

NAROPIN(R) with FENTANYL

Ropivacaine hydrochloride with fentanyl citrate

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some of the common questions people ask about Naropin with Fentanyl. It does not contain all the information that is known about Naropin with Fentanyl.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you being given Naropin with Fentanyl against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Naropin with Fentanyl is for

Naropin with Fentanyl is used after surgery to treat post-operative pain.

NAROPIN is a local anaesthetic (an-a-set-ik). When injected, it makes the nerves nearby unable to pass messages to the brain and will therefore prevent or relieve pain.

FENTANYL belongs to a group of medicines called narcotic analgesics. It is a powerful drug used to relieve pain. It works by changing the way your brain receives pain messages.

Naropin with Fentanyl is a combination of the two drugs and produces anaesthesia (loss of feeling) and analgesia (pain relief).

Your doctor will have explained why you are being treated with Naropin with Fentanyl and told you what dose you will be given.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

As it contains fentanyl, Naropin with Fentanyl can be addictive, but when it is used only to relieve or prevent pain it is unlikely to become habit forming.

Before you are given Naropin with Fentanyl

Before you are given it

You must tell your doctor if:

- 1. you have previously been given Naropin or fentanyl and had problems with them.**
- 2. you have any allergies to**
 - * other local anaesthetics eg. lignocaine
 - * other strong pain killers eg. morphine or pethidine
 - * any ingredients listed at the end of this leaflet

3. you have any of these medical conditions

- * problems with your blood pressure or circulation
- * blood poisoning
- * problems with the clotting of your blood
- * acidosis, or too much acid in the blood
- * head injury
- * muscle disease or weakness (e.g. myasthenia gravis)
- * nerve problems
- * heart, liver or kidney problems
- * diseases of the brain or spine
- * problems with your breathing
- * diabetes

4. you are pregnant, are breast-feeding or intend to breast-feed.

Your doctor will discuss the possible risks and benefits of using Naropin with fentanyl during pregnancy and breast-feeding.

It may not be safe for you to be given Naropin with Fentanyl if you have any of these conditions.

Naropin is not recommended for children under 12 years of age.

Naropin with fentanyl will only be used if the solution is clear, the package is undamaged and the use by (expiry) date marked on the pack has not been passed.

Taking other medicines

Tell your doctor if you are taking any other medicines, including

- * medicines that control your heart beat
- * sedatives, medicines to help you sleep
- * pain killers
- * fluvoxamine, a medicine used to treat depression.
- * ketoconazole, a medicine used to treat fungal infections
- * medicines for depression or mental illness
- * medicine used to thin your blood, including aspirin
- * low molecular weight heparin or other medicines used to prevent blood clots.
- * monoamine oxidase inhibitors (medicines used for treating depression) taken within the last 14 days.
- * medicines that you buy at the chemist, supermarket or health food shop.

These medicines may affect the way Naropin with Fentanyl works.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor about any of these things, tell them before you are given any Naropin with Fentanyl.

How Naropin with Fentanyl is given

Naropin with Fentanyl will be injected by your doctor into the epidural space, near your spinal cord, through a space between the bones in your lower back. A thin tube will be inserted so a dose can be given over a period of time.

This is called an epidural infusion and it will result in a feeling of numbness in your lower body, in an area that may seem unrelated to the injection.

Naropin with Fentanyl is not injected directly into the blood.

The dosage you will be given will depend on your body size, age and the type of pain relief required.

Your doctor will have had a lot of experience injecting Naropin with Fentanyl or other similar drugs and will choose the best dose for you. They will be willing to discuss this decision with you.

Overdose

The doctor giving you Naropin with Fentanyl will be experienced in the use of this type of medicine, so it is unlikely that you will be given too much.

However, if you are particularly sensitive to Naropin with Fentanyl, or the dose is accidentally injected directly into your blood, you may develop problems for a short time with your sight or hearing.

You may get a numb feeling in or around the mouth, feel dizzy or stiff, or have twitchy muscles.

In rare cases, these effects may be followed by drowsiness and fits. In extreme cases you may have problems with your breathing or your heart and you may become unconscious.

Whenever you are given Naropin with Fentanyl, equipment will be available to care for you if you are given too much.

While you are being given it

Things to be careful of

Be careful driving or operating machinery after you have been given Naropin with Fentanyl.

You may be drowsy and your reflexes may be slow.

Do not stand up or walk unless somebody is there to help you.

Naropin with fentanyl can make your legs numb and you might fall.

Do not drink alcohol while you are being given Naropin with Fentanyl.

If you drink alcohol while you are being given Naropin with Fentanyl your blood pressure may drop making you feel dizzy and faint.

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Naropin with Fentanyl.

Naropin with Fentanyl will prevent or relieve pain in most people, but it may have unwanted side-effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you:

- * headache
- * irregular or slow heart beat
- * nervousness
- * dizziness
- * fever or shivering
- * blurred vision
- * excessive sweating
- * drowsiness
- * ringing in the ears
- * numbness or tingling (pins and needles)
- * feeling strange (disoriented)
- * nausea (feeling sick), vomiting
- * itching
- * unable to pass urine

These are all mild side effects of Naropin with Fentanyl.

Tell your doctor or nurse immediately if you notice any of the following:

- * extreme dizziness
- * slow heart beat
- * fits
- * chest pain
- * breathing problems
- * slow heart beat
- * stiff or twitching muscles
- * painful joints

On rare occasions you may lose consciousness.

These are all serious side effects. You may need urgent medical attention

Serious side effects are rare.

Tell your doctor or nurse if you notice anything else that is making you feel unwell.

Some people may get other side effects while taking Naropin with Fentanyl.

After using it

Storage

Naropin with Fentanyl will be stored by your doctor or pharmacist under the recommended conditions.

It should be kept in a cool dry place where the temperature stays below 30 degrees C.

Disposal

Any Naropin with Fentanyl which is not used will be disposed of in a safe manner by your doctor or pharmacist.

Product description

Naropin with Fentanyl contains ropivacaine hydrochloride plus fentanyl citrate as the active ingredients.

It is available in 2 strengths:

- * ropivacaine hydrochloride 2mg/mL with fentanyl 2mcg/mL
- * ropivacaine hydrochloride 2mg/mL with fentanyl 4mcg/mL.

Naropin with Fentanyl also contains

sodium chloride

sodium hydroxide 2M or hydrochloric acid 2M for pH adjustment

water for injections

Naropin with Fentanyl is available in 100mL or 200mL Polybag in sterile theatre packs.

Manufacturer

AstraZeneca Pty Ltd
ACN 009 682 311
Alma Road
NORTH RYDE NSW 2113
Tel: 1 800 805 342

NAROPIN (2mg/mL) with FENTANYL (2mcg/mL)

100mL Polybag Aust R 72874

200mL Polybag Aust R 72873

NAROPIN (2mg/mL) with FENTANYL (4mcg/mL)

100mL Polybag Aust R 72876

200mL Polybag Aust R 72875

This leaflet was prepared July 2000.

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