

Package leaflet: Information for the user
LAPAINOL 10 mg/ml solution for injection
nalbuphine hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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1. What LAPAINOL 10 mg/ml solution for injection is and what it is used for

LAPAINOL 10 mg/ml solution for injection is a medicinal product that belongs to a group of pain killers (analgesics) with opioid properties.

It is used for short-term treatment of moderate to severe pain. It can also be used before or after an operation.

2. What you need to know before you use LAPAINOL 10 mg/ml solution for injection

Do not use LAPAINOL 10 mg/ml solution for injection

- if you are allergic to nalbuphine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you have severe renal impairment
- if you have hepatic impairment
- if you use other opioids

Warnings and precautions

Take special care with LAPAINOL 10 mg/ml solution for injection

- if you suffer from head injury, inner head injury or already existing increased intracranial pressure, LAPAINOL 10 mg/ml solution for injection might intensify this. It is also possible that the use of LAPAINOL 10 mg/ml solution for injection in patients with head injury can disguise symptoms. if you suffer from a deranged kidney function, the dosage of LAPAINOL 10 mg/ml solution for injection must then be reduced.
- if LAPAINOL 10 mg/ml solution for injection is administered to the mother during labour and delivery. Newborns should be monitored for respiratory depression and arrhythmias if LAPAINOL 10 mg/ml solution for injection has been used. if you suffer from impaired breathing or if you get difficulties with your breathing during the treatment, your doctor may have to monitor you closely.
- if you suffer with heart failure, paralysed gut, gallbladder pains, epilepsy or reduced function of the thyroid.
- Abuse of LAPAINOL 10 mg/ml solution for injection can lead to psychological and physical addiction and habituation.

- if you are addicted on heroine, methadone or other opioid substances. LAPAINOL 10 mg/ml solution for injection cannot be used as a replacement. In these cases the acute withdrawal symptoms can be considerably intensified.

Ask your doctor, if one of the above mentioned warnings applies to you or has applied to you in the past.

Other medicines and LAPAINOL 10 mg/ml solution for injection

Other medicines can have an influence on the effect of LAPAINOL 10 mg/ml solution for injection.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, herbal medicines or natural products.

- Combination with specific narcotics (opioids) is not indicated. The painkilling effect might be reduced.
- Alcohol and medicinal products containing alcohol must be avoided.
- The use of LAPAINOL 10 mg/ml solution for injection in combination with other medicines that diminish fear and anxiety (anxiolytics) or the concurrent use of LAPAINOL 10 mg/ml solution for injection with narcotic analgesics (pain killers), phenothiazines (medicines used for schizophrenia) or other sedative, sleep enhancing or similar medication that affect the central nervous system can show worsening of the side effects. Your doctor must adapt the dosage of LAPAINOL 10 mg/ml solution for injection or the other medicinal product.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

There are insufficient data on the possible harmful effects in humans with the use of LAPAINOL 10 mg/ml solution for injection in pregnancy. If LAPAINOL 10 mg/ml solution for injection is administered to the mother during labour and delivery, newborns should be monitored for respiratory depression and arrhythmias (see section 4 possible side effects).

LAPAINOL 10 mg/ml solution for injection is excreted in the breast-milk. Lactation should be discontinued for 24 hours during treatment with LAPAINOL 10 mg/ml solution for injection.

Ask your doctor or nurse for advice before taking any medicine.

Driving and using machines

LAPAINOL 10 mg/ml solution for injection reduces your ability to react quickly. You should therefore avoid driving and using machines while you are treated with LAPAINOL 10 mg/ml solution for injection. Other side effects that may occur are listed in section 4.

NALPAIN 10 mg/ml solution for injection contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to use LAPAINOL 10 mg/ml solution for injection

LAPAINOL 10 mg/ml solution for injection is only used by the physician or nurse.

Posology

Use in adults

The common used dose for adults is 10 to 20 mg for persons with 70 kg body weight: intravenous, intramuscular or subcutaneous administration. This dose can be repeated after 3 to 6 hours, if necessary. The dosage must be adapted according to the intensity of the pain and the condition of the patient.

Use in children and adolescents

The usual dosage for children is 0,1 to 0,2 mg/kg body weight: intravenous, intramuscular or subcutaneous administration. This dose can be repeated after 3 to 6 hours, if necessary. The single maximum dose is defined with 0,2 mg nalbuphine hydrochloride per kilogram body weight.

Duration of treatment

The duration of treatment is specified by your doctor.

If you notice that the effect of LAPAINOL 10 mg/ml solution for injection is too strong or even too weak, please ask your doctor or nurse for advice.

If you get more LAPAINOL 10 mg/ml solution for injection than you should

The usage of a high dosage of LAPAINOL 10 mg/ml solution for injection can cause symptoms such as respiratory depression, drowsiness or unconsciousness.

As this medicine will be given to you whilst you are in hospital, it is unlikely that you will be given too much.

If you have any further questions on the use of this product, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may appear:

Very common (more than 1 out of 10 persons): Sedation

Common (more than 1 out of 100 persons and less than 1 out of 10 persons): Sweating, sleepiness, dizziness, Dry mouth, Headache, Vomiting, sickness, decreased feeling of happiness

Rare (more than 1 out of 10,000 persons and less than 1 out of 1,000 persons): Light numbness in the head, nervousness, shiver, Withdrawal symptoms, disturbed feeling of the skin, Respiratory difficulties

Very rare (less than 1 out of 10,000 persons): illusions, Confusion, personality disorder trait, slow heartbeat, rapid heartbeat, fluid retention in the Lung, increased feeling of happiness, low blood pressure, high blood pressure, Watery eyes, Blurred vision, Allergic reaction, Pain in the puncture, reddened skin, nettle-rash, respiratory depression in newborn children, retarded circulation in newborn children

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517. Website: www.hpra.ie. E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store LAPAINOL 10 mg/ml solution for injection

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the ampoule and carton after “exp”. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the ampoules in the outer carton, in order to protect from light.

The product has to be used immediately after first opening.

This medicinal product is for single use only. Discard any unused solution.

Do not use LAPAINOL 10 mg/ml if you notice discolouration, cloudiness or particles in the solution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What LAPAINOL 10 mg/ml solution for injection contains

- The active substance is nalbuphine hydrochloride.
1 ml of solution contains 10 mg nalbuphine hydrochloride.
1 ampoule of 2 ml contains 20 mg nalbuphine hydrochloride.
- The other ingredients are
citric acid, anhydrous
sodium citrate
sodium chloride
hydrochloric acid (for pH adjustment)
water for injection

What LAPAINOL 10 mg/ml solution for injection looks like and contents of the pack

One ampoule contains 2 ml of a clear and colourless solution for injection.

LAPAINOL 10 mg/ml solution for injection is available in packs with 10 ampoules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Orpha-Devel Handels und Vertriebs GmbH
Wintergasse 85/1B
3002 Purkersdorf
Austria

Manufacturer

AOP Orphan Pharmaceuticals GmbH
Leopold-Ungar-Platz 2
A-1190 Vienna
Austria

This medicinal product is authorised in the Member States of the EEA under the following names:

Czech Republic: Nalbuphin OrPha 10 mg/ml injekční roztok
Germany NALPAIN 10 mg/ml Injektionslösung

Finland: NALPAIN 10 mg/ml injektioneste, liuos
Greece: NALPAIN 10 mg/ml ενέσιμο διάλυμα
Hungary: NALPAIN 10 mg/ml oldatos injekció
Ireland: LAPAINOL 10 mg/ml solution for injection
Netherlands: Nalbufine HCl OrPha 10 mg/ml oplossing voor injectie
Poland: NALPAIN 10 mg/ml roztwór do iniekcji
Slovenia: NALPAIN 10 mg/ml raztopina za injiciranje

This leaflet was last revised in December 2021