

Package leaflet: Information for the user

Naropin® 2 mg/ml, 7.5 mg/ml, 10 mg/ml solution for injection Naropin® 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 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Naropin is and what it is used for

The name of your medicine is “Naropin solution for injection” or “Naropin solution for infusion”.

- It contains a medicine called ropivacaine hydrochloride.
- It belongs to a group of medicines called local anaesthetics
- It will be given to you either as an injection or as an infusion, depending on what it is being used for.

Naropin 7.5 and 10 mg/ml 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.

Naropin 2 mg/ml 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 take Naropin

Do not take Naropin:

- If you are allergic (hypersensitive) to ropivacaine hydrochloride or any of the other ingredients of Naropin (see Section 6: Further information).
- 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 Naropin.

Warnings and precautions

Talk to your doctor or pharmacist before taking Naropin:

- if you have heart, liver or kidney problems. Your doctor may need to adjust the dose of Naropin.

- 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 Naropin.
- in children up to and including 12 years as some injections to numb parts of the body are not established in younger children.
- in children up to and including 12 years as the use of Naropin 7.5 mg and 10 mg/ml injections to numb parts of the body is not established. The strengths of Naropin 2mg/ml and 5 mg/ml may be more appropriate

Other medicines and Naropin

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 Naropin can affect the way some medicines work and some medicines can have an effect on Naropin.

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 Naropin 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 Naropin if you are taking these medicines. If you are taking either of these medicines, prolonged use of Naropin 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 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

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

Naropin contains

up to 3.7 milligrams (mg) of sodium in each millilitre (ml) of solution. If you are on a sodium controlled diet you will need to take this into account.

3. How to take Naropin

Naropin 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.

Naropin will be given to you as an injection or as an infusion. The part of the body where it will be used will depend on why you are being given Naropin. Your doctor will give you Naropin 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 Naropin 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 too much Naropin

Serious side effects from getting too much Naropin need special treatment and the doctor treating you is trained to deal with these situations. The first signs of being given too much Naropin 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 Naropin as soon as these signs appear. This means that if any of these happen to you, or you think you have received too much Naropin, **tell your doctor immediately.**

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

4. Possible side effects

Like all medicines, Naropin may cause side effects although not everybody gets them.

Important side effects to look out for:

Sudden life-threatening allergic reactions (such as anaphylaxis) 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; and shortness of breath, wheezing or difficulty breathing. **If you think that Naropin is causing an allergic reaction, tell your doctor immediately.**

Other possible side effects:

Very common (affects more than 1 user in 10)

- Low blood pressure (hypotension). This might make you feel dizzy or light-headed.
- Feeling sick (nausea).

Common (affects 1 to 10 users in 100)

- 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 (affects 1 to 10 users in 1,000)

- 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 Naropin (see also “If you have been given too much Naropin” 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 (affects 1 to 10 users in 10,000)

- 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 Naropin include:

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

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C. Do not freeze.
- Your doctor or the hospital will normally store Naropin and they are responsible for the quality of the product when it has been opened if it is not used immediately. 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.
- They are also responsible for disposing of any unused Naropin correctly.

6. Contents of the pack and other information

What Naropin contains

The active ingredient is ropivacaine hydrochloride. Naropin comes in the following strengths: 2 mg, 7.5 mg or 10 mg of ropivacaine hydrochloride per ml of solution.

The other ingredients are sodium chloride, hydrochloric acid and/or sodium hydroxide, and water for injections.

What Naropin looks like and contents of the pack

Naropin is a clear, colourless solution for injection or infusion.

Naropin solution for injection 2 mg/ml, 7.5 mg/ml and 10 mg/ml is available as follows:

- 10 ml polypropylene ampoules (Polyamp) in packs of 5 or 10.
- 20 ml polypropylene ampoules (Polyamp) in packs of 5 or 10.

Naropin solution for infusion 2 mg/ml is available as follows:

- 100 ml polypropylene bags (Polybag) in packs of 5.
- 200 ml polypropylene bags (Polybag) in packs of 5.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisations for Naropin are held by Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland

Tel: +44 (0)1 748 828 391

The manufacturer responsible for batch release is AstraZeneca AB, S-151 85 Södertälje, Sweden and AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, United Kingdom.

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

Austria, Belgium, Denmark, Germany, Ireland, Luxembourg, Netherlands, United Kingdom: Naropin.

France: Naropeine.

Italy: Naropina.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Naropin 2 mg/ml infusion & 2, 7.5, 10 mg/ml injection
Reference number	PL 39699/0081, 0082, 0083, 0080

This is a service provided by the Royal National Institute of Blind People

This leaflet was last approved in January 2018.

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