

PART III: CONSUMER INFORMATION

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

This leaflet is part III of a three-part "Product Monograph" published when NAROPIN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about NAROPIN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

WHAT THE MEDICATION IS USED FOR:

NAROPIN is used to anaesthetise part of the body for surgical operations and also for pain relief, and 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.

WHAT IT DOES:

NAROPIN acts by temporarily preventing the nerves in the injected area from transmitting sensations of pain, heat or cold. However, you may still experience sensations such as pressure and touch. In this way the part of the body in the area of the nerve(s) is anaesthetised and prepared for surgery. In many cases this means that the nerves to the muscles in the area will also be blocked, causing temporary weakness or paralysis.

WHEN IT SHOULD NOT BE USED:

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 (see WHAT THE NONMEDICINAL INGREDIENTS ARE below)

Because of the potential for irreversible joint damage, pain following joint surgery should not be managed by infusing NAROPIN into the joint (i.e. by use of a post-operative "pain pump").

WHAT THE MEDICINAL INGREDIENT IS:

ropivacaine hydrochloride 2, 5 and 10 mg/mL

WHAT THE NONMEDICINAL INGREDIENTS ARE:

NAROPIN also contains sodium chloride, hydrochloric acid and/or sodium hydroxide and water for injection.

WHAT DOSAGE FORMS IT COMES IN:

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

NAROPIN 5 mg/mL and 10 mg/mL for injection are available in 20 mL and in 10 and 20 mL ampoules respectively.

WARNINGS AND PRECAUTIONS

You should talk to your doctor prior to surgery:

- 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 other medicines such as drugs used to treat irregular heart activity (anti-arrhythmics);
- 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 are planning to drive or operate any tools or machinery on the day of surgery, because NAROPIN may temporarily interfere with your reactions and muscular coordination.
- If you have been diagnosed with porphyria, a rare hereditary disorder.

INTERACTIONS WITH THIS MEDICATION

Many drugs interact with NAROPIN. Tell your doctor about all prescription, over-the-counter and natural health products that you are using (See WARNINGS AND PRECAUTIONS above).

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

PROPER USE OF THIS MEDICATION

USUAL DOSE:

NAROPIN should be administered by a doctor, or occasionally 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:

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.

- Tingling in the ears.
- Problems with your sight (vision).

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.

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, **seek immediate emergency assistance.**

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medication, NAROPIN may cause side effects in some people.

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.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Sudden life-threatening allergic reactions (such as anaphylaxis) are rare, affecting less than 1 in 1,000 people. 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, seek immediate emergency assistance.**

There are other possible side effects that have been reported for NAROPIN. Tell your doctor or anaesthesia professional or seek immediate emergency assistance if you experience any of the following side effects:

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor		Seek immediate emergency
		Only if severe	In all cases	
Common	Pins and needles		X	
	Feeling dizzy		X	
	Headache	X		
	Slow or fast heart beat (bradycardia, tachycardia)			X
	High blood pressure (hypertension)		X	
	Being sick (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 (hypothermia)		X	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor		Seek immediate emergency assistance
		Only if severe	In all cases	
Very Common	Low blood pressure (hypotension). This might make you feel dizzy or light-headed		X	
	Feeling sick (nausea)	X		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor		Seek immediate emergency assistance
	Only if severe	In all cases	
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 "OVERDOSE" section 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			X
Rare	Heart attack (cardiac arrest)		X
	Uneven heart beat (arrhythmias)		X

Other 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).

This is not a complete list of side effects. For any unexpected effects while or after taking NAROPIN contact your doctor or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

NOTE: This CONSUMER INFORMATION leaflet provides you with the most current information at the time of printing.

For the most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at:

www.astrazeneca.ca,

or by contacting the sponsor, AstraZeneca Canada Inc. at:

Customer Inquiries – 1 (800) 668-6000,

Renseignements – 1 (800) 461-3787.

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Last revised: February 25, 2011