

Package leaflet: Information for the user

Naloxone Hydrochloride 400 micrograms/ml solution for injection/infusion

Read all of this leaflet carefully before you are given 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.

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.

The name of your medicine is Naloxone Hydrochloride 400 micrograms/ml solution for injection/infusion, it will be called Naloxone Injection for ease here after.

What is in this leaflet:

1. What Naloxone Injection is and what it is given for
2. What you need to know before you are given Naloxone Injection
3. How Naloxone Injection is given to you
4. Possible side effects
5. How to store Naloxone Injection
6. Contents of the pack and other information

1. What Naloxone Injection is and what it is given for

Naloxone belongs to a group of medicines known as opioid antagonist. Opioid medicines are strong painkillers such as morphine and codeine. In high doses these painkillers can result in side effects which cause difficulty in breathing and drowsiness. These effects can be reversed by an opioid antagonist (blocks the effects of opioids).

Naloxone Injection may be used:

- to reverse the depressant effects on breathing caused by opioid painkillers
- to help determine whether a patient has taken or received an overdose of opioid drugs
- to reverse the depressant effects on breathing and on other parts of the brain and spinal cord in newborn babies (resulting from the use of opioid painkillers in the mother during childbirth).

2. What you need to know before you are given Naloxone Injection

You should not be given Naloxone Injection

- 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 you are given Naloxone Injection

- if you have received large doses of opioid drugs or you have a drug addiction problem
- if you have a newborn baby who requires this injection; tell the doctor beforehand if you have received large doses of opioid drugs before you gave birth or if you have a drug addiction problem
- if you have a heart problem or circulatory problems and/or are taking medicines to treat these conditions
- if you are suffering from diseases of the kidney, liver or lung
- if you suffer from high blood pressure, irregular heartbeat or difficulty in breathing.

Remember that naloxone rapidly reverses the effects of opioid drugs. If you are receiving large doses of opioids, or if you have a drug addiction problem, naloxone might cause acute opioid withdrawal symptoms. (see Section 4).

Tell your doctor if any of these apply to you before you are given this medicine.

Other medicines and Naloxone Injection:

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

In particular, tell your doctor if you are taking any of the following:

- Medicines used to relieve pain such as buprenorphine, pentazocine, nalbuphine, dextropropoxyphene (narcotic or opioid analgesic)
- Sleeping pills
- Medicines that may affect your heart or blood circulation (e.g. antihypertensive drugs e.g. clonidine, cyclic antidepressants, calcium channel blockers, beta-blockers and digoxin), even those not prescribed (methamphetamine, cocaine).

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 you are given this medicine.

Naloxone should only be used during pregnancy and breastfeeding if your doctor considers it essential. Naloxone Injection must be used with caution in breastfeeding mothers.

Driving and using machines:

After receiving Naloxone Injection, 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 effect of opioids may possibly recur.

Naloxone Injection contains sodium:

This medicine contains 3.55 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.18% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Naloxone Injection is given to you

Naloxone injection is always given by a doctor or nurse. Naloxone injection is usually given by injection into a vein, a muscle or the tissue just under the skin. It may also be given slowly by a drip into a vein. Your doctor will decide on the dose to be given.

If you are given more Naloxone Injection than you should

This is unlikely as your injection will be administered by a doctor or nurse. If you are concerned about the dose, discuss this with your doctor.

If you think you have missed a dose of Naloxone Injection

This is unlikely as the injection is given by a healthcare professional. If you are concerned about missing a dose, speak to your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side-effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

The most likely side effects in patients after surgery and those previously suffered with heart problems are:

- Accumulation of fluid in the lung which may cause breathing problems (pulmonary oedema)
- Heart problems such as low or high blood pressure, a fast heartbeat, or a change in heart's rhythm.

Although it is not known if the cause was directly due to Naloxone, tell your doctor immediately if you notice any of these effects.

Patients have felt nausea (feeling sick) and vomiting (being sick) after surgery when they received Naloxone in doses higher than those recommended in order to achieve the desired response.

Naloxone reverses the effects of opioid drugs. If you were receiving large doses of opioids, or if you have a drug dependence problem, naloxone might cause acute withdrawal symptoms such as:

- Nausea and vomiting
- Sweating
- Heart problems such as a fast heartbeat, high blood pressure, heart failure
- Accumulation of fluid in the lung which may cause breathing problems (pulmonary oedema)
- Shaking or trembling
- Fits.

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

Other side effects may include:

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

- Dizziness
- Headache
- Post-operative pain

If too large a dose is given after an operation, you may become excited and feel pain (because the pain killing effects of 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)

- Over breathing (hyperventilation)
- Diarrhoea
- Dry mouth
- Irritation of the walls of the veins has been reported after intravenous administration
- Local irritation, burning and redness have been reported after the intra-muscular administration.

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

- Tension

Very Rare: (may affect up to 1 in 10,000 people)

- Severe problems with the heart (Fibrillation and cardiac arrest)
- 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 HPRA

Pharmacovigilance

Website: www.hpra.ie

5. How to store Naloxone Injection

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 label after 'EXP'. The expiry date refers to the last day of that month.

Keep the ampoule in the outer carton in order to protect from light. Do not store above 25°C.

For single use only.

Diluted solutions should be used within 24 hours and any unused solution should be discarded.

Do not use if the ampoule is damaged or if the contents are discoloured or deteriorated.

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 Injection contains:

The active substance is Naloxone Hydrochloride. Each 1 ml of solution contains naloxone hydrochloride dihydrate equivalent to 400 micrograms (0.4 mg) naloxone hydrochloride.

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

What Naloxone Injection looks like and contents of pack:

Naloxone Injection is a clear, colourless solution containing 400 micrograms (0.4 mg) of naloxone hydrochloride present as naloxone hydrochloride dihydrate in 1 ml clear glass ampoules.

Pack sizes: 3, 5 or 10 ampoules may be packaged together in cardboard cartons.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Mercury Pharmaceuticals (Ireland) Ltd,
4045, Kingswood Road, City West Business Park, Co Dublin,
Ireland

Manufacturer:

Delpharm Tours, La Baraudiere, 37170 Chambray-Les-Tours, France.

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