PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Naloxone 400 micrograms/ml solution for injection/infusion

naloxone hydrochoride

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.

What is in this leaflet:

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 was given analgetic 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 central nervous system.

2. What you need to know before Naloxone 400 micrograms/ml solution for injection/infusion is administered to you

Naloxone 400 micrograms/ml solution for injection/infusion must not be administered
- If you are **allergic (hypersensitive)** to naloxone hydrochloride or to any of the 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.

Special care will be taken
- If you are **physically dependent to 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 too 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 or have recently taken any other medicines.
- 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 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
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
There is no adequate information available regarding the use of Naloxone 400 micrograms/ml solution for injection/infusion in pregnant women. During pregnancy, your doctor will outweigh the benefit of Naloxone 400 micrograms/ml solution for injection/infusion against possible risks to the unborn baby. Naloxone 400 micrograms/ml solution for injection/infusion can cause withdrawal symptoms in the newborn baby.

Breastfeeding
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 is not recommended for 24 hours after treatment

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 take part in road traffic, operate machinery or engage in any other physically or mentally demanding activity for at least 24 hours since the effects of opioids may possibly recur.

Naloxone 400 micrograms/ml solution for injection/infusion contains sodium
This medicinal product contains **3.8 mmol (88.5 mg) sodium** per maximum daily dose. Please tell your doctor, if you are on low sodium diet, he/she will take it into account.

3. How Naloxone 400 micrograms/ml solution for injection/infusion is administered

The recommended 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 and treatment 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 an additional dose is necessary, the dose can be increased in the next injection to 0.1 mg/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, cyclic 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 beat (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 intravenous infusion (over a longer period). Naloxone 400 micrograms/ml solution for injection/infusion will be given by your anaesthetist or 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.

The following side effects may be serious. If any of the following side effects occur, consult a doctor immediately:

Common (may affect up to 1 in 10 people):
- Fast heart beat

Uncommon (may affect up to 1 in 100 people):
- Changes in the way your heart beats, slow heart rate

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

- Seizures

Very rare (may affect up to 1 in 10,000 people):
- Allergic reactions (nettle rash, nasal catarrh or a cold, difficult breathing, Quincke's oedema (giant swelling)), allergic shock
- Fibrillation, cardiac arrest
- Fluids on the lungs (pulmonary oedema)

Other side effects include:

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

Common (may affect up to 1 in 10 people):
- Dizziness, headache
- Increased or decreased blood pressure (you may have a headache or feel faint)
- Vomiting
- If a too large 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 (tremor), sweating
- Diarrhoea, dry mouth
- Over breathing (hyperventilation)
- Irritation of 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):
- Tension

Very rare (may affect up to 1 in 10,000 people):
- Discoloration and lesions of the skin (erythema multiforme)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom:
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

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

5. How to store Naloxone 400 micrograms/ml solution for injection/infusion

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

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 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 ampoule with 1 ml 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:
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany

Postal address:
34209 Melsungen
Germany

Phone: +49 5661/71-0
Fax: +49 5661/71-4567

Manufacturer:

hameln pharmaceuticals gmbh
Langes Feld 13, 31789 Hameln,
Germany

Tel.: +49 5151/581-0
Fax: +49 5151/581-258

and

B. Braun Medical S.A.
Carretera de Terrassa, 121
08191 Rubí (Barcelona)
Spain

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

Austria	Naloxon B. Braun 0,4 mg/ml Injektions-/Infusionslösung
Belgium	Naloxon B. Braun 0,4 mg/ml oplossing voor injectie/infusie
Denmark	Naloxon B. Braun injektions-/infusionsvæske, opløsning
Finland	Naloxon B. Braun 0,4 mg/ml injektio-/infuusioneste, liuos
Germany	Naloxon B. Braun 0,4 mg/ml Injektions-/Infusionslösung
Greece	Naloxon B. Braun 0,4 mg/ml ενέσιμο διάλυμα/διάλυμα για έγχυση
Iceland	Naloxon B. Braun 0,4 mg/ml stungulyf/innrennslislyf, lausn
Ireland	Naloxone 400 micrograms/ml solution for injection/infusion
Italy	Naloxone B. Braun 0,4 mg/ml soluzione iniettabile/per infusione
Luxembourg	Naloxon B. Braun 0,4 mg/ml Injektions-/Infusionslösung
Norway	Naloxon B. Braun 0,4 mg/ml injeksjons-/infusjonsvæske, oppløsning
Portugal	Naloxona B. Braun 0,4 mg/ml solução injetável/para perfusão
Spain	Naloxona B. Braun 0,4 mg/ml solución para inyección/perfusión
Sweden	Naloxon B. Braun 0,4 mg/ml injektions-/infusionsvätska, lösning
The Netherlands	Naloxon HCl B. Braun 0,4 mg/ml, oplossing voor injectie/infusie
United Kingdom	Naloxone 400 micrograms/ml solution for injection/infusion

This leaflet was last revised in 12/2017.

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Blue box content

The following information is intended for healthcare professionals only:

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.

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.