Package leaflet: Information for the patient

Ropivacaine Readyfusor 10 mg/h solution for infusion in administration system

Ropivacaine hydrochloride

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, pharmacist 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ropivacaine Readyfusor is and what it is used for

The name of your medicine is Ropivacaine Readyfusor 10 mg/h solution for infusion in administration system. It contains an active substance called ropivacaine hydrochloride. It belongs to a group of medicines called local anaesthetics.

Ropivacaine Readyfusor is used for acute, postoperative pain management in adults. It numbs (anaesthetises) parts of the body.

2. What you need to know before Ropivacaine Readyfusor is given to you

You must not be given Ropivacaine Readyfusor:
- If you are allergic to ropivacaine hydrochloride 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 decreased volume of blood (hypovolaemia).
- Into a blood vessel, 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 Readyfusor.

Warnings and precautions
Talk to your doctor before Ropivacaine Readyfusor 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.

Ropivacaine Readyfusor should not be given into the spine or a joint.

Other medicines and Ropivacaine Readyfusor
Tell your doctor if you are taking, or have recently taken, any other medicines. This is because Ropivacaine Readyfusor can affect the way some medicines work and some medicines can have an effect on Ropivacaine Readyfusor.

In particular, tell your doctor if you are using any of the following medicines:
- Other local anaesthetics.
- Strong pain killers, such as morphine or codeine.
- Medicines 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 Readyfusor 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 Readyfusor if you are taking these medicines.

If you are taking either of these medicines, prolonged use of Ropivacaine Readyfusor 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 this medicine is given to you.

It is not known if ropivacaine hydrochloride affects pregnancy or passes into breast milk.

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

Ropivacaine Readyfusor contains sodium
This medicine contains 3.4 mg of sodium (main component of cooking/table salt) in each millilitre (ml) of solution. This is equivalent to 0.17 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Ropivacaine Readyfusor

Ropivacaine Readyfusor will be given to you by a doctor.

For postoperative pain management, Ropivacaine Readyfusor will be given to you as an infusion into the surrounding of a nerve (perineurally).

The ReadyfusOR administration system is an administration system that contains the solution for infusion and has a tubing line with connector permanently attached to it that can be connected to a port near the nerve site.

Your doctor or nurse will activate the administration system and connect it to a port near the nerve site. You will not need to do anything to the administration system.

After its activation the administration system will continuously administer a defined dose of the active substance, sufficient for the relief of your pain.

Warnings
- Kinking of the tubing line must be avoided as this could result in an improper fluid delivery rate.
- Do not place tight wrappings around the tubing line.
- Do not use the administration system if any part has been damaged or cracked, or if the connector on the tubing line appears broken, cracked, or damaged in any way.
- The flow restrictor (clear rectangle) must remain taped to your skin. Removing the tape or allowing the flow restrictor to lose contact with your skin may result in an improper fluid delivery rate.
- Do not place hot or cold packs over the flow restrictor as this could result in an improper fluid delivery rate.
- Do not reconnect the administration system, if it is accidentally disconnected from the port during medicine delivery, as this may cause an infection. Contact your doctor or nurse and let them know the administration system has become disconnected.
- Do not bathe or shower with the administration system, or while the port is still in place, as this could cause an infection.
- Do not tamper with the wound dressings or with the port as this could cause an infection.

If you have been given too much Ropivacaine Readyfusor
As the administration system continuously administers a defined dose of the active substance, serious side effects from getting too much Ropivacaine Readyfusor 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 Readyfusor 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 Readyfusor 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 Readyfusor, **tell your doctor immediately**.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist 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, including anaphylactic shock) are rare (may affect up to 1 in 1,000 people). Possible symptoms include sudden onset of rash, itching or lumpy rash (hives); swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or difficulty breathing; a feeling of loss of consciousness. **If you think that Ropivacaine Readyfusor 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 heartbeat (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 Readyfusor (see also "If you have been given too much Ropivacaine Readyfusor" 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 Readyfusor

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ropivacaine Readyfusor

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.

Do not refrigerate.

Your doctor or the hospital will normally store Ropivacaine Readyfusor and they are responsible for the quality of this medicine. This medicine 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 Readyfusor correctly.

6. Contents of the pack and other information

What Ropivacaine Readyfusor contains

- The active substance is ropivacaine hydrochloride.
  1 ml solution for infusion contains ropivacaine as ropivacaine hydrochloride monohydrate, equivalent to 2 mg ropivacaine hydrochloride.
  1 bottle of 250 ml solution for infusion contains ropivacaine as ropivacaine hydrochloride monohydrate, equivalent to 500 mg ropivacaine hydrochloride.
  The administration system delivers a flow rate of approximately 5 ml/h, equivalent to 10 mg/h, over a maximum of 48 hours.
- The other ingredients are sodium chloride, sodium hydroxide solution 4 % and/or hydrochloric acid 3.6 % (for pH adjustment) and water for injections.

What Ropivacaine Readyfusor looks like and contents of the pack

Ropivacaine Readyfusor is a clear, colourless solution for infusion.

The administration system (ReadyfusOR) contains a translucent high-density polyethylene (HDPE) bottle with 250 ml solution for infusion. The administration system is an orange cylinder with black caps on each side. A tubing line with connector (Luer or NRFit lock) is permanently attached to it.

Each pack contains one ReadyfusOR and a carrying pouch.

Marketing Authorisation Holder

BioQ Pharma B.V.
Basisweg 10
1043 AP Amsterdam
Netherlands

Manufacturer

BioQ Pharma B.V.
Basisweg 10
1043 AP Amsterdam
Netherlands

Copea Pharma Europe Limited
Unit 2, Medici House, Ashbourne Manufacturing Park
Ashbourne, Co. Meath A84 KH58
Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Bulgaria	Ropivacaine ReadyfusOR 10 mg/h Инфузионен разтвор в система за прилагане
Estonia	Ropivacaine ReadyfusOR 10 mg/h Infusioonilahus manustamissüsteemis
Germany	Ropivacain BioQ Pharma ReadyfusOR 10 mg/Stunde Infusionslösung in einem Applikationssystem
Ireland	Ropivacaine Readyfusor 10 mg/h solution for infusion in administration system
Latvia	Ropivacaine ReadyfusOR 10 mg/h Šķīdums infūzijām ievadīšanas sistēmā
Lithuania	Ropivacaine ReadyfusOR 10 mg/h Infuzinis tirpalas įleidimo sistemoje
Romania	Ropivacaină BioQ Pharma ReadyfusOR 10 mg/oră soluţie perfuzabilă in sistem de administrare
Slovenia	Ropivakain Readyfusor 10 mg/h raztopina za infundiranje v sistemu za aplikacijo zdravila

This leaflet was last revised in 04/2025.

The following information is intended for healthcare professionals only:

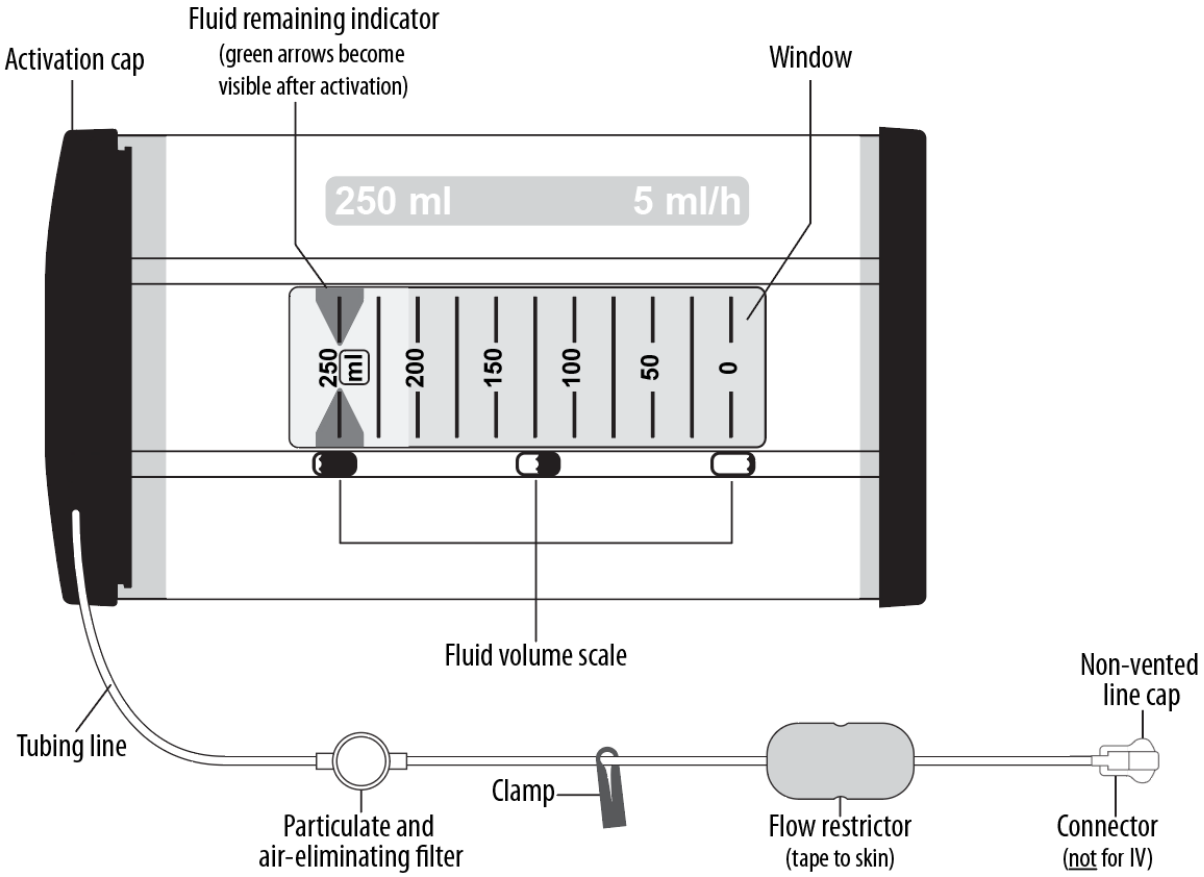
Ropivacaine Readyfusor is intended for single use only.

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.

<u>The administration system (ReadyfusOR)</u>
The ReadyfusOR is a non-electric medicinal product administration system that has been designed for point of care use. All materials needed for the administration of the medicinal product are included.

The fluid remaining indicator is a set of green arrows that indicates the amount of fluid which remains to be delivered.

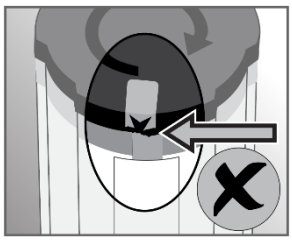
As the flow rate of 5 ml/h is sensitive to temperature deviations, the administration system should be used under ambient temperature conditions, and the flow restrictor should remain taped in contact with the patient's skin at all times.



<u>Instructions for use</u>

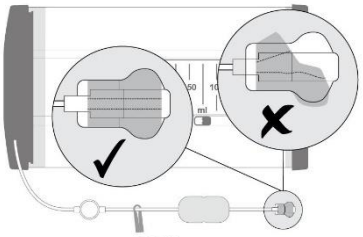
1. Inspect the administration system, flow restrictor, and tubing line for damage or tampering.

   ☐ Verify that the orange sticker seal on the activation cap is intact.

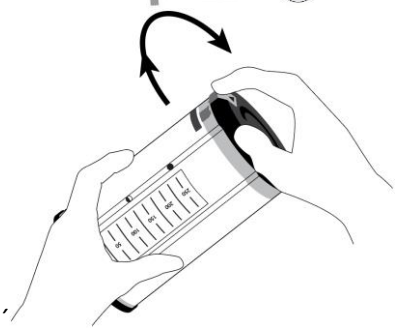


☐ Verify that the orange tamper seal over the line cap is intact.

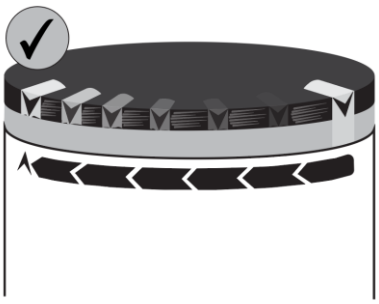
If damage is observed, or either seal has been removed or compromised, do not use this administration system.



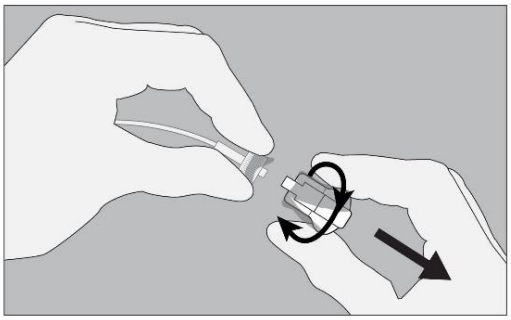
2. Initiate fluid delivery by turning the activation cap clockwise until the arrow on the orange sticker seal roughly lines up with the arrow on the label. High force is required. This is normal and prevents accidental activation. Parts inside the administration system will move during activation.



The administration system is activated when the green fluid remaining indicator arrows become visible in the window. Fluid flow can be seen upstream of the filter within seconds, but flow will stop until the non-vented cap is removed.



3. Twist off the tubing line cap to break the tamper seal.

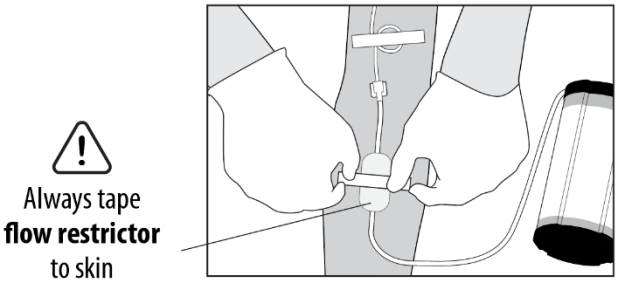


Check that the clamp is not engaged and ensure that fluid delivery has started by observing fluid flowing through the tubing line and the flow restrictor.

After 1 – 2 minutes, fluid will start to drip very slowly from the end of the tubing line.

4. Connect the tubing line of the administration system to the patient's port. **Do not connect to an IV line.**

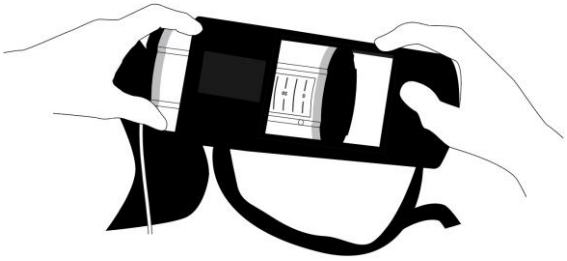
5. Tape the flow restrictor (clear rectangle) to the patient's skin. Apply tape directly over the flow restrictor as shown, away from the wound site, and make sure you do not pull at the tubing line or disturb the port placement. Finally, secure tubing line and connections with tape.



Warning: The flow restrictor must remain taped in contact with the patient's skin. If it loses contact, an improper fluid delivery rate may result.

6. Place the administration system 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.

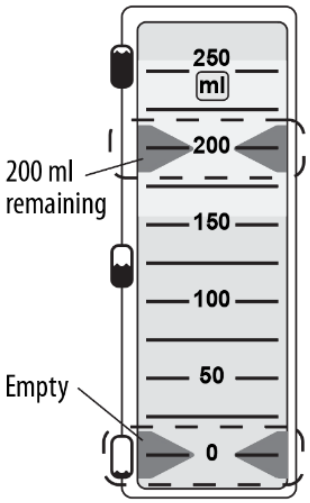
   To prevent the port from being pulled out, it is recommended to keep the pouch attached to the patient with the administration system inside at all times.



7. Fluid delivery can be observed through the window of the administration system. The administration system will deliver approximately 5 ml of fluid per hour.

   The green arrows in the window indicate the amount of fluid remaining (in ml) in the administration system.

   Monitor the position of the fluid indicator arrows periodically for excessive flow rate. For symptoms of an overdose see section 3.



8. Delivery is complete when the unit is empty, as shown by the green fluid remaining indicator arrows reaching zero in the window.

9. Remove the administration system from the patient after delivery is complete.

10. After use, discard the empty administration system, including any unused solution, in accordance with local requirements.

Warnings

- The administration system is only intended for single use. It must not be reused.
- The administration system must not be autoclaved. The fluid path in the dispensing system has been sterilised.
- The administration system must not be connected to an IV line.
- Kinking of the tubing line must be avoided, as this could result in an improper fluid delivery rate.
- No tight wrappings should be placed around the tubing line.
- The administration system should not be used if any part has been damaged or cracked, or if the connector on the tubing line appears broken, cracked, or damaged in any way.
- The flow restrictor (clear rectangle) must remain taped to the patient's skin. Removing the tape or allowing the flow restrictor to lose contact with the skin may result in an improper fluid

delivery rate.

- Do not place hot or cold packs over the flow restrictor as this could result in an improper fluid delivery rate.
- The administration system should not be reconnected if it is accidentally disconnected from the port during medication delivery, as this may cause an infection.
- The patient should not bathe or shower with the administration system, or while the port is still in place, as this could cause an infection.
- The patient should not tamper with the wound dressings or with the port as this could cause an infection.