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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ropivacaine is and what it is used for

The name of your medicine is "Ropivacaine 2 mg/ml solution for infusion".
- It contains a medicine called ropivacaine hydrochloride.
- It belongs to a group of medicines called local anaesthetics

Ropivacaine 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 should not be given Ropivacaine
- 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 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 this medicine.

Warnings and precautions
Talk to your doctor or nurse before you are given Ropivacaine:
- if you have **heart, liver or kidney** problems. Your doctor may need to adjust the dose of Ropivacaine.
- if you have ever been told that you or anyone in your family has a **rare disease** of the blood pigment called "**porphyria**". Your doctor may need to give you a different anaesthetic medicine.
- about any diseases or medical conditions that you have.

Special care should be given:
- in newborn children as they are more susceptible to Ropivacaine.
- in children up to and including 12 years as some injections to numb parts of the body are not established in younger children.

Other medicines and Ropivacaine
Tell your doctor if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal 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 you are given this medicine. It is not known if ropivacaine hydrochloride affects pregnancy or passes into breast milk.

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

Ropivacaine contains sodium.
This medicine contains 338 mg sodium (main component of cooking/table salt) in each 100 ml bag. This is equivalent to 16.9% of the recommended maximum daily dietary intake of sodium for an adult.
This medicine contains 676 mg sodium (main component of cooking/table salt) in each 200 ml bag. This is equivalent to 33.8% of the recommended maximum daily dietary intake of sodium for an adult.
This medicine contains 1690 mg sodium (main component of cooking/table salt) in each 500 ml bag. This is equivalent to 84.5% of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your doctor if you need 116 ml or more Ropivacaine daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How you will be given 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.

This medicine will be given to you by a doctor as an infusion. The part of the body where it will be used will depend on why you are being given this medicine. 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.

If you have been given too much Ropivacaine
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 of this medicine 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 giving you this medicine 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, **tell your doctor immediately**.

More serious side effects from being given too much of this medicine include problems with your speech, twitching of your muscles, tremors, trembling, fits (seizures), and loss of consciousness. The doctor treating you is trained to deal with these situations.

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, including anaphylactic shock) are rare affecting 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 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 the injection was given into a blood vessel by mistake, or if you have been given too much Ropivacaine (see also "If you have been given too much Ropivacaine" 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).

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 include:
- Damaged nerves. Rarely (may affect up to 1 in 1,000 people), this may cause permanent problems.
- If too much Ropivacaine is given into the spinal fluid, the whole body may become numbed (anaesthetised).

Additional side effects in children
In children, the side effects are the same as in adults except for low blood pressure which happens less often in children (affecting up to 1 in 10 children) 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 Yellow Card Scheme at: 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 carton and the bag after EXP. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- 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. The 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 correctly.

6. Contents of the pack and other information

What Ropivacaine contains
- The active ingredient is ropivacaine hydrochloride.
  Ropivacaine comes in the following strength: 2 mg of ropivacaine hydrochloride per ml of solution.
  Each bag of 100 ml solution contains 200 mg ropivacaine hydrochloride.
  Each bag of 200 ml solution contains 400 mg ropivacaine hydrochloride.
  Each bag of 500 ml solution contains 1000 mg ropivacaine hydrochloride.

- The other ingredients are sodium chloride, hydrochloric acid and/or sodium hydroxide (for pH adjustment), and water for injections.

What Ropivacaine looks like and contents of the pack
Ropivacaine is a clear, colourless solution for infusion supplied in 100ml, 200ml and 500ml polyolefin bags. The bags are equipped with two tubing ports: one is closed by an Injection port with breakable cap and the another one is closed with a Twist-off port. Each bag is put in an overpouch.

Pack sizes of 5, 10 and 20 bags.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Istituto Biochimico Italiano G. Lorenzini SpA
Via Fossignano 2
04011 Aprilia (LT)
Italy

Manufacturer:
Infomed Fluids Srl
Theodor Pallady Blv
Nr. 50, Sector 3,
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The following information is intended for medical or healthcare professionals only.

This leaflet is an abbreviated form of the Summary of Product Characteristics. Information is strictly limited to that required at the point of administration for correct preparation and handling of the product, and is not adequate for the purposes of making a prescribing decision. Please consult the SmPC for further information.

1. Product

Ropivacaine 2 mg/ml solution for infusion

2. Preparation

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

This medicinal product contains 338 mg sodium per 100 ml bag, equivalent to 16.9% of the WHO recommended maximum daily intake of 2 g sodium for an adult.
This medicinal product contains 676 mg sodium per 200 ml bag, equivalent to 33.8% of the WHO recommended maximum daily intake of 2 g sodium for an adult.
This medicinal product contains 1690 mg sodium per 500 ml bag, equivalent to 84.5% of the WHO recommended maximum daily intake of 2g sodium for an adult.

The maximum daily dose of this product is equivalent to 67.6% of the WHO recommended maximum daily intake for sodium.

Ropivacaine 2 mg/ml is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

Ropivacaine 2 mg/ml solution for infusion is chemically and physically compatible with the following drugs. Compatibilities with other solutions than those mentioned below have not been investigated:

Concentration of Ropivacaine: 1-2 mg/ml	
Additive	**Concentration***
Fentanyl citrate	1.0 – 10.0 microgram/ml
Sufentanil citrate	0.4 – 4.0 microgram/ml
Morphine sulphate	20.0 – 100.0 microgram/ml
Clonidine hydrochloride	5.0 – 50.0 microgram/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 hydrochloride have not been evaluated in clinical studies.

3. Instructions for use, handling and disposal

Ropivacaine should only be used by, or under the supervision of, clinicians experienced in regional anaesthesia.

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

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

Shelf life after first opening

From a microbiological point of view, the product should be used immediately. In-use storage times and conditions prior to use are the responsibility of the user.
The mixtures are chemically and physically stable for 72 hours at 20 to 30°C.

Posology - adults and adolescents above 12 years of age

The following table is a guide to dosage for the more commonly used blocks. The smallest dose required to produce an effective block should be used. The clinician's experience and knowledge of the patient's physical status are of importance when deciding the dose.

	Conc.	Volume	Dose	Onset	Duration
	mg/ml	ml	mg	minutes	hours
ACUTE PAIN MANAGEMENT					
Lumbar Epidural Administration					
Bolus	2.0	10-20	20–40	10–15	0.5–1.5
Intermittent injections (top up) (e.g. labour pain management)	2.0	10–15 (minimum interval 30 minutes)	20–30		
Continuous infusion e.g. Labour pain	2.0	6–10 ml/h	12–20 mg/h	n/a	n/a
Postoperative pain management	2.0	6–14 ml/h	12–28 mg/h	n/a	n/a
Thoracic Epidural Administration					
Continuous infusion (postoperative pain management)	2.0	6–14 ml/h	12–28 mg/h	n/a	n/a
Field Block					
(e.g. minor nerve blocks and infiltration)	2.0	1–100	2.0–200	1-5	2-6
Peripheral nerve block (Femoral or interscalene block)					
Continuous infusion or intermittent injections (e.g. postoperative pain management)	2.0	5–10 ml/h	10–20 mg/h	n/a	n/a

The doses in the table are those considered to be necessary to produce a successful block and should be regarded as guidelines for use in adults. Individual variations in onset and duration occur. The figures in the column 'Dose' reflect the expected average dose range needed. Standard textbooks should be consulted for both factors affecting specific block techniques and individual patient requirements.

n/a = not applicable.

Method of administration - adults and adolescents above 12 years of age

Careful aspiration before and during injection is recommended to prevent intravascular injection. When a large dose is to be injected, a test dose of 3–5 ml lidocaine (lignocaine) with adrenaline (epinephrine) is recommended. An inadvertent intravascular injection may be recognised by a temporary increase in heart rate and an accidental intrathecal injection by signs of a spinal block.

Aspiration should be performed prior to and during administration of the main dose, which should be injected slowly or in incremental doses, at a rate of 25–50 mg/min, while closely observing the patient's vital functions and maintaining verbal contact. If toxic symptoms occur, the injection should be stopped immediately.

When prolonged blocks are used, either through continuous infusion or through repeated bolus administration, the risks of reaching a toxic plasma concentration or inducing local neural injury must be considered. Cumulative doses up to 675 mg ropivacaine for postoperative analgesia administered over 24 hours were well

tolerated in adults, as were postoperative continuous epidural infusions at rates up to 28 mg/hour for 72 hours. In a limited number of patients, higher doses of up to 800 mg/day have been administered with relatively few adverse reactions.

For treatment of postoperative pain, the following technique can be recommended: Unless preoperatively instituted, an epidural block with ropivacaine 7.5 mg/ml is induced via an epidural catheter. Analgesia is maintained with Ropivacaine 2 mg/ml infusion. Infusion rates of 6–14 ml (12–28 mg) per hour provide adequate analgesia with only slight and non-progressive motor block in most cases of moderate to severe postoperative pain. The maximum duration of epidural block is 3 days. However, close monitoring of analgesic effect should be performed in order to remove the catheter as soon as the pain condition allows it. With this technique a significant reduction in the need for opioids has been observed.

When prolonged peripheral nerve blocks are applied, through continuous infusion, the risks of reaching a toxic plasma concentration or inducing local neural injury must be considered.

Paediatric population

Posology – Epidural block: Paediatric patients 0 (term neonates) up to and including 12 years of age

	Conc. mg/ml	Volume ml/kg	Dose mg/kg
ACUTE PAIN MANAGEMENT (per- and postoperative)			
Single Caudal Epidural Block			
Blocks below T12, in children with a body weight up to 25 kg	2.0	1	2
Continuous Epidural Infusion			
In children with a body weight up to 25 kg			
0 up to 6 months			
Bolus dose[a]	2.0	0.5-1	1-2
Infusion up to 72 hours	2.0	0.1 ml/kg/h	0.2 mg/kg/h
6 up to 12 months			
Bolus dose[a]	2.0	0.5-1	1-2
Infusion up to 72 hours	2.0	0.2 ml/kg/h	0.4 mg/kg/h
1 to 12 years			
Bolus dose[b]	2.0	1	2
Infusion up to 72 hours	2.0	0.2 ml/kg/h	0.4 mg/kg/h

The dose in the table should be regarded as guidelines for use in paediatrics. Individual variations occur. In children with a high body weight, a gradual reduction of the dosage is often necessary and should be based on the ideal body weight. The volume for single caudal epidural block and the volume for epidural bolus doses should not exceed 25 mL in any patient. Standard textbooks should be consulted for factors affecting specific block techniques and for individual patient requirements.

[a] Doses in the low end of the dose interval are recommended for thoracic epidural blocks while doses in the high end are recommended for lumbar or caudal epidural blocks.

[b] Recommended for lumbar epidural blocks. It is good practice to reduce the bolus dose for thoracic epidural analgesia.

Peripheral nerve blocks: Infants and children aged 1-12 years

	Conc.	Volume	Dose
	mg/ml	ml/kg	mg/kg
ACUTE PAIN MANAGEMENT (per- and postoperative)			
Single injection for peripheral nerve block (e.g. ilioinguinal nerve block, brachial plexus block, fascia iliaca compartment block)	2.0	0.5-0.75	1.0-1.5
Multiple blocks	2.0	0.5-1.5	1.0-3.0
Continuous infusion for peripheral nerve block in children 1 to 12 years. Infusion up to 72 hours	2.0	0.1-0.3 ml/kg/h	0.2-0.6 mg/kg/h

The dose in the table should be regarded as guidelines for use in pediatrics.
Individual variations occur in children with a high body weight a gradual reduction of the dosage is often necessary and should be based on the ideal body weight. Standard textbooks should be consulted for factors affecting specific block techniques patient requirements.

Method of Administration - paediatric patients 0 up to and including 12 years of age:

Careful aspiration before and during injection is recommended to prevent intravascular injection. The patient's vital functions should be observed closely during the injection. If toxic symptoms occur, the injection should be stopped immediately.

Fractionation of the calculated local anaesthetic dose is recommended, whatever route of administration.

The doses for peripheral block in infants and children provide guidance for use in children without severe disease. More conservative doses and close monitoring are recommended for children with severe diseases.

The use of ropivacaine in premature children has not been documented.