

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

NAROPIN®

ropivacaine hydrochloride injection

ropivacaine hydrochloride for epidural infusion

This Patient Medication Information is written for the person who will be receiving **NAROPIN**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **NAROPIN**, talk to a healthcare professional.

Serious warnings and precautions box

- NAROPIN is for healthcare professional use only.
- Your healthcare professional will be trained in the management and care of local anaesthetics, such as NAROPIN. They will prepare and give you NAROPIN in a hospital setting with the adequate equipment for the proper management of unwanted side effects. They will also monitor your health throughout the treatment.

What NAROPIN is used for:

NAROPIN is used in adults to prevent or relieve pain to an area of the body. This can include before and after a surgery, during labour, or after a sudden injury.

How NAROPIN works:

NAROPIN belongs to a group of medicines known as local anaesthetics. They act by temporarily preventing the nerves around the injection site from transmitting sensations of pain, heat or cold. However, you may still experience sensations such as 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 (loss of voluntary muscle function). Overall, this helps to prevent or relieve pain to an area of the body.

The ingredients in NAROPIN are:

Medicinal ingredient: ropivacaine hydrochloride.

Non-medicinal ingredients: sodium chloride, hydrochloric acid and/or sodium hydroxide (to adjust pH), and water for injection.

NAROPIN comes in the following dosage form:

- Sterile isotonic solution in infusion bags; 2 mg/ ml
- Sterile isotonic solution in ampoules; 5 mg/ ml and 10 mg/ ml

Do not use NAROPIN if:

- you are allergic to ropivacaine, other anaesthetics that end with "-caine, or any of the other ingredients in NAROPIN. If you are unsure, ask your healthcare professional.

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

- are taking any other medications, including other local anaesthetics or medicines used to treat abnormal heartbeat and heart rhythms.
- have inflamed skin or a severe reaction to an infection (sepsis) at or near the proposed site of injection for NAROPIN.
- have a condition that causes weakness or frailty.
- are severely ill.
- have low blood pressure.
- have heart, blood vessel or blood circulation problems.
- have liver or kidney disease.
- have porphyria (an inherited or acquired disorder involved in making red blood pigment).
- are pregnant or planning to become pregnant. NAROPIN should only be used during pregnancy if your healthcare professional has decided that the potential benefits outweigh the potential risks to your unborn child.
- are breastfeeding or planning to breastfeed. NAROPIN can pass into your breast milk.

Other warnings you should know about:

NAROPIN may cause serious side effects, including:

- **Hypotension** (low blood pressure) or **Bradycardia** (low heart rhythm) when NAROPIN is administered into the space around the spinal cord (epidural). The risk of experiencing hypotension and bradycardia increases as you get older.
- **Cardiac arrest** (heart suddenly stops beating): This rarely occurred during the usual administration of NAROPIN, and occurred after its accidental administration into a blood vessel in patients with heart disease.

See the **Serious side effects and what to do about them** table for more information on this and other serious side effects.

Irreversible chondrolysis (permanent loss of cartilage in a joint): You may experience this side effect if NAROPIN is not administered as it should be. In most reported cases, the shoulder joint was affected. Symptoms included joint pain, stiffness and loss of motion, and began as early as 2 months after

administration. Tell your healthcare professional **right away** if you experience these symptoms after surgery. You may require further therapeutic procedures or surgery.

Homer's syndrome (a rare neurological syndrome): You may experience this side effect when NAROPIN is administered into the space around the spinal cord (epidural). It usually goes away once your treatment with NAROPIN is discontinued. Tell your healthcare professional **right away** if you experience decreased size of the pupil of the eye, drooping eyelid, decreased sweating on the affected side of the face.

Driving and using machines: NAROPIN may temporarily interfere with your reactions and coordination. Before you do tasks that may require your attention, you should wait until you know how you react to your treatment.

Testing and monitoring: Your healthcare professional will regularly monitor your health throughout your treatment. This may include monitoring:

- how you react to your dose;
- your blood pressure, heart rate, heart rhythm, and heart and blood vessel functions;
- your breathing and lung function;
- your vision.

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:

- antiarrhythmics, medicines used to treat abnormal heartbeat and heart rhythms (e.g., procainamide, disopyramide, flecainide, mexiletine, amiodarone)
- other local anaesthetics, medicines used to prevent pain during surgery (e.g., lidocaine, bupivacaine, mepivacaine, prilocaine)
- sedatives, medicines that can increase drowsiness
- antidepressants, medicines used to treat depression (e.g., fluvoxamine, imipramine)
- theophylline, used to treat asthma and other lung problems

How NAROPIN is given:

NAROPIN will be administered to you:

- by a healthcare professional in a healthcare setting.
- into the space around your spinal cord (epidural) or near a nerve or a group of nerves (block/infiltration). NAROPIN should not be given by any other route.
- slowly and gradually.

Your healthcare professional may administer a test dose at first before administering NAROPIN. The test dose will consist of a fast-acting local anaesthetic. This is to ensure you react well to this type of medication and to ensure the needle or catheter is properly placed

Usual dose:

NAROPIN will be administered by your healthcare professional. Your dose will depend on:

- your age and weight,
- your medical condition,
- how you respond to the treatment,
- if you take other medicines, and/or
- the type of surgery.

The lowest effective dose of NAROPIN will be used.

Overdose:

Your healthcare professional will monitor you for signs and symptoms of an overdose. If an overdose is suspected, your healthcare professional will act accordingly to manage your side effects.

Symptoms of an overdose with NAROPIN include:

- 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 vision
- problems with speech
- twitching muscles or tremors (shaking)
- seizures (fits)
- loss of consciousness
- change in heart rhythm
- low blood pressure
- cardiac arrest (heart suddenly stops beating)

If you notice any of these symptoms, tell your healthcare professional **right away**.

If you think you, or a person you are caring for, have been given too much NAROPIN, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Possible side effects from using NAROPIN:

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

Side effects with NAROPIN include:

- Back pain
- Headache

- Itching
- Nausea or vomiting
- Reactions at the site of injection (e.g., bruising, pain, redness, burning sensation)
- Sensation of tingling, numbness or burning in the skin
- Feeling dizzy or anxious
- Low body temperature
- Bladder infection

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very common			
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)		✓	
Common			
Arrhythmias (abnormal heart rhythms): rapid (tachycardia), slow (bradycardia), or irregular heartbeat		✓	
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations		✓	
Urinary retention (inability to pass urine or to empty the bladder): hard to start the flow of urine, slow urine stream, or unable to completely empty your bladder when urinating		✓	
High body temperature (fever) or chills		✓	
Uncommon			
Fainting	✓		
Difficulty breathing	✓		
Toxicity symptoms: convulsions, seizures, feeling dizzy or light-	✓		

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
headed, numbness of the lips and around the mouth, numbness of the tongue, hearing problems, vision problems, problems with speech, stiff muscles, and trembling			
Numbness		✓	
Nerve problems: back pain, loss or impairment of motor and sensory function, paralysis, decreased sensitivity or feeling in the skin, or other sensory disturbances		✓	
Rare			
Cardiac arrest (heart suddenly stops beating): fatigue, loss of consciousness, dizziness, difficulty breathing, nausea, chest pain, or heart palpitations		✓	
Allergic reaction: difficulty swallowing, wheezing, drop in blood pressure, feeling sick to your stomach, vomiting, hives, rash, swelling of the face, lips, tongue or throat, itching, shortness of breath, difficulty breathing, skin redness, fast heart rate, sneezing, nausea, dizziness, or excessive sweating		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

NAROPIN will be stored by your healthcare professional or the hospital as follows:

- The medicine should be stored between 15 to 25°C in its carton prior to use.
- It should not be frozen.

Your healthcare professional should not use this medicine if they see particles in the ampoule or infusion bag, if the solution appears cloudy or discoloured, or if the product is leaking. Keep 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 the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.aspenpharma.ca); or by calling 1-844-330-1213.

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