Package leaflet: Information for the user

Ropivacaine Altan 7.5 mg/ml solution for injection
Ropivacaine hydrochloride

Read all of this leaflet carefully before you start using 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, 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 Altan is and what it is used for
2. What you need to know before you use Ropivacaine Altan
3. How to use Ropivacaine Altan
4. Possible side effects
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1. What Ropivacaine Altan is and what it is used for

Ropivacaine Altan contains ropivacaine hydrochloride which belongs to a group of medicines called local anaesthetics of the amide type.

Ropivacaine Altan is used in adults and children above 12 years of age to numb (anaesthetise) parts of the body. It is used to stop pain happening or to provide pain relief. It can be used to:
- Numb parts of the body during surgery, including having a baby by Caesarean section.
- Relieve pain during childbirth, after surgery, or after an accident.

2. What you need to know before you use Ropivacaine Altan

Do not use Ropivacaine Altan
- If you are allergic to ropivacaine, other local anaesthetics of the amide type (such as lidocaine or bupivacaine) or any of the other ingredients of this medicine (listed in section 6).
- In case of intravenous regional anaesthesia (injection into a blood vessel to numb a specific area of your body), or obstretric paracervical anaesthesia (injection into the neck of the womb to relieve pain during childbirth).
- If you have been told that you have decreased volume of blood (hypovolaemia) as you can develop a decrease in the blood pressure.

If you are not sure if any of the above apply to you, talk to your doctor before you are given Ropivacaine Altan.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Ropivacaine Altan:

- 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.

Children and adolescents
Use of Ropivacaine Altan in premature infants has not been studied.

Take special care with Ropivacaine Altan:
- in children up to and including 12 years as some injections in order to numb parts of the body are not established in younger children. Other strengths (2 mg/ml) may be more appropiate.

Other medicines and Ropivacaine Altan
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 Altan can affect the way some medicines work and some medicines can have an effect on Ropivacaine Altan.

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 Altan 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 Altan if you are taking these medicines. If you are taking either of these medicines, prolonged use of Ropivacaine Altan should be avoided.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before this medicine is given to you.

Ropivacaine Altan should not be used during pregnancy and breast-feeding unless at the discretion of the doctor it is clearly necessary.
It is not known if ropivacaine hydrochloride affects pregnancy or passes into breast milk.

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

Ropivacaine Altan contains sodium
This medicine contains 3.15 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.16% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Ropivacaine Altan

Method of administration

Ropivacaine Altan will be given to you by a doctor or, occasionally, by a nurse under medical supervision.

Doses
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 Altan will be given to you as an injection. The part of the body where it will be used will depend on why you are being given Ropivacaine Altan. Your doctor will give you Ropivacaine Altan 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 injection or infusion (into the area around the spinal cord).

When Ropivacaine Altan 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.

If you have been given more Ropivacaine Altan than you should
Serious side effects from getting too much Ropivacaine Altan need special treatment and the doctor treating you is trained to deal with these situations. The first signs of being given too much Ropivacaine Altan 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 Ropivacaine Altan 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 Altan, **tell your doctor immediately**.

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

If you experience any of these symptoms or you think you may have received too much Ropivacaine Altan tell to your doctor or healthcare personnel immediately.

In case of acute toxicity, healthcare personnel will take the appropriate corrective measures 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, 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; shortness of breath,

wheezing or difficulty breathing; a feeling of loss of consciousness. If you think that Ropivacaine Altan is causing an allergic reaction, tell your doctor immediately.

Other possible side effects:

Very common (affects more than 1 patients in 10)	• Low blood pressure (hypotension). This might make you feel dizzy or light-headed. • Feeling sick (nausea).
Common: (affects 1 to 10 patients in 100)	• Headache. • Tingling or abnormal sensation of the sensitivity (parestesia). • Feeling dizzy. • 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). • Back pain.
Uncommon (affects 1 to 10 patients in 1,000)	• Anxiety. • Some symptoms can happen if the injection was given into a blood vessel by mistake, or if you have been given too much Ropivacaine Altan (see also section 3 'If you have been given more Ropivacaine Altan than you should' 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 (dysarthria), stiff muscles and trembling). • Decrease in the sense of touch (hypoestesia). • Fainting (syncope). • Difficulty breathing (dyspnoea). • Low body temperature (hypothermia).
Rare (affects 1 to 10 patients in 10,000)	• Heart attack (cardic arrest). • Uneven heart beat (arrhythmias).
Not known (frequency cannot be estimated from the available data)	• 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 observed with other local anaesthetics that may also been produced by Ropivacaine Altan include:

- Damaged nerves. Rarely (affecting 1 to 10 users in 10,000) this may cause permanent problems.

- If too much Ropivacaine Altan 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ropivacaine Altan

Keep this medicine out of the sight and reach of children.

Do not freeze.

Do not use this medicine after the expiry date which is stated on the carton or the label after CAD. The expiry date refers to the last day of that month.

From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Do not throw away any medicines via wastewater or household waste. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What Ropivacaine Altan contains

-The active substance is ropivacaine hydrochloride. Each 10 ml ampoule contains 75 mg ropivacaine hydrochloride.
-The other ingredients (excipients) are: sodium chloride, sodium hydroxide (to adjust pH), hydrochloric acid (to adjust pH) and water for injections.

What Ropivacaine Altan looks like and contents of the pack

Ropivacaine Altan is a clear, colourless solution for injection.
Each container contains 5 ampoules of 10 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Altan Pharma Ltd
The Lennox Building, 50 South Richmond street
Dublin 2, D02FK02
Ireland

Manufacturer
Altan Pharmaceuticals S.A.
Polígono Industrial de Bernedo s/n
01118 Bernedo (Álava), España

Or

Altan Pharmaceuticals S.A.
Avda. de la Constitución, 198-199, Polígono Industrial Monte Boyal,
Casarrubios del Monte, 45950 Toledo, España

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The following information is intended for healthcare professionals only:

Ropivacaine Altan is used in different ways:

- injection of the solution on the tissue in which the surgery is going to be performed.
- injection around a nerve or group of nerves which lead to the part of the body where the surgery is going to be performed, e.g., injection on the underarm before a surgery in forearm or hand.
- injection on lower part of the spinal column when it is necessary to anaesthetize your legs or lower parts of the body.

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**
SURGICAL ANAESTHESIA					
Lumbar Epidural Administration					
Surgery	7.5	15–25	113–188	10–20	3–5
Caesarean section	7.5	15–20	113–150[(1)]	10–20	3–5
Thoracic Epidural Administration					
To establish block for postoperative	7.5	5–15	38–113	10–20	n/a[(2)]

pain relief		(dependent on the level of injection)			
Major Nerve Block*					
Brachial plexus block	7.5	30–40	225–300(3)	10–25	6–10
Field Block (e.g. minor nerve blocks and infiltration)	7.5	1–30	7.5–225	1–15	2–6

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.

* With regard to major nerve block, only for brachial plexus block a dose recommendation can be given. For other major nerve blocks lower doses may be required. However, there is presently no experience of specific dose recommendations for other blocks.

(1) Incremental dosing should be applied, the starting dose of about 100 mg (97.5 mg = 13 ml; 105 mg = 14 ml) to be given over 3–5 minutes. Two extra doses, in total an additional 50mg, may be administered as needed.

(2) n/a = not applicable.

(3) The dose for a major nerve block must be adjusted according to site of administration and patient status. Interscalene and supraclavicular brachial plexus blocks may be associated with a higher frequency of serious adverse reactions, regardless of the local anaesthetic used, (see section 4.4 Special warnings and precautions for use).

In general, surgical anaesthesia (e.g. epidural administration) requires the use of the higher concentrations and doses. The 10 mg/ml formulation is recommended for epidural anaesthesia in which a complete motor block is essential for the surgery. For analgesia (e.g. epidural administration for acute pain management) the lower concentrations and doses are recommended.

Method of administration
Perineural and epidural use.

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.

In epidural block for surgery, single doses of up to 250 mg ropivacaine have been used and well tolerated.

In brachial plexus block a single dose of 300 mg has been used in a limited number of patients and was well tolerated.

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 surgery and 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 a concentration of 7.5 mg/ml is induced via an epidural catheter. Analgesia is maintained with Ropivacaine Altan 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, either through continuous infusion or through repeated injections, the risks of reaching a toxic plasma concentration or inducing local neural injury must be considered. In clinical studies, femoral nerve block was established with 300 mg Ropivacaine 7.5 mg/ml and interscalene block with 225 mg Ropivacaine 7.5 mg/ml, respectively, before surgery. Analgesia was then maintained with Ropivacaine 2 mg/ml. Infusion rates or intermittent injections of 10–20 mg per hour for 48 hours provided adequate analgesia and were well tolerated.

Concentrations above 7.5 mg/ml Ropivacaine have not been documented for Caesarean section.

Paediatric patients from 0 up to and including 12 years of age
The use of Ropivacaine 7.5 and 10 mg/ml may be associated with systemic and central toxic events in children. Lower strengths (2 mg/ml) are more appropriate for administration to this population.

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

Incompatibilities
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

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

Prior to administration, the solution should be visually inspected. Do not use unless the solution is clear and colourless and the container is not damaged.

The intact container must not be re-autoclaved.

Other presentations:
Ropivacaine Altan 2 mg/ml solution for injection: 10 ml ampoules.
Ropivacaine Altan 10 mg/ml solution for injection: 10 ml ampoules.
Ropivacaine Altan 2 mg/ml solution for infusion: 100 ml bags covered with an extractable overwrapping.
Ropivacaine Altan 2 mg/ml solution for infusion: 200 ml bags covered with an extractable overwrapping.