

Read all of this leaflet carefully before this medicine is administered to 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Naloxone 400 micrograms/ml solution for injection

- naloxone hydrochloride -

In this leaflet:

1. What Naloxone 400 micrograms/ml solution for injection is and what it is used for
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1. WHAT NALOXONE 400 MICROGRAMS/ML SOLUTION FOR INJECTION IS AND WHAT IT IS USED FOR

Naloxone 400 micrograms/ml solution for injection is a drug used to counter the effects of opioid overdose, for example morphine overdose.

Naloxone 400 micrograms/ml solution for injection is used for reversal of unwanted effects of opioids for countering life-threatening depression of the central nervous system and respiratory system (breathing difficulties).

Naloxone 400 micrograms/ml solution for injection is also used to diagnose an acute opioid overdose or intoxication.

If a woman has been given analgesic drugs during labour, a newborn child can be treated with Naloxone 400 micrograms/ml solution for injection for reversal of unwanted effects of opioids, e.g. if he/she suffers from breathing problems or depression of the central nervous system.

2. BEFORE NALOXONE 400 MICROGRAMS/ML SOLUTION FOR INJECTION IS ADMINISTERED TO YOU

Naloxone 400 micrograms/ml solution for injection must not be administered

- If you are allergic (hypersensitive) to naloxone hydrochloride or to any of the ingredients of this medicinal product.

Take special care with Naloxone 400 micrograms/ml solution for injection and tell your doctor

- If you are physically dependent on opioids (for example morphine) or have received high doses of these drugs (you may get strong withdrawal symptoms after receiving Naloxone 400 micrograms/ml solution for injection because of a rapid reversal of the opioid effect; these symptoms may be high blood pressure, palpitations, severe difficulties in breathing or cardiac arrest).
- If you have any heart or circulation problems (because side effects like high or low blood pressure, palpitations or severe difficulties in breathing may appear more likely).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- If you are taking painkilling medication like buprenorphine. The painkilling effect may even become stronger while you are treated with Naloxone 400 micrograms/ml solution for injection. However, the reversal of unwanted effects, like respiratory depression caused by buprenorphine is limited.

- If you are taking sedatives, as Naloxone 400 micrograms/ml solution for injection may possibly have a less rapid effect.
- If you are taking any medication that may affect your heart or circulation (e.g. antihypertensive drugs e.g. clonidine), even those not prescribed.

Using Naloxone 400 micrograms/ml solution for injection with food and drink

Please inform your doctor if you drank alcohol. In patients with multi-intoxication (with opioids and sedatives or alcohol) Naloxone 400 micrograms/ml solution for injection may have a less rapid effect.

Pregnancy and breast-feeding

There is no sufficient information available regarding the use of Naloxone 400 micrograms/ml solution for injection in pregnant women. During pregnancy, your doctor will assess the benefit of Naloxone 400 micrograms/ml solution for injection against possible risks to the embryo or to the foetus.

It is not known whether Naloxone 400 micrograms/ml solution for injection passes into breast milk and it has not been established whether infants who are breast-fed are affected by Naloxone 400 micrograms/ml solution for injection. Therefore, breast-feeding should be avoided for 24 hours after treatment. Ask your doctor for advice before taking any medicine.

Driving and using machines

After receiving Naloxone 400 micrograms/ml solution for injection for the reversal of the effects of opioids you must not drive a vehicle, operate machinery or engage in any other physically or mentally demanding activity for at least 24 hours as the effects of opioids may possibly recur.

Important information about some of the ingredients of Naloxone 400 micrograms/ml solution for injection

This medicinal product contains 3.8 mmol (88.5 mg) sodium per maximum daily dose. Please tell your doctor, if you are on a low sodium diet, he/she will take it into account.

3. HOW NALOXONE 400 MICROGRAMS/ML SOLUTION FOR INJECTION IS ADMINISTERED

The usual doses given to you are

Reversal of the unwanted effects of opioids

Adults: 0.1-0.2 mg, if necessary additional injections of 0.1 mg may be given

Children: 0.01-0.02 mg per kg body weight, if necessary additional injections of the same dose may be given

Diagnosis of opioid overdose or intoxication

Adults: 0.4-2 mg, if necessary the injections can be repeated at intervals of 2-3 minutes. The maximum dose of 10 mg should not be exceeded.

Children: 0.01 mg per kg body weight, if necessary an additional injection of 0.1 mg per kg may be given

Reversal of the unwanted effects of opioids in neonates whose mothers have received opioids

0.01 mg per kg body weight, if necessary additional injections may be given:

For reversal of the unwanted effects of opioids (in adults, children and also in neonates) patients are monitored to ensure that the desired effect of Naloxone 400 micrograms/ml solution for injection occurs. Additional doses may be given every 1-2 hours if necessary.

In elderly patients with heart or circulation problems or in those receiving medicines that can produce heart or circulation disorders (e.g. cocaine, methamphetamine, tricyclic antidepressants, calcium channel blockers, beta-blockers, digoxin) Naloxone 400 micrograms/ml solution for injection will be used with caution since serious side effects such as fast heart beats (ventricular tachycardia and fibrillation) have occurred.

If you have the impression that the effect of Naloxone 400 micrograms/ml solution for injection is too strong or too weak, talk to your doctor.

Method of administration

Naloxone 400 micrograms/ml solution for injection will be given to you always by intravenous or intramuscular injection (into a vein or into a muscle) or, after dilution, as an intravenous infusion (over a longer period). Naloxone 400 micrograms/ml solution for injection will be given by your anaesthetist or an experienced physician.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Naloxone 400 micrograms/ml solution for injection can cause side effects, although not everybody gets them.

The frequency of side effects is classified into the following categories:

Very common	in more than 1 in 10 patients
Common	in more than 1 in 100 patients, but less than 1 in 10 patients
Uncommon	in more than 1 in 1,000 patients, but less than 1 in 100 patients
Rare	in more than 1 in 10,000 patients, but less than 1 in 1,000 patients
Very rare	in less than 1 in 10,000 patients, including isolated reports

It may be difficult to know what side effects Naloxone 400 micrograms/ml solution for injection has, because it is always given after other drugs have also been used.

Immune system disorders

Very rare: Allergic reactions (nettle rash, nasal catarrh or a cold, difficulty breathing, Quincke's oedema (facial swelling)), allergic shock.

Nervous system disorders

Common: Dizziness, headache.
Uncommon: Involuntary trembling or quivering (tremour), sweating.
Rare: Seizures, tension.

Cardiac disorders

Common: Fast heart beat.
Uncommon: Changes in the way your heart beats, slow heart rate.
Very rare: Fibrillation, cardiac arrest.

Vascular disorders

Common: Increased or decreased blood pressure (you may have a headache or feel faint).

Respiratory disorders

Very rare: Fluid on the lungs (pulmonary oedema).

Gastrointestinal disorders

Very common: Nausea.
Common: Vomiting.
Uncommon: Diarrhoea, dry mouth.

Skin and subcutaneous tissue disorders

Very rare: Discolouration and lesions of the skin (erythema multiforme).

General disorders and administration site conditions

Common: If too large a dose is given after an operation, you may become excited and feel pain (because the painkilling effects of the medicines you were given will have been counteracted as well as the effects on your breathing).

Uncommon: Over breathing (hyperventilation), irritation of the blood vessel wall has been reported after i.v. administration; local irritation and inflammation have been reported after i.m. administration.

If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE NALOXONE 400 MICROGRAMS/ML SOLUTION FOR INJECTION

Keep out of the reach and sight of children.

Naloxone 400 micrograms/ml solution for injection should not be administered after the expiry date, which is stated on the ampoule label and the carton. The expiry date refers to the last day of that month.

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

Store below 25°C.

Store diluted solutions below 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Naloxone 400 micrograms/ml solution for injection contains

The active substance is naloxone hydrochloride.

Each 1 ml ampoule contains 0.4 mg naloxone hydrochloride (as naloxone hydrochloride dihydrate).

The other ingredients are sodium chloride, hydrochloric acid diluted (for pH adjustment) and water for injections.

What Naloxone 400 micrograms/ml solution for injection looks like and contents of the pack

Naloxone 400 micrograms/ml solution for injection is a clear and colourless solution in colourless glass ampoules containing 1 ml solution for injection.

Pack sizes: 5 and 10 ampoules

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Marketing authorisation holder

hameln pharma plus gmbh
Langes Feld 13, 31789 Hameln, Germany

Manufacturer

hameln pharmaceuticals gmbh
Langes Feld 13, 31789 Hameln, Germany

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

Finland	Naloxon Hameln 0,4 mg/ml injektioneste, liuos
Germany	Naloxon-hameln 0,4 mg/ml Injektionslösung
Norway	Naloxon Hameln 0,4 mg/ml injeksjonsvæske, oppløsning
Sweden	Naloxon Hameln 0,4 mg/ml injektionsvätska, lösning
The Netherlands	Naloxon HCl-hameln 0,4 mg/ml, oplossing voor injectie
United Kingdom	Naloxone 400 micrograms/ml solution for injection

This leaflet was last approved in 11/2007