

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

NAROPIN 2 mg/ml POLYAMP

NAROPIN 5 mg/ml POLYAMP

NAROPIN 7,5 mg/ml POLYAMP

NAROPIN 10 mg/ml POLYAMP

Injection

NAROPIN 2 mg/ml POLYBAG

Infusion

The active substance is ropivacaine hydrochloride.

Read all of this leaflet carefully before you are given NAROPIN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- NAROPIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT NAROPIN CONTAINS

NAROPIN 2 mg/ml POLYAMP:

Each 1 ml of sterile solution for injection contains 2,0 mg ropivacaine hydrochloride.

NAROPIN 5 mg/ml POLYAMP:

Each 1 ml of sterile solution for injection contains 5,0 mg ropivacaine hydrochloride.

NAROPIN 7,5 mg/ml POLYAMP:

Each 1 ml of sterile solution for injection contains 7,5 mg ropivacaine hydrochloride.

NAROPIN 10 mg/ml POLYAMP:

Each 1 ml of sterile solution for injection contains 10,0 mg ropivacaine hydrochloride.

NAROPIN 2 mg/ml POLYBAG:

Each 1 ml of sterile solution for infusion contains 2,0 mg ropivacaine hydrochloride.

The other ingredients are sodium chloride, water for injection.

Sugar free

WHAT NAROPIN IS USED FOR

NAROPIN is used to anaesthetise parts of the body for surgical operations and also for pain relief. Its most important uses are described below:

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

NAROPIN acts by 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.

BEFORE NAROPIN IS USED ON YOU

Tell your doctor:

- about any disease you are suffering from
- about medicines you use regularly
- if you have a heart, liver or kidney disease, since the dose of NAROPIN may have to be adjusted.

WHEN NAROPIN MUST NOT BE USED

- If you are allergic to ropivacaine (active ingredient in NAROPIN) or to other local anaesthetics. Tell your doctor if you have ever had an allergic, unpleasant or unusual reaction to NAROPIN, or to any other medicine.

USE OF NAROPIN IN CHILDREN

- NAROPIN cannot be recommended to children below the age of 1 year.

Pregnancy and breastfeeding

PREGNANCY

Before you are given NAROPIN, tell your doctor if you are pregnant or plan to become pregnant. If you are pregnant, or plan to become pregnant, ask your doctor about the risks and benefits of using NAROPIN.

BREASTFEEDING

Before you are given NAROPIN, tell your doctor if you are breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving NAROPIN.

TAKING OTHER MEDICINES WITH NAROPIN

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

- Certain other medicines e.g. other local anaesthetics and some medicines used to treat irregular heart activity can be of importance for calculating the correct dose of NAROPIN.
- Fluvoxamine, an anti-depressive medicine, and enoxacin, which is an antibiotic, both reduce the rate by which NAROPIN is excreted from the body. Prolonged use of NAROPIN should therefore be avoided if you are treated with fluvoxamine or enoxacin.

Driving and using machinery

Do not operate any tools or machinery on the day of surgery because NAROPIN (and possibly concomitantly given medicines) may temporarily interfere with your reactions and muscular coordination.

HOW TO USE NAROPIN

Do not share medicines prescribed for you with others.

NAROPIN should be administered by a doctor, or occasionally by a nurse under the supervision of a doctor. The dose to be given is decided by the doctor, bases on the clinical need and your physical condition.

IF YOU HAVE BEEN GIVEN TOO MUCH NAROPIN

Serious adverse effects resulting from an overdose are extremely rare and need special treatment. The doctor treating you is trained and equipped to handle such situations.

The first signs that too much NAROPIN has been given usually take the form of light-headedness, numbness of the lips and round the mouth, numbness of the tongue, hearing disturbances and visual disturbances. Tell your doctor immediately if you notice any of these symptoms. Speech disturbances, muscular twitching or tremors are more serious. In the event of serious overdosage or a misplaced injection, trembling, seizures or unconsciousness may occur.

If the administration of NAROPIN is stopped as soon as early signs of overdosage appear, the risk of serious adverse effects rapidly decreases.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.

POSSIBLE SIDE EFFECTS

Not all side effects reported for NAROPIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

NAROPIN can have side effects.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

Lowering of blood pressure; nausea; abnormal sensations (pins and needles); dizziness; headache; decreased heart rate; elevated heart rate; elevated blood pressure; vomiting;

difficulties in urinating; fever; chill; back pain.

The following side effects have been reported less frequently:

Anxiety; toxicity symptoms (convulsions, seizures, light-headedness, numbness of the lips and round the mouth, numbness of the tongue, hearing disturbances, visual disturbances, speech disturbances, muscular stiffness, trembling); decreased sensitivity of the sensory organs; fainting; difficulties in breathing; low body temperature; cardiac arrest and/or dysrhythmias; allergic reactions (including anaphylactic reactions, angioedema (angioneurotic oedema) and nettle-rash).

Numbness due to nerve irritation caused by the needle or the injection may occur, but rarely last for long.

- Tell your doctor as soon as possible if you do not feel well during treatment with NAROPIN.
- If you notice any side effects not mentioned in this leaflet, please inform you doctor or pharmacist.

STORING AND DISPOSING OF NAROPIN

NAROPIN is stored at or below 30 °C. It should not be frozen.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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

PRESENTATION OF NAROPIN

NAROPIN 2; 5; 7,5; 10 mg/ml POLYAMP:

Polypropylene ampoules (POLYAMP) available in pack sizes of 10 ml and 20 ml, either blister packed into transparent polypropylene blisters, or single.

The blisters are packed into a cardboard unit carton with a leaflet.

NAROPIN 2 mg/ml POLYBAG:

Naropin 2 mg/ml Polybags are available in polypropylene infusion bags of 125 ml (containing 100 ml of solution) and 250 ml (containing 200 ml of solution). The polybag contains a chlorobutyl rubber stopper.

The polybag is covered with a polypropylene blister, with an outer cover of autoclave paper.

Not all packs or pack sizes are necessarily marketed.

IDENTIFICATION OF NAROPIN

NAROPIN 2; 5; 7,5; 10 mg/ml POLYAMP:

A sterile, isotonic, isobaric, clear and colourless solution for injection designed to fit luer lock and luer fit.

NAROPIN 2 mg/ml POLYBAG:

A sterile, isotonic, isobaric, clear and colourless solution for infusion.

REGISTRATION NUMBERS

NAROPIN 2 mg/ml POLYAMP: 31/4/0124

NAROPIN 2 mg/ml POLYBAG: 31/4/0125

NAROPIN 5 mg/ml POLYAMP: 35/4/0409

NAROPIN 7,5 mg/ml POLYAMP: 31/4/0126

NAROPIN 10 mg/ml POLYAMP: 31/4/0127

**NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE
CERTIFICATE OF REGISTRATION**

PHARMACARE LIMITED

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2 mg/ml POLYBAG	04/4/1815
7,5 mg/ml POLYAMP	04/4/1816
10 mg/ml POLYAMP	04/4/1817

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