

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ropivacaina Molteni 2 mg/ml solution for infusion Ropivacaina Molteni 2 mg/ml, 7.5 mg/ml, 10 mg/ml solution for injection

Ropivacaine Hydrochloride

Read all of this leaflet carefully before having this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Ropivacaina Molteni is and what it is used for
2. Before you use Ropivacaina Molteni
3. How to use Ropivacaina Molteni
4. Possible side effects
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1. What Ropivacaina Molteni is and what it is used for

Ropivacaina Molteni is a 'local anaesthetic' and it is used to:

- numb (anaesthetise) parts of your body during surgery
- relieve pain during childbirth
- relieve pain after an operation.

Ropivacaina Molteni 2 mg/ml solution for infusion (injection)

It can be used in adults, adolescents and children under 12 years.

Ropivacaina Molteni 7.5 mg/ml (10 mg/ml) solution for injection

It can be used in adults and adolescents starting from 12 years.

2. Before you use Ropivacaina Molteni

Do not use Ropivacaina Molteni:

- if you are allergic (hypersensitive) to ropivacaine or any of the other ingredients (listed in section 6).
 - if you have had an allergic reaction to other anaesthetics in the past (including 'amide type' anaesthetics)
 - if you have been told that you have 'hypovolaemia' (low blood volume)
 - at the same time as another anaesthetic given by injection or infusion (drip).
- Do not have Ropivacaine if any of the above apply to you. If you are not sure, talk to your doctor before having Ropivacaine.

Take special care with Ropivacaina Molteni

Check with your doctor before having this medicine if:

- you have heart problems or hardening of your arteries (vascular disease)
 - you have severe liver or kidney problems
 - you are on a 'low sodium' diet.
 - If you or anyone in your family has ever been told that you have a rare disease of the blood pigment (porphyria). If so, tell your doctor because he may need to give you another anaesthetic medicine.
- If you are not sure if any of the above apply to you, talk to your doctor before having this medicine.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular tell your doctor if you are taking any of the following:

- medicines used for an uneven heart beat (anti-arrhythmics)
- medicines for depression (such as fluvoxamine)
- medicines used for pain (opioids)
- antibiotics (such as enoxacin).

If you are not sure if any of the above apply to you, talk to your doctor before having this medicine.

Pregnancy and breast-feeding

Talk to your doctor before having this medicine if you are pregnant and they do not know.

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

Driving and using machines

Talk to your doctor before driving or using any tools or machines. This is because Ropivacaina Molteni can make you sleepy and slow down your reactions. Ask your doctor if you can drive, or use tools and machines.

Important information about some of the ingredients of Ropivacaina Molteni

Ropivacaina Molteni contains sodium. It contains 3 mg of sodium per ml. To be taken into consideration by patients on a controlled sodium diet.

3. How to use Ropivacaina Molteni

Your doctor will give you Ropivacaina Molteni. It will be given by injection or infusion (drip).

How much Ropivacaina Molteni you will be given

- The doctor will decide how much of this medicine to give you.
- The dose will depend on what it is being used for and also on other factors, such as your health, age and weight.
- The smallest possible dose will be used.
- The usual dose for adults and adolescent over 12 is between 2 mg and 300 mg.
- The usual dose for newborn infants, infants and children under 12 is between 1 mg and 2 mg, for each kilogram of body weight.

If you have too much Ropivacaina Molteni

It is unlikely that you will be given too much of this medicine, as it will be given by a doctor.

If you think you have been given too much, **tell your doctor immediately**. The signs may include:

- 'pins and needles' (tingling, pricking or numbness of your skin)
- sudden movements of your body that you cannot control
- numbness around your mouth
- changes in the way you see or hear things
- feeling dizzy or light-headed due to low blood pressure
- stiffening of your muscles
- uneven heart beats.

Tell your doctor immediately if you notice any of the signs above.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, Ropivacaina Molteni can cause side effects, although not everybody gets them.

The following terms are used to describe how often side effects have been reported.

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000

The following side effects may happen:

See your doctor straight away if you notice any of the following:

- allergic reactions - the signs may include: swelling of your face, lips, mouth or throat, feeling dizzy or light-headed due to low blood pressure and skin rashes (itching). These are rare.
- uneven heart beat, which can lead to a heart attack. These are rare.
- fast or slow heart beat. These are common.

See a doctor straight away if you notice any of these signs.

Very common

- low blood pressure
- feeling sick.

Common

- 'pins and needles' (tingling, pricking, or numbness of the skin)
- difficulty passing urine
- high blood pressure
- feeling dizzy
- headaches
- being sick.

Uncommon

- a drop in temperature (hypothermia). Signs of this include shivering and feeling confused
- numbness or loss of feeling around your mouth and tongue
- difficulty in breathing or shortness of breath
- changes in the way you see or hear things
- loss of feeling or sensitivity of skin
- muscles stiffening or twitching
- feeling light-headed
- difficulty speaking
- feeling nervous (anxiety)
- fits (convulsions)
- fainting.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. How to store Ropivacaina Molteni

- Keep out of the reach and sight of children.
- Do not use Ropivacaina Molteni after the expiry date which is stated on the label and the carton. The expiry date refers to the last day of that month.
- Do not store above 25°C. Do not refrigerate or freeze.
- Do not use Ropivacaina Molteni if you notice any particles in the solution or if the solution is not clear.

Ropivacaina Molteni 2 mg/ml solution for infusion

- Once the bag is opened, the solution should be used immediately. If not used immediately, storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C.

6. Further information

What Ropivacaina Molteni contains

The active substance is ropivacaine hydrochloride.

- 2 mg/ml solution for infusion: each 1 millilitre of solution contains 2 mg of ropivacaine hydrochloride. One bag of 100 ml or 200 ml solution contains 200 mg or 400 mg of ropivacaine hydrochloride, respectively.
- 2 mg/ml solution for injection: each 1 millilitre of solution contains 2 mg of ropivacaine hydrochloride. One ampoule of 10 ml or 20 ml solution contains 20 mg or 40 mg of ropivacaine hydrochloride, respectively.
- 7.5 mg/ml solution for injection: each 1 millilitre of solution contains 7.5 mg of ropivacaine hydrochloride. One ampoule of 10 ml or 20 ml solution contains 75 mg or 150 mg of ropivacaine hydrochloride, respectively.
- 10 mg/ml solution for injection: each 1 millilitre of solution contains 10 mg of ropivacaine hydrochloride. One ampoule of 10 ml or 20 ml solution contains 100 mg or 200 mg of ropivacaine hydrochloride, respectively.

The other ingredients are sodium chloride, hydrochloric acid 3.6% w/v (E507), sodium hydroxide (E524) and water for injection.

What Ropivacaina Molteni looks like and contents of the pack

Solution for infusion or for injection.

Ropivacaina Molteni is a clear, colourless solution for infusion or for injection.

It is available in the following packs:

- 2 mg/ml solution for infusion in 100ml or 250ml transparent polypropylene bags, in packs of 5.
- 2 mg/ml solution for injection in 10ml or 20ml transparent polypropylene ampoules, in packs of 5.
- 7.5 mg/ml solution for injection in 10ml or 20ml transparent polypropylene ampoules, in packs of 5.
- 10 mg/ml solution for injection in 10ml or 20ml transparent polypropylene ampoules, in packs of 5.

Not all pack-sizes may be marketed.

Marketing Authorisation Holder

L. Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A.
Strada Statale 67 Frazione Granatieri, 50018 Scandicci (Firenze), Italy

Manufacturer

L. Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A.
Strada Statale 67 Frazione Granatieri, 50018 Scandicci (Firenze), Italy

This leaflet was last approved in 09/2011

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

Germany	Ropivacainhydrochlorid Molteni
Greece	Ropivacaine Hydrochloride Molteni
Italy	Ropivacaina Molteni
Poland	ROPIMOL
The Netherlands	Ropivacaïne Hydrochloride Molteni