Package leaflet: Information for the user

Ropivakain Sintetica 2 mg/ml solution for infusion
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 or pharmacist.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ropivakain Sintetica is and what it is used for

Ropivakain Sintetica 2 mg/ml solution for infusion contains the active substance ropivacaine hydrochloride which is a type of medicine called local anaesthetic.

Ropivakain Sintetica 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 use Ropivakain Sintetica

Do not use Ropivakain Sintetica
- if you are **allergic to ropivacaine hydrochloride**, other so called local anaesthetics of the amide type or any of the other ingredients of Ropivakain Sintetica (listed in section 6).
- if you have a **decrease in blood volume** (hypovolaemia). This is measured by healthcare personnel.
- for **infusion into a blood vessel** to numb a specific area of your body.
- for **infusion into the neck of the womb** to relieve pain during childbirth.

Warnings and precautions
Talk to your doctor or pharmacist before using Ropivakain Sintetica
Special care should be taken to **avoid any administration** of Ropivakain Sintetica **directly into a blood vessel** to prevent any immediate toxic effects. Administration should not be performed in inflamed areas.

Please tell your doctor:
- if you are in a **poor general conditon** 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 Ropivakain Sintetica.

Please tell your doctor:
- 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.

Children
Special care shoud be given:
- In newborn children as they are more susceptible to Ropivakain Sintetica.
  In children < 12 years as some injections of Ropivakain Sintetica in order to numb parts of the body are not established in younger children.

Other medicines and Ropivakain Sintetica
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Caution should be exercised if you are receiving:
- **Other local anaesthetics** (e.g. lidocaine) or agents structurally related to amide-type local anaesthetics, e.g. certain medicines used to treat an irregular heart beat (arrhythmia), such as mexiletine or amiodarone
- **General anaesthetics** or **opioids**, such as morphine or codeine
- Medicines used to treat **depression** (e.g. fluvoxamine)
- **Certain antibiotics** (e.g. enoxacin)

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 or pharmacist for advice before taking this medicine. It is not known if ropivacaine hydrochloride affects pregnancy or passes into breast milk.

If this medicine is given to you during pregnancy, it may reduce the baby's heart rate (known as fetal heart rate), so your doctor will monitor the fetal heart rate.

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

Discuss with your doctor or pharmacist if you are unsure about anything.

Ropivakain Sintetica contains sodium
This medicinal product contains:
- 338,3 mg sodium (main component of cooking/table salt) in each dosage unit of 100 ml. This is equivalent to 16,9% of the recommended maximum daily dietary intake of sodium for adult.
- 676,6 mg sodium (main component of cooking/table salt) in each dosage unit of 200 ml. This is equivalent to 33,8% of the recommended maximum daily dietary intake of sodium for an adult.
-845,7 mg sodium (main component of cooking/table salt) in each dosage unit of 250 ml. This is equivalent to 42,3% of the recommended maximum daily dietary intake of sodium for an adult.
- 1691,5 mg sodium (main component of cooking/table salt) in each dosage unit of 500 ml. This is equivalent to 84,6% of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your pharmacist or doctor if you need 1 or more bags of the 200 ml, 250 ml or 500 ml solution for infusion daily for a prolonged period of time, especially if you have been advised to have a low salt diet.
The maximum recommended daily dose of this medicinal product contains 1353,2 mg sodium (found in table salt). This is equivalent to 67,7% of the adult recommended maximum daily dietary intake for sodium.

3. How to use Ropivakain Sintetica

Dosage
The recommended dose will depend on what it is being used for and also on your health, age and weight. The smallest dose that can produce effective numbing (anaesthesia) of the required area should be used.

The recommended dose
- for **adults and adolescents older than 12 years of age** is between **2 mg and 200 mg** of ropivacaine hydrochloride.
- in **infants** and **children (0 up to and including 12 years of age)** is **1-2 mg for each kilogram** of body weight.

Method of administration
Your doctor will administer Ropivakain Sintetica to you. It is administered by infusion.

Duration of treatment
Administration of ropivacaine hydrochloride 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 Ropivakain Sintetica than you should be
The first symptoms of being given too much ropivacaine hydrochloride are usually problems with
- hearing and sight,
- numbness 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 heart beat.

These symptoms may proceed to cardiac arrest, breathing arrest or severe fits.
If you experience any of these symptoms or think you may have received too much Ropivakain Sintetica, tell your doctor or healthcare personnel immediately.

In case of acute toxicity, appropriate corrective actions will be taken immediately by the healthcare personnel.

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

4. Possible side effects

Like all medicines, Ropivakain Sintetica 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, angioneurotic oedema and urticaria) 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 Ropivakain Sintetica is causing an allergic reaction, tell your doctor or healthcare personnel immediately.

Other possible side effects:

Very common ***may be 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***

- Headache, pins and needles (paraesthesia), feeling dizzy
- Slow or fast heart beat (bradycardia, tachycardia)
- High blood pressure (hypertension)
- Being sick (vomiting)
- Difficulty in passing urine (urinary retension)
- Back pain,
- Increased temperature shivering (chills). muscular stiffness (rigor)

Uncommon ***may affect up to 1 in 100 people***

- Anxiety
- Some symptoms can happen if the infusion was given into a blood vessel by mistake, or if you have been given too much Ropivakain Sintetica (see also section 3 “If you are given more Ropivakain Sintetica than you should be” above). These include fits (convulsions, 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), muscular twitching and trembling, reduced sense of touch (hypoaesthesia)
- Fainting (syncope)
- Difficulty breathing (dyspnoea)
- Low body temperature

Rare ***may affect up to 1 in 1000 people***

- Heart attack (cardiac arrest), irregular heart beat (cardiac arrhythmias)

Not known: ***frequency cannot be estimated from 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 seen with other local anaesthetics which might also be caused by Ropivakain Sintetica include:

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

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 less than 1 in 10 children) and being sick which happens more often in children (affecting more than 1 in 10 children).

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

Reporting of side effects
If you get any side effects, talk your doctoror pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ropivakain Sintetica

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

Do not use Ropivakain Sintetica after the expiry date which is stated on the bag. The expiry date refers to the last day of that month.

Do not freeze.

Do not use Ropivakain Sintetica if you notice any precipitation in the solution for infusion.

Your doctor or the hospital will normally store Ropivakain Sintetica 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 Ropivakain Sintetica correctly.

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

6. Contents of the pack and other information

What Ropivakain Sintetica contains

- The active substance is ropivacaine hydrochloride 2 mg/ml.
  Each 100 ml polypropylene bag contains 200 mg ropivacaine (as hydrochloride).
  Each 200 ml polypropylene bag contains 400 mg ropivacaine (as hydrochloride).
  Each 250 ml polypropylene bag contains 500 mg ropivacaine (as hydrochloride).
  Each 500 ml polypropylene bag contains 1000 mg ropivacaine (as hydrochloride).

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

What Ropivakain Sintetica looks like and contents of the pack

Ropivakain Sintetica solution for infusion is a clear, colourless, sterile, isotonic, isobaric aqueous solution for infusion.
Ropivakain Sintetica 2 mg/ml solution for infusion is available in 100 ml, 200 ml, 250 ml and 500 ml polypropylene bags.

Pack sizes:
5 bags
10 bags
20 bags

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

[To be completed nationally]

Manufactured by:

Sintetica GmbH
Albersloher Weg 11
48155 Münster
Germany

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

{Name of the Member State} {Name of the medicinal product}
{Name of the Member State} {Name of the medicinal product}

This leaflet was last revised in 2025-12-17

The following information is intended for medical or healthcare professionals only:

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

Shelf life

Shelf-life before opening

3 years

Shelf-life after opening

From a microbiological point of view, the product 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 to 8 °C.

Ropivakain Sintetica products are preservative free and 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.

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.

	Concentration mg/ml	Volume ml	Dose mg	Onset minutes	Duration hours
ACUTE PAIN MANAGEMENT (pre-and postoperative)					
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	-	-
Postoperative pain management	2.0	6-14 ml/h	12-28 mg/h	-	-
Thoracic Epidural Administration					
Continuous infusion (postoperative pain management)	2.0	6-14 ml/h	12-28 mg/h	-	-
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	-	-

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.

In general, surgical anaesthesia (e.g. epidural administration) requires the use of the higher concentrations and doses. The Ropivakain Sintetica 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 administration by infusion.

Careful aspiration before and during administration is recommended to prevent intravascular administration. 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 infusion 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 infusion 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 hydrochloride 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 Ropivakain Sintetica 7.5 mg/ml is induced via an epidural catheter. Analgesia is maintained with Ropivakain Sintetica 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.

In clinical studies an epidural infusion of ropivacaine hydrochloride 2 mg/ml alone or mixed with fentanyl 1-4 μg/ml has been given for postoperative pain management for up to 72 hours. The combination of ropivacaine hydrochloride and fentanyl provided improved pain relief but caused opioid side effects. The combination of ropivacaine hydrochloride and fentanyl has been investigated only for ropivacaine hydorchloride 2 mg/ml.

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 hydrochloride 7.5 mg/ml and interscalene block with 225 mg ropivacaine hydrochloride 7.5 mg/ml, respectively, before surgery. Analgesia was then maintained with ropivacaine hydrochloride 2 mg/ml. Infusion rates or intermittent injections of 10-20 mg per hour for 48 hours provided adequate analgesia and were well tolerated.

Paediatric patients 0 up to and including 12 years of age

	Concentration mg/ml	**Volume ml/kg**	**Dose mg/kg**
ACUTE PAIN MANAGEMENT (pre-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 at the low end of the dose intervals 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.

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

Infants and children aged 1-12 years:

Indication	**Concentration mg/ml**	**Volume ml/kg**	**Dose mg/kg**
ACUTE PAIN MANAGEMENT			

(pre-and postoperative)			
Single injections for peripheral nerve block e.g. ilioinguinal nerve block, brachial plexus 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 h.	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 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. Standard textbooks should be consulted for factors affecting specific block techniques and for individual patient requirements.

Method of administration
Epidural administration by infusion.

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

A single caudal epidural injection of ropivacaine hydrochloride 2 mg/ml produces adequate postoperative analgesia below T12 in the majority of patients when a dose of 2 mg/kg is used in a volume of 1 ml/kg. The volume of the caudal epidural injection may be adjusted to achieve a different distribution of sensory block, as recommended in standard textbooks. In children above 4 years of age, doses up to 3 mg/kg of a concentration of ropivacaine hydrochloride 3 mg/ml have been studied. However, this concentration is associated with a higher incidence of motor block.

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

In case injection of ropivacaine hydrochloride is recommended, Ropivakain Sintetica solution for injection can be used.
Incompatibilities
Compatibilities with other solutions than those mentioned below have not been investigated.
In alkaline solutions precipitation may occur as ropivacaine hydrochloride shows poor solubility at pH > 6.0.

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

Concentration of Ropivakain Sintetica: 1-2 mg/ml

Additive	**Concentration**
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 Ropivakain Sintetica/sufentanil citrate, Ropivakain Sintetica/morphine sulphate and Ropivakain/clonidine hydrochloride 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.