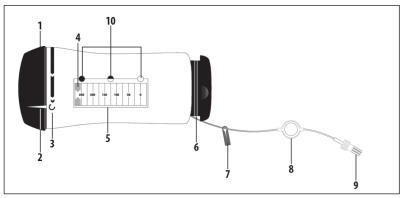
This leaflet was last revised in Feb. 2019.

The following information is intended for healthcare professionals only:

Ropivacaine Hydrochloride 0.2% is preservative-free and is intended for single use only.
The solution should be visually inspected prior to use. The solution should only be used if it is clear, practically free from particles and if the container is undamaged.

The ROPIVACAINE READYFUSOR

The ROPIVACAINE READYFUSOR is a non-electric medication dispenser that has been designed for point of care use. All materials needed for the administration of the medicinal product are included.
The ROPIVACAINE READYFUSOR contains a bellows bottle with 250 ml ropivacaine hydrochloride monohydrate solution for infusion. A tube with luer lock fitting is permanently connected. A sterile fenestrated catheter for placement in the wound is enclosed in the package. Both, the tube with luer lock fitting as well as the sterile fenestrated catheter are latex free.
During surgery, a fenestrated catheter should be placed in the wound. The catheter uniformly distributes Ropivacaine Hydrochloride 0.2% along the length of the wound in a 360° radius.
The ROPIVACAINE READYFUSOR contains a fluid indicator that allows determination of the amount of fluid that remains during the delivery regimen.



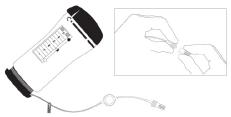
1. Device cap
2. Indicator arrow
3. ON position
4. Monitor arrows
5. Fluid indicator window
6. Tubing line
7. Line clamp
8. Filter
9. Tubing line cap
10. Circular indicators

Instruction for use

1. Remove the tamper proof seal from the dispenser. If the seal has been removed or compromised, do not use this dispenser.

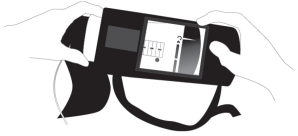
2. Initiate fluid delivery by turning the device cap (1) clockwise until the indicator arrow (2) is aligned with the ON position (3). Fluid delivery has begun when the green monitor arrows (4) become visible in the fluid indicator window (5).
Note: a slight jump may occur due to the activating mechanism.

3. Uncap the tubing line cap (9) and ensure that the device has been initiated by observing fluid flowing through the tubing line. Fluid flow can be seen upstream of the filter (8) within a few seconds. It may take several minutes for the fluid to be seen at the terminus of the tubing line.

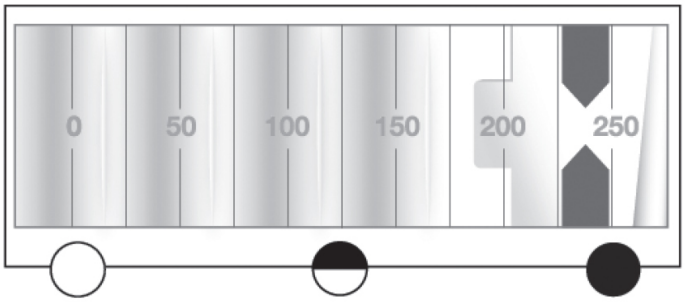


4. Connect the tubing line (6) of the dispenser to the patient's port.

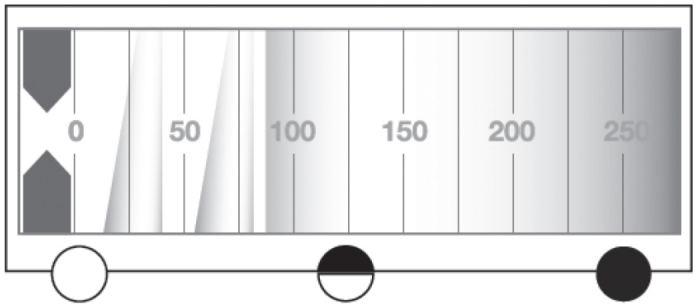
5. Place the dispenser in the carrying pouch provided. The carrying pouch may either be attached to the patient as a sling around the shoulder or around the waist as a belt.



6. Fluid delivery can be observed through the fluid indicator window (5) of the dispenser. The dispenser will deliver approximately 5 ml of fluid.
   The green monitor arrows (4) in the fluid indicator window show the volume remaining (in ml) in the dispenser.
   Fluid can also be monitored by the circular indicators (10) where the closed circle indicates a full dispenser and an open circle indicates an empty dispenser.
   Monitor the fluid indicator periodically for excessive flow rate. For symptoms of an overdose see section 4.



7. Delivery is completed when the unit is empty, as shown by the location of the green monitor arrows (4) in the fluid indicator window.



8. Remove the dispenser from the patient after delivery is complete.
9. Discard the empty Ropivacaine Readyfusor, including any unused solution, after use.

Warnings

- The Ropivacaine Readyfusor is only intended for single use. Do not reuse or reconnect the Ropivacaine Readyfusor.
- The Ropivacaine Readyfusor must not be autoclaved. The fluid path in the dispensing system has been sterilized.
- Kinking of the tube must be avoided, as otherwise the maintenance of the peripheral block of the nerve cannot be warranted and re-institution of the block will require the repeated administration of ropivacaine 7.5 mg/ml.
- No tight wrappings should be placed around the tube.
- The Ropivacaine Readyfusor should not be used if any part has been damaged or cracked, or if the port on the tubing appears broken, cracked, or damaged in any way.
- The Ropivacaine Readyfusor should not be reconnected if it is accidentally disconnected from the tubing during medication delivery, as this may cause an infection.
- The patient should not bathe or shower with the Ropivacaine Readyfusor, or while the tubing is still in place under the skin, as this could cause an infection.
- The patient should not tamper with the wound dressings or with the tubing under the skin as this could cause an infection.