PACKAGE LEAFLET

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 is a drug used to counter the effects of opioid overdose, for example morphine overdose.
Naloxone 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 is also used to diagnose an acute opioid overdose or intoxication.

2. What you need to know before you 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

Pregnancy
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).

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

Breast-feeding
It is not known whether Naloxone passes into breast milk and it has not been established whether infants who are breast-fed are affected by Naloxone. 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 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 medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

3. How to use Naloxone

Dose
Your doctor will determine the right dose.

Adults
- i.v. injection: 0.1 to 0.2 mg naloxone hydrochloride, if necessary additional i.v. injections of 0.1 mg can be administered at 2 – 3 minute intervals. An additional injection can be necessary again within 1 to 2 hours.

Children and adolescents
- Initially, i.v. injection of 0.01 – 0.02 mg naloxone hydrochloride per kg body weight, at intervals of 2 -3 minutes. Additional doses may be necessary at 1 to 2 hour intervals. The doses can be different due to local recommendations.

Elderly
- In elderly patients with pre-existing heart disease or in those receiving potentially cardiotoxic drugs, naloxone hydrochloride should be used with caution.

Diagnosis of suspected acute opioid overdose or intoxication

Adults
- Starting dose is 0.4 - 2 mg naloxone hydrochloride i.v. If needed, the dose can be repeated at 2-3 minute intervals.

Children and adolescents
- Starting dose is 0.01 mg/kg body weight i.v. If a satisfactory response is not achieved, an increased additional dose of 0.1 mg/kg can be administered.
- The dose in children and adolescents can be different due to local recommendations.

Neonates whose mothers have received opioids
- Usual dose is 0.01 mg/kg body weight i.v. If needed, the dose can be repeated at 2-3 minute intervals.
- The dose in neonates can be different due to local recommendations.

Method of administration
Nexodal can be injected into a vein (i.v.), into a muscle (i.m.) or can be given via intravenous infusion by a doctor or a nurse.
The i.m. administration of naloxone hydrochloride should only be used in cases where an i.v. administration is not possible.
It 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, Quincke´s oedema), anaphylactic shock, Erythema multiforme

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.
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 0.4 mg/ml is diluted with sodium chloride 0.9% w/v or glucose 5% w/v.
5 ampoules of Naloxone 0.4 mg/ml (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 solution contains 400 microgram/ml 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 solution.
Naloxone is available in packs with 10 ampoules of 1 ml solution of injection or solution.

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

Manufacturer
AOP Orphan Pharmaceuticals GmbH
A-1190 Vienna, Austria

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

Estonia, Nexodal 0,4 mg/ml süste-/infusioonilahus
Finland, Nexodal 0,4 mg/ml injektio-/infuusioneste, liuos
Hungary, Nexodal 0,4 mg/ml oldatos injekció vagy infúzió
Ireland, Naloxone 400 microgram/ml solution for injection or infusion
Netherlands, Naloxon Orpha 0,4 mg/ml oplossing voor injectie of infusie
Romania, Nexodal 0,4 mg/ml soluţie injectabilă sau perfuzabilă
Slovenia, Nexodal 0,4 mg/ml raztopina za injiciranje ali infundiranje
United Kingdom, Naloxone 400 microgram/ml solution for injection or infusion

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