

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

NAROPIN®
Ropivacaine Hydrochloride Injection for Epidural Infusion and
Ropivacaine Hydrochloride Injection

Read this carefully before you start taking **NAROPIN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **NAROPIN**.

What is NAROPIN used for?

NAROPIN is used as an anaesthetic and for pain relief. It can be used:

- to anaesthetise the area of the body where surgery is performed;
- to provide pain relief in labour and after surgery or acute injury.

NAROPIN is not for use in children under 18 years of age.

How does NAROPIN work?

NAROPIN temporarily prevents the nerves in the injected area from transmitting feelings of pain, heat or cold. You may still feel pressure and touch. In many cases the nerves to the muscles in the area will also be blocked. This may cause temporary weakness or paralysis. The duration of pain relief depends on the dose and how it is given.

What are the ingredients in NAROPIN?

Medicinal ingredients: ropivacaine hydrochloride

Non-medicinal ingredients: sodium chloride, hydrochloric acid and/or sodium hydroxide and water for injection.

NAROPIN comes in the following dosage forms:

NAROPIN 2mg/mL for infusion is available in 100 and 200 mL infusion bags.

NAROPIN 5 mg/mL for injection is available in 20 mL ampoules.

NAROPIN 10 mg/mL for injection is available in 10 mL and 20 mL ampoules.

Do not use NAROPIN if:

NAROPIN should not be used in patients who:

- are allergic to ropivacaine, any other “-caine” type anaesthetics, or any of the non-medicinal ingredients in the product

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take NAROPIN. Talk about any health conditions or problems you may have, including:

- about all health problems you have now or have had in the past;
- about other medicines you take, including ones you can buy without a prescription;
- if you are taking drugs used to treat irregular heart activity (anti-arrhythmics, such as amiodarone);

- if you have ever had a bad, unusual allergic reaction to ropivacaine or any other medicines ending with “-caine”;
- if you have a heart, liver or kidney disease, since the dose of NAROPIN may have to be adjusted;
- if you are pregnant, plan to become pregnant or are breastfeeding;
- if you have been diagnosed with porphyria, a rare hereditary disorder.

Other warnings you should know about:

- NAROPIN could cause irreversible joint damage if it is used to manage your pain after joint surgery.
- NAROPIN may temporarily interfere with your ability to drive or operate tools or machinery.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with NAROPIN:

- drugs that treat heart rhythm problems (e.g. mexiletine, amiodarone);
- other local anaesthetics;
- sedative drugs;
- if using NAROPIN for a long time:
 - fluvoxamine or imipramine, used to treat depression
 - enoxacin, an antibiotic
 - theophylline, used to treat lung diseases

Usage of some medicines at the same time as NAROPIN may increase the risk of serious side effects.

How to take NAROPIN:

Usual dose:

NAROPIN should be administered by a doctor. It can be administered by an anaesthesia professional under the supervision of a doctor.

The dose to be given is decided by the doctor, based on the clinical need and your physical condition.

Overdose:

You can have serious side effects from getting too much NAROPIN. You may need treatment to deal with the side effects from the overdose. 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.
- Tingling in the ears.
- Problems with your sight (vision).

More serious side effects from being given too much NAROPIN include:

- problems with speech
- twitching muscles
- tremors
- trembling
- seizures
- loss of consciousness
- change in heart rhythm
- heart attack
- decrease in blood pressure

To reduce the risk of serious side effects, your doctor will stop giving you NAROPIN as soon as these signs appear.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

What are possible side effects from using NAROPIN?

These are not all the possible side effects you may feel when taking NAROPIN. If you experience any side effects not listed here, contact your healthcare professional.

Medicines affect different people in different ways. Just because side effects have occurred in some patients, does not mean that you will get them.

Tell your doctor as soon as possible if you do not feel well during treatment with NAROPIN.

Possible side effects include: Numbness, due to nerve irritation caused by the needle or the injection. This does not usually last for long.

Possible side effects seen with other local anaesthetics which might also be caused by NAROPIN include:

Damaged nerves. Rarely (affecting less than 1 in 1,000 people), this may cause permanent problems.

If too much NAROPIN is given into the spinal fluid, the whole body may become numbed (anaesthetised).

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON Low blood pressure: feeling dizzy or light-headed		X	
Nausea	X		
COMMON Pins and needles		X	

Feeling dizzy		X	
Headache	X		
Slow or fast heart beat			X
High blood pressure		X	
Vomiting	X		
Difficulty in passing urine		X	
High temperature (fever) or stiffness (rigor)		X	
Back Pain	X		
UNCOMMON			
Anxiety	X		
Decreased sensitivity or feeling in the skin		X	
Fainting		X	
Difficulty breathing			X
Low body temperature		X	
Some symptoms can happen if the injection was given into a blood vessel by mistake, or if you have been given too much NAROPIN: seizures, feeling dizzy or light-headed, numbness of the lips and around the mouth, numbness of the tongue, hearing problems, problems with sight, problems with speech, stiff muscles, and trembling			X
Numbness			X
Nerve Damage			X
RARE			
Heart attack			X
Severe allergic reaction (anaphylaxis): 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.			X
Uneven heart beat			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Your doctor or the hospital will normally store NAROPIN. The staff is responsible for storing, dispensing and disposing of NAROPIN in the correct way.

NAROPIN will be kept out of reach and sight of children.

If you want more information about NAROPIN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>; the manufacturer's website www.apsenpharma.ca, or by calling 1-844-330-1213.

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