

## Package leaflet: Information for the user

Ropivacaine 2 mg/ml solution for infusion

Ropivacaine hydrochloride

**Read all of this leaflet carefully before you are given this medicine 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, nurse or any other healthcare professional.
- If you get any side effects, talk to your doctor, nurse or any other healthcare professional. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is “Ropivacaine 2 mg/ml solution for infusion, in the rest of the leaflet it will be referred to as “Ropivacaine”.

### What is in this leaflet

1. What Ropivacaine is and what it is used for
2. What you need to know before you are given Ropivacaine
3. How to use Ropivacaine
4. Possible side effects
5. How to store Ropivacaine
6. Contents of the pack and other information

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

- Ropivacaine contains a medicine called ropivacaine hydrochloride.
- It belongs to a group of medicines called local anaesthetics.

Ropivacaine 2 mg/ml solution for infusion is used in adults and children of all ages for acute pain management. It numbs (anaesthetises) parts of the body e.g. after surgery.

### 2. What you need to know before you are given Ropivacaine

#### You must not be given Ropivacaine

- If you are **allergic** (hypersensitive) 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 been told that you have **decreased volume of blood** (hypovolaemia).
- **Into a blood vessel** 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 apply to you, talk to your doctor before you are given Ropivacaine.

### Warnings and precautions

Special care should be taken to **avoid any administration** of Ropivacaine **directly into a blood vessel** to prevent any immediate toxic effects. Administration should not be performed in inflamed areas.

Talk to your doctor, nurse or to any other healthcare professional before Ropivacaine Kabi is given to you

- if you are in a **poor general condition** due to your age or other factors.
- if you have **heart problems** (partial or complete heart conduction block)
- if you have advanced **liver problems**
- if you have severe **kidney problems**.

Tell your doctor if you have any of these problems because your doctor may need to adjust the dose of Ropivacaine .

Talk to your doctor, nurse or to any other healthcare professional before Ropivacaine is given to you

- if you suffer from **acute porphyria** (problems with building up red blood pigment, sometimes resulting in neurological symptoms).

Tell your doctor if you or somebody in your family have porphyria because your doctor may need to use another anaesthetic.

Tell your doctor before treatment about any diseases or medical conditions you have.

## Children

Take special care:

- In newborn children as they are more susceptible to Ropivacaine 2 mg/ml solution for infusion.
- In children < 12 years as some injections of Ropivacaine 2 mg/ml solution for infusion in order to numb parts of the body are not established in younger children.

## Other medicines and Ropivacaine

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

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 work out the correct dose of Ropivacaine for you.

Also tell your doctor if you are taking any of the following medicines:

- Medicines for 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 if you are taking these medicines. If you are taking either of these medicines, prolonged use of Ropivacaine 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 affects pregnancy or passes into breast milk. If you are given this medicine while pregnant, it may lower your baby's heart rate (known as foetal heart rate) and your doctor should monitor foetal heart rate.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

## Driving and using machines

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

### **Ropivacaine contains sodium chloride**

This medicinal product 3.4 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.17% of the recommended maximum daily dietary intake of sodium for an adult.

### **3. How to use Ropivacaine**

Ropivacaine will be given to you by a doctor. The dose that your doctor gives you will depend on the type of pain relief that you need. It will also depend on your body size, age, and physical condition.

Ropivacaine will be given to you as an infusion. The part of the body where it will be used will depend on why you are being given Ropivacaine. Your doctor will give you Ropivacaine in one of the following places:

- The part of the body that needs to be numbed.
- Near to the part of the body that needs to be numbed.
- In an area away from the part of the body that needs to be numbed. This is the case if you are given an epidural infusion (into the area around the spinal cord).

When Ropivacaine is used in one of these ways, it stops the nerves from being able to pass pain messages to the brain. It will stop you feeling pain, heat or cold in where it is used however you may still have other feelings like pressure or touch.

Your doctor will know the correct way to give you this medicine.

### **Dosage**

The dose used will depend on what it is being used for and also on your health, age and weight.

### **Duration of treatment**

Administration of ropivacaine usually takes between 0.5 to 6 hours but can take up to 72 hours in case of pain relief during or after surgery.

### **If you are given more Ropivacaine than you should be**

Serious side effects from getting too much Ropivacaine need special treatment and the doctor treating you is trained to deal with these situations. The first signs of being given too much Ropivacaine are usually as follows:

- problems with hearing and sight (vision),
- numbness of lips, tongue and around the mouth,
- dizziness or light-headedness,
- tingling,
- speech disorder characterised by poor articulation (dysarthria),
- muscular stiffness, muscular twitching, fits (convulsions),
- low blood pressure,
- slow or irregular heartbeat.

These symptoms may precede to cardiac arrest, breathing arrest or severe fits.

To reduce the risk of serious side effects, your doctor will stop giving you Ropivacaine as soon as these signs appear. This means that if any of these happen to you, or you think you may have received too much Ropivacaine, **tell your doctor or healthcare personnel immediately.**

More serious side effects from being given too much Ropivacaine include problems with your speech, twitching of your muscles, tremors, trembling, fits (seizures), and loss of consciousness.

Tell your doctor or health care professional if you notice any of the symptoms above.

#### 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, affecting 1 to 10 in 10,000 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 is causing an allergic reaction, tell your doctor or healthcare personnel 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 (paraesthesia)
- Feeling dizzy
- Headache
- Slow or fast heart beat (bradycardia, tachycardia)
- High blood pressure (hypertension)
- Being sick (vomiting)
- Difficulty in passing urine (urinary retention)
- High temperature (fever) or shivering (chills)
- Stiffness (rigor)
- 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 the infusion was given into a blood vessel by mistake, or if you have been given too much Ropivacaine (see also section 3 “If you are given more Ropivacaine than you should be” 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 heartbeat (arrhythmias)

**Not known** (frequency cannot be estimated from the data available)

- Horner's Syndrome

**Other possible side effects include:**

- Numbness, due to nerve irritation caused by the needle or the injection. This does not usually last for long.
- Involuntary muscle movements (dyskinesia).

**Possible side effects seen with other local anaesthetics which might also be caused by Ropivacaine Kabi include:**

- Damaged nerves. Rarely (affecting 1 to 10 people in 10,000), this may cause permanent problems.
- If too much Ropivacaine Kabi is given into the spinal fluid, the whole body may become numbed (anaesthetised).
- Receiving an epidural injection (injection into the space around your spinal nerves) may cause a disruption of a nerve pathway from the brain to the head and neck, especially in pregnant women, which may sometimes result in a condition called Horner's syndrome. This is characterized by decrease in the size of the pupil, drooping of the upper eyelid, and failure of the sweat glands to make sweat. It will resolve on its own when the treatment is stopped.

**Children**

In children, the side effects are the same as in adults except for low blood pressure which happens less often in children (affecting 1 to 10 children in 100) and being sick which happens more often in children (affecting more than 1 in 10 children).

**Reporting of side effects**

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Ropivacaine**

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 bag. The expiry date refers to the last day of that month.

Store below 30°C.

Do not use this medicine if you notice any precipitation in the solution for infusion.

Your doctor or the hospital will normally store Ropivacaine and they are responsible for the quality of the product when it has been opened if it is not used immediately. They are also responsible for disposing of any unused Ropivacaine correctly.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

### **What Ropivacaine contains**

- The active substance is ropivacaine hydrochloride 2 mg/ml.  
Each 100 ml plastic bag contains 200 mg ropivacaine hydrochloride.  
Each 200 ml plastic bag contains 400 mg ropivacaine hydrochloride.
- The excipients are sodium chloride, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), and water for injections.

### **What Ropivacaine looks like and contents of the pack**

Ropivacaine 2 mg/ml solution for infusion is a clear, colourless solution for infusion.

Ropivacaine 2 mg/ml solution for infusion is available in 100 ml and 200 ml transparent plastic bags.

Pack sizes:

1 bag in foil overpouch

5 bags in foil overpouch

10 bags in foil overpouch

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Fresenius Kabi Limited  
Cestrian Court, Eastgate Way,  
Manor Park, Runcorn,  
Cheshire WA7 1NT  
United Kingdom

### **Manufacturer**

HP Halden Pharma AS  
Svinesundsveien 80  
1788 Halden  
Norway

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

<b>Name of the Member State</b>	<b>Name of the medicinal product</b>
Netherlands	Ropivacaïne HCl Fresenius Kabi 2 mg/ml oplossing voor infusie
Austria	Ropivacainhydrochlorid Kabi 2 mg/ml Infusionslösung
Belgium	Ropivacaïne Fresenius Kabi 2 mg/ml oplossing voor infusie
Cyprus	Ropivacaine/Kabi 2mg διάλυμα για έγχυση
Germany	Ropivacainhydrochlorid Kabi 2 mg/ml Infusionslösung
Denmark	Ropivacaine Fresenius Kabi, infusionsvaeske, opløsning, 2 mg/ml
Estonia	Ropivacaine Kabi
Greece	Ropivacaine/Kabi 2mg διάλυμα για έγχυση
Spain	Ropivacaina Kabi 2 mg/ml solución para perfusión
Finland	Ropivacain Fresenius Kabi 2 mg/ml infusioneste, liuos
France	Ropivacaïne Kabi 2 mg/ml solution pour perfusion en poche
Hungary	Ropivacaine Fresenius Kabi 2 mg/ml oldatos infúzió
Italy	Ropivacaina Kabi
Latvia	Ropivacaine Kabi 2 mg/ml šķīdums infūzijām
Lithuania	Ropivacaine hydrochloride Kabi 2 mg/ml infuzinis tirpalas
Luxembourg	Ropivacaïne Fresenius Kabi 2 mg/ml Infusionslösung
Malta	Ropivacaine Kabi 2 mg/ml
Norway	Ropivacain Fresenius Kabi 2 mg/ml, infusjonsvæske, oppløsning
Portugal	Ropivacaína Kabi
Slovenia	Ropivakainijev klorid Kabi 2 mg/ml raztopina za infundiranje
Sweden	Ropivacain Fresenius Kabi 2 mg/ml, infusionsvätska, lösning
United Kingdom (Northern Ireland)	Ropivacaine 2 mg/ml solution for infusion

**This leaflet was last revised in March 2026.**

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 The following information is intended for healthcare professionals only:

Handling

Ropivacaine should only be used by, or under the supervision of, clinicians experienced in regional anaesthesia (see section 3).

#### Shelf-life after opening

To be used immediately.

Ropivacaine products are intended for single use only. Discard any unused solution.

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.

The intact container must not be re-autoclaved. A bag wrapped in a foil overpouch should be chosen when a sterile outside is required.

#### Incompatibilities

Compatibilities with other solutions than those mentioned below have not been investigated.

In alkaline solutions precipitation may occur as ropivacaine shows poor solubility at pH > 6.0.

#### Compatibility

Ropivacaine solution for infusion in plastic infusion bags is chemically and physically compatible with the following drugs:

<b>Concentration of Ropivacaine: 1-2 mg/ml</b>	
<b>Additive</b>	<b>Concentration*</b>
Fentanyl citrate	1.0 - 10.0 µg/ml
Sufentanil citrate	0.4 – 4.0 µg/ml
Morphine sulphate	20.0 – 100.0 µg/ml
Clonidine hydrochloride	5.0 – 50 µg/ml

\* The concentration ranges stated in the table are wider than those used in clinical practice. Epidural infusions of Ropivacaine /sufentanil citrate, Ropivacaine /morphine sulphate and Ropivacaine/clonidine have not been evaluated in clinical studies.

The mixtures are chemically and physically stable for 30 days at 20 to 30°C. From a microbiological point of view, the mixtures should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C.

#### Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.