

Naloxone 400 micrograms/ml solution for injection/infusion
- naloxone hydrochloride -

Read all of this leaflet carefully before this medicine is administered to you 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 NALOXONE 400 MICROGRAMS/ML SOLUTION FOR INJECTION/INFUSION IS AND WHAT IT IS USED FOR

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

Naloxone 400 micrograms/ml solution for injection/infusion 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/infusion 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/infusion for reversal of unwanted effects of opioids, e.g. if he/she suffers from breathing problems or depression of the central nervous system.

2. WHAT YOU NEED TO KNOW BEFORE NALOXONE 400 MICROGRAMS/ML SOLUTION FOR INJECTION/INFUSION IS ADMINISTERED TO YOU

Do not take Naloxone 400 micrograms/ml solution for injection/infusion:

- if you are **allergic** to naloxone hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before Naloxone 400 micrograms/ml solution for injection/infusion is administered to you.

Take special care with Naloxone 400 micrograms/ml solution for injection/infusion 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/infusion 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).

Other medicines and Naloxone 400 micrograms/ml solution for injection/infusion

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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/infusion. 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/infusion 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.

Naloxone 400 micrograms/ml solution for injection/infusion with food, drink and alcohol

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/infusion 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/infusion in pregnant women. During pregnancy, your doctor will assess the benefit of Naloxone 400 micrograms/ml solution for injection/infusion against possible risks to the embryo or to the foetus.

It is not known whether Naloxone 400 micrograms/ml solution for injection/infusion 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/infusion. Therefore, breast-feeding should be avoided for 24 hours after treatment.

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.

Driving and using machines

After receiving Naloxone 400 micrograms/ml solution for injection/infusion 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.

Naloxone 400 micrograms/ml solution for injection/infusion contains sodium

This medicine contains 3.54 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.2% of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO ADMINISTER NALOXONE 400 MICROGRAMS/ML SOLUTION FOR INJECTION/INFUSION

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 the dose can be **increased** in the next injection to 0.1 mg per kg.

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/infusion 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/infusion 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/infusion is too strong or too weak, talk to your doctor.

Method of administration

Naloxone 400 micrograms/ml solution for injection/infusion 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/infusion 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, this medicine can cause side effects, although not everybody gets them.

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

Very common (may affect more than 1 in 10 people):

- nausea

Common (may affect up to 1 in 10 people):

- dizziness
- headache
- fast heart beat
- increased or decreased blood pressure (you may have a headache or feel faint)
- vomiting
- 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 (may affect up to 1 in 100 people):

- involuntary trembling or quivering (tremour)
- sweating
- changes in the way your heart beats
- slow heart rate
- diarrhea
- dry mouth
- 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

Rare (may affect up to 1 in 1,000 people):

- seizures
- tension

The following information is intended for healthcare professionals only:

Naloxone 400 micrograms/ml solution for injection/infusion

Shelf-life after first opening

After first opening the medicinal product should be used immediately.

Shelf-life after dilution

Chemical and physical in-use stability has been demonstrated for 24 hours below 25°C.

From the microbiological point of view, the dilutions should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

Very rare (may affect up to 1 in 10.000 people):

- allergic reactions (nettle rash, nasal catarrh or a cold, difficulty breathing, Quincke's oedema (facial swelling))
- allergic shock
- fibrillation
- cardiac arrest
- fluid on the lungs (pulmonary oedema)
- discolouration and lesions of the skin (erythema multiforme)

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 the Yellow Card Scheme at Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

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

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 label and the carton after "EXP". 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.

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

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

Pack sizes: 5 and 10 ampoules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

hameln pharma ltd
Nexus, Gloucester Business Park
Gloucester, GL3 4AG, United Kingdom

Manufacturer:

Siegfried Hameln GmbH
Langes Feld 13, 31789 Hameln, Germany

hameln rds s.r.o.
Horná 36, 900 01 Modra, Slovakia

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

Denmark	Naloxon Hameln 0,4 mg/ml injektions-/infusionsvæske, opløsning
Germany	Naloxon-hameln 0,4 mg/ml Injektions-/Infusionslösung
Norway	Naloxon Hameln 0,4 mg/ml injeksjons-/infusjonsvæske, oppløsning
Sweden	Naloxon Hameln 0,4 mg/ml injektions-/infusionsvätska, lösning
The Netherlands	Naloxon HCl-hameln 0,4 mg/ml, oplossing voor injectie/infusie
United Kingdom	Naloxone 400 micrograms/ml solution for injection/infusion

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For i.v. infusion Naloxone 400 micrograms/ml solution for injection/infusion is diluted only with sodium chloride 0.9 % or glucose 5 %. 5 ampoules of Naloxone 400 micrograms/ml solution for injection/infusion (2 mg) per 500 ml give 4 µg/ml.

It is recommended that infusions of Naloxone 400 micrograms/ml solution for injection/infusion should not be mixed with preparations containing bisulphite, metabisulphite, long-chain or high-molecular-weight anions, or solutions with an alkaline pH.

This medicinal product is for single use only.

Please inspect the medicinal product visually prior to use (also after dilution). Use only clear and colourless solutions practically free from particles.