Package leaflet: Information for the user

Naloxone 400 microgram/ml solution for injection or infusion
naloxone 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. Do not pass it on to others. It may harm them, even if their symptoms 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

1. What Naloxone is and what it is used for

Naloxone 400 microgram/ml solution for injection is a drug used to counter the effects of opioid overdose, for example morphine overdose.
Naloxone 400 microgram/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 microgram/ml solution for injection is also used to diagnose an acute opioid overdose or intoxication.

What you need to know before use Naloxone
Do not use Naloxone
- if you are allergic to naloxone hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Take special care with Naloxone
- if you are physically dependent to morphine or similar drugs or when you have received high doses of these drugs, you may develop withdrawal symptoms like high blood pressure, rapid heartbeat, serious respiratory problems or stop of the heartbeat.
- if Naloxone must be administered to your newborn baby, as acute withdrawal symptoms can occur.
- if you have cardiovascular complaints (because side effects like high and low blood pressure, rapid heartbeat or serious respiratory problems probably can occur sooner).
- if you take the analgesic drug buprenorphine. In that case naloxone is effective to a limited extend (see also the paragraph ‘’Taking other medicines”).

Please consult your doctor even if these statements were applicable to you at any time in the past.

Other medicines and Naloxone
Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
Please note that these statements may also apply to products used some time ago or at some time in

the future.

- If you use analgesics, such as buprenorphine, the analgesic effects can be increased when you are treated with Naloxone.An administration of Naloxone in coma as a consequence of clonidine-overdose, serious high blood pressure has been reported. Clonidine is a medicine used in withdrawal symptoms occurring after stopping opioides. It is also administered in high blood pressure, migraine and menopausal flushes.

Naloxone with food and drink
Please inform your doctor if you drank alcohol. In patients with multiple intoxication (with opioids and sedatives or alcohol) Naloxone onset of effect can be less rapid.

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 no adequate data available on the use of Naloxone in pregnant women. During pregnancy, your doctor will outweigh the benefits of the use of Naloxone against the possible risks for the unborn baby. Naloxone can cause withdrawal symptoms in the baby (see paragraph Take special care with Naloxone).

It is not known whether Naloxone 400 microgram/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 microgram/ml solution for injection. Therefore, breast-feeding is not recommended for 24 hours after treatment.

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

Driving and using machines
After receiving Naloxone 400 microgram/ml solution for injection 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 contains sodium
This medicinal product contains 17.7 mg sodium per 2 mg dose (5 ml) of naloxone hydrochloride. To be taken into consideration by patients on a controlled sodium diet.

2. How to use Naloxone

Dose
Your doctor will determine the right dose.

Adults
- Overdose of opioides: 400 microgram. If needed, the dose can be repeated at 2 - 3 minute intervals.
- Reducing the effect of opioides used in anaesthesia for an operation: 100 – 200 microgram at 2-3 minute intervals.

Use in children and adolescents
- Overdose of opioides: 10 – 20 microgram/kg body weight. If needed, the dose can be repeated at 2 - 3 minute intervals.

Use in neonates
- Decreased respiration caused by opioides: 10 microgram/kg body weight. If needed, the dose can be repeated at 2 - 3 minute intervals.

Use in **e**lderly
In elderly patients with heart diseases Naloxone must be used with caution.

Method of administration
Naloxone is administered as an injection. It is injected into a vein (=intravenous) or into a muscle (=intramuscular) by a doctor or a nurse.
It also can be given as intravenous infusion after dilution with sodium chloride 0.9% or glucose 5%.

Duration of treatment
Your doctor will determine the duration of treatment.

If you have the impression that the effect of Naloxone *is too strong or too weak, talk to your doctor or pharmacist.*

If you use more Naloxone than you should
If you may have received more Naloxone than you should, talk to your doctor or nurse immediately. He/she will take further measures, if necessary.

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.

The following side effects may appear:

Very common (*affects more than 1 user in 10*): sickness, feeling of being sick

Common (*affects 1 to 10 users in 100)*: dizziness, headache, rapid heartbeat, low blood pressure, high blood pressure, vomiting, postoperative pain

Uncommon (*affects 1 to 10 users in 1,000)*: shiver, sweating, heart rhythm disturbance, slow heartbeat, diarrhoea, dry mouth, rapid and deep breathing (hyperventilation), irritation of vessel wall (after intravenous administration)

Rare (*affects 1 to 10 users in 10,000)*: fits, tension

Very rare (*affects less than 1 user in 10,000)*: rapid and irregular heartbeat, stop of heartbeat, fluid accumulation in the lungs, allergic reactions (urticaria, rhinitis, respiratory difficulties, anaphylactic shock)

When Naloxone is administered to persons addicted to morphine or similar drugs, acute withdrawal symptoms can occur (for example high blood pressure and heart symptoms). This can also occur in babies of opioid-dependent mothers.

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).

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 Naloxone

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 carton and ampoule 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.

After first opening the medicinal product must be used immediately.
After dilution, the product 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 under controlled and validated aseptic conditions.

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

Do not use Naloxone if you notice a discolouration, cloudiness or particles in the solution.

For i.v. infusion, Naloxone 400 microgram/ml solution for injection is diluted with sodium chloride 0.9% w/v or glucose 5% w/v.
5 ampoules of Naloxone 400 microgram/ml solution for injection (2 mg) diluted to 500 ml give a final concentration of 4 microgram/ml.

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 contains

The active substance is naloxone hydrochloride.
Each ampoule of 1 ml of solution for injection or infusion contains 400 microgram naloxone hydrochloride (as naloxone hydrochloride dihydrate).
The other ingredients are sodium chloride, hydrochloric acid (diluted) and water for injections.

What Naloxone looks like and contents of the pack

Naloxone is a clear and colourless solution for injection or infusion.
Naloxone is available in packs with 10 ampoules of 1 ml solution for injection or infusion.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Orpha-Devel Handels und Vertriebs GmbH
3002 Purkersdorf, Austria

Manufacturer
Hikma Italia S.p.A.
27100 Pavia, Italy

G.L. Pharma GmbH
A-1160 Vienna, Austria

Amomed Pharma GmbH

A-1150 Vienna, Austria

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

Bulgaria, Nexodal 0,4 mg/ml инжекционен разтвор или инфузия
Denmark, Nexodal 0,4 mg/ml injektions-/infusionsvæske, opløsning
Estonia, Nexodal 0,4 mg/ml süste-/infusioonilahus
Finland, Nexodal 0,4 mg/ml injektio-/infuusioneste, liuos
Germany, Nexodal 0,4 mg/ml Injektionslösung oder Infusionslösung
Greece, Naloxon Orpha 0,4 mg/ml διάλυμα για ένεση/έγχυση
Hungary, Nexodal 0,4 mg/ml oldatos injekció vagy infúzió
Ireland, Naloxone 400 microgram/ml solution for injection or infusion
Italy, Nexodal 0,4 mg/ml soluzione iniettabile
Latvia, Nexodal 0,4 mg/ml šķīdums injekcijām vai infūzijām
Lithuania, Nexodal 0,4 mg/ml injekcinis/infuzinis tirpalas
Netherlands, Naloxon Orpha 0,4 mg/ml oplossing voor injectie of infusie
Norway, Nexodal 0,4 mg/ml injeksjons-/infusjonsvæske, oppløsning
Poland, Nexodal 0,4 mg/ml roztwór do wstrzykiwań lub infuzji
Romania, Nexodal L 0,4 mg/ml soluţie injectabilă sau perfuzabilă
Slovenia, Nexodal 0,4 mg/ml raztopina za injiciranje ali infundiranje
Sweden, Nexodal 0,4 mg/ml injektions-/infusionsvätska, lösning
United Kingdom, Naloxone 400 microgram/ml solution for injection or infusion

This leaflet was last revised in 05/2017